



2016 INTERIM MEETING

To access the handbook online, visit ama-assn.org/go/hodhandbook.

MEMORANDUM FROM THE SPEAKER OF THE HOUSE OF DELEGATES

- All Delegates, Alternate Delegates and others receiving this material are reminded that it refers only to items to be considered by the House.
- No action has been taken on anything herein contained, and it is informational only.
- Only those items that have been acted on finally by the House can be considered official.
- The Interim Meeting is focused on advocacy issues. A resolution committee (see AMA Bylaw 2.13.3) considers each resolution and recommends that the item be considered or not considered at the Interim Meeting. Items that meet the following definition of advocacy or that are considered urgent are recommended for acceptance:

Active use of communication and influence with public and private sector entities responsible for making decisions that directly affect physician practice, payment for physician services, funding and regulation of education and research, and access to and delivery of medical care.

Resolutions pertaining to ethics should also be included in the agenda. Remaining items are recommended against consideration, but any delegate may request consideration when resolutions are presented for consideration (during Sunday's "Second Opening" Session). A simple majority of those present and voting is required for consideration.

- **REMINDER:** *Only the Resolve portions of the resolutions are considered by the House of Delegates. The Whereas portions or preambles are informational and explanatory only.*



UNDERSTANDING THE RECORDING OF AMERICAN MEDICAL ASSOCIATION POLICY

Current American Medical Association (AMA) policy is catalogued in PolicyFinder, an electronic database that is updated after each AMA House of Delegates (HOD) meeting and available online. Each policy is assigned to a topical or subject category. Those category headings are alphabetical, starting with “abortion” and running to “women”; the former topic was assigned the number 5, and “women” was assigned 525. Within a category, policies are assigned a 3 digit number, descending from 999, meaning that older policies will *generally* have higher numbers within a category (eg, 35.999 was initially adopted before 35.984). A policy number is not affected when it is modified, however, so a higher number may have been altered more recently than a lower number. Numbers are deleted and not reused when policies are rescinded.

AMA policy is further categorized into one of four types, indicated by a prefix:

- “H” – for statements that one would consider positional or philosophical on an issue
- “D” – for statements that direct some specific activity or action. There can be considerable overlap between H and D statements, with the assignment made on the basis of the core nature of the statement.
- “G” – for statements related to AMA governance
- “E” – for ethical opinions, which are the recommendations put forward in reports prepared by the Council on Ethical and Judicial Affairs and adopted by the AMA-HOD

AMA policy can be accessed at ama-assn.org/go/policyfinder.

The actions of the AMA-HOD in developing policy are recorded in the *Proceedings*, which are available [online](#) as well. Annotations at the end of each policy statement trace its development, from initial adoption through any changes. If based on a report, the annotation includes the following abbreviations:

BOT – Board of Trustees	CME – Council on Medical Education
CCB – Council on Constitution and Bylaws	CMS – Council on Medical Service
CEJA – Council on Ethical and Judicial Affairs	CSAPH – Council on Science and Public Health
CLRPD – Council on Long Range Planning and Development	

If a resolution was involved, “Res” is indicated. The number of the report or resolution and meeting (A for Annual; I for Interim) and year (two digits) are also included (eg, BOT Rep. 1, A-14 or Res. 319, I-12).

AMA policy is recorded in the following categories, and any particular policy is recorded in only a single category.

5.000 Abortion	10.000 Accident Prevention/Unintentional Injuries
15.000 Accident Prevention: Motor Vehicles	20.000 Acquired Immunodeficiency Syndrome
25.000 Aging	30.000 Alcohol and Alcoholism
35.000 Allied Health Professions	40.000 Armed Forces
45.000 Aviation Medicine	50.000 Blood
55.000 Cancer	60.000 Children and Youth
65.000 Civil and Human Rights	70.000 Coding and Nomenclature
75.000 Contraception	80.000 Crime
85.000 Death and Vital Records	90.000 Disabled
95.000 Drug Abuse	100.000 Drugs
105.000 Drugs: Advertising	110.000 Drugs: Cost
115.000 Drugs: Labeling and Packaging	120.000 Drugs: Prescribing and Dispensing
125.000 Drugs: Substitution	130.000 Emergency Medical Services
135.000 Environmental Health	140.000 Ethics
145.000 Firearms: Safety and Regulation	150.000 Foods and Nutrition

155.000 Health Care Costs	160.000 Health Care Delivery
165.000 Health Care/System Reform	170.000 Health Education
175.000 Health Fraud	180.000 Health Insurance
185.000 Health Insurance: Benefits and Coverage	190.000 Health Insurance: Claim Forms and Claims Processing
195.000 Health Maintenance Organizations	200.000 Health Workforce
205.000 Health Planning	210.000 Home Health Services
215.000 Hospitals	220.000 Hospitals: Accreditation Standards
225.000 Hospitals: Medical Staff	230.000 Hospitals: Medical Staff - Credentialing and Privileges
235.000 Hospitals: Medical Staff - Organization	240.000 Hospitals: Reimbursement
245.000 Infant Health	250.000 International Health
255.000 International Medical Graduates	260.000 Laboratories
265.000 Legal Medicine	270.000 Legislation and Regulation
275.000 Licensure and Discipline	280.000 Long-Term Care
285.000 Managed Care	290.000 Medicaid and State Children's Health Insurance Programs
295.000 Medical Education	300.000 Medical Education: Continuing
305.000 Medical Education: Financing and Support	310.000 Medical Education: Graduate
315.000 Medical Records and Patient Privacy	320.000 Medical Review
330.000 Medicare	335.000 Medicare: Carrier Review
340.000 Medicare: PRO	345.000 Mental Health
350.000 Minorities	355.000 National Practitioner Data Bank
360.000 Nurses and Nursing	365.000 Occupational Health
370.000 Organ Donation and Transplantation	373.000 Patients
375.000 Peer Review	380.000 Physician Fees
383.000 Physician Negotiation	385.000 Physician Payment
390.000 Physician Payment: Medicare	400.000 Physician Payment: Medicare - RBRVS
405.000 Physicians	406.000 Physician-Specific Health Care Data
410.000 Practice Parameters	415.000 Preferred Provider Arrangements
420.000 Pregnancy and Childbirth	425.000 Preventive Medicine
430.000 Prisons	435.000 Professional Liability
440.000 Public Health	445.000 Public Relations
450.000 Quality of Care	455.000 Radiation and Radiology
460.000 Research	465.000 Rural Health
470.000 Sports and Physical Fitness	475.000 Surgery
478.000 Technology - Computer	480.000 Technology - Medical
485.000 Television	490.000 Tobacco Use, Prevention and Cessation
495.000 Tobacco Products	500.000 Tobacco: AMA Corporate Policies and Activities
505.000 Tobacco: Federal and International Policies	510.000 Veterans Medical Care
515.000 Violence and Abuse	520.000 War
525.000 Women	600.000 Governance: AMA House of Delegates
605.000 Governance: AMA Board of Trustees and Officers	610.000 Governance: Nominations, Elections, and Appointments
615.000 Governance: AMA Councils, Sections, and Committees	620.000 Governance: Federation of Medicine
625.000 Governance: Strategic Planning	630.000 Governance: AMA Administration and Programs
635.000 Governance: Membership	640.000 Governance: Advocacy and Political Action

LIST OF MATERIAL INCLUDED IN THIS HANDBOOK (I-16)

Resolutions and reports have been collated by referral according to reference committee assignment. In the listing below, referral is indicated by letter in parenthesis following the title of the report. Resolutions have been numbered according to referrals (i.e., those referred to the Reference Committee on Amendments to Constitution and Bylaws begin with 1, Reference Committee B begins with 201, etc.).

The informational reports contain no recommendations and will be filed on Sunday, November 13, unless a request is received for referral and consideration by a Reference Committee (similar to the use of a consent calendar).

- 1. Memorandum from the Speaker**
- 2. Understanding the Recording of American Medical Association Policy**
- 3. Declaration of Professional Responsibility - Medicine's Social Contract with Humanity**
- 4. Delegate / Alternate Delegate Job Description, Roles and Responsibilities**
- 5. Seating Allocation and Seating Chart for the House of Delegates**
- 6. Hotel Maps**
- 7. Official Call to the Officers and Members of the AMA**
 - Listing of Delegates and Alternate Delegates**
 - Officials of the Association and AMA Councils**
 - House of Delegates Reference Committee Members**
- 8. Note on Order of Business**
- 9. Summary of Fiscal Notes**

FOLLOWING COLLATED BY REFERRAL

- 10. Report(s) of the Board of Trustees - Patrice A. Harris, MD, Chair**
 - 01 2016 AMA Advocacy Efforts (Info. Report)
 - 02 AMA Support for State Medical Societies' Efforts to Implement MICRA-Type Legislation (B)
 - 03 Model State Legislation Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid Prescribing (B)
 - 04 Redefining the AMA's Position on the ACA and Healthcare Reform - Update (Info. Report)
 - 05 IOM "Dying in America" Report (Amendments to C&B)
 - 06 Designation of Specialty Societies for Representation in the House of Delegates (Amendments to C&B)
 - 07 Supporting Autonomy for Patients with Differences of Sex Development (Amendments to C&B)
 - 08 Medical Reporting for Safety Sensitive Positions (Amendments to C&B)
 - 09 Product-Specific Direct-to-Consumer Advertising of Prescription Drugs (K)
 - 10 AMA Initiatives on Pharmaceutical Costs (Info. Report)
 - 11 2017 Strategic Plan (Info. Report)

- 11. Report(s) of the Council on Constitution and Bylaws - Colette R. Willins, MD, Chair**
 - 01 Membership and Representation in the Organized Medical Staff Section - Updated Bylaws (Amendments to C&B)
 - 02 Bylaw Amendments Pertaining to Late Resolutions and Emergency Business (Amendments to C&B)
- 12. Report(s) of the Council on Ethical and Judicial Affairs - Ronald J. Clearfield, MD, Chair**
 - 01 Collaborative Care (Amendments to C&B)
 - 02 Competence, Self-Assessment and Self Awareness (Amendments to C&B)
 - 03 CEJA and House of Delegates Collaboration (Info. Report)
 - 04 Ethical Physician Conduct in the Media (Info. Report)
- 13. Opinion(s) of the Council on Ethical and Judicial Affairs - Ronald J. Clearfield, MD, Chair**
 - 01 Modernized Code of Medical Ethics (Info. Report)
 - 02 Ethical Practice in Telemedicine (Info. Report)
- 14. Report(s) of the Council on Long Range Planning and Development - Mary T. Herald, MD, Chair**
 - 01 Minority Affairs Section and Integrated Physician Practice Section, Five-Year Reviews (F)
- 15. Report(s) of the Council on Medical Education - Patricia L. Turner, MD, Chair**
 - 01 Access to Confidential Health Services for Medical Students and Physicians (C)
- 16. Report(s) of the Council on Medical Service - Peter S. Lund, MD, Chair**
 - 01 Infertility Benefits for Veterans (J)
 - 02 Health Care While Incarcerated (J)
 - 03 Providers and the Annual Wellness Visit (J)
 - 04 Concurrent Hospice and Curative Care (J)
 - 05 Incorporating Value into Pharmaceutical Pricing (J)
 - 06 Integration of Mobile Health Applications and Devices into Practice (J)
 - 07 Hospital Discharge Communications (J)
- 17. Report(s) of the Council on Science and Public Health - S. Bobby Mukkamala, MD, Chair**
 - 01 Urine Drug Testing (K)
 - 02 National Drug Shortages: Update (Info. Report)
 - 03 Genome Editing and its Potential Clinical Use (K)
 - 04 Hormone Therapies: Off-Label Uses and Unapproved Formulations (K)
- 18. Report(s) of the HOD Committee on Compensation of the Officers - Anthony M. Padula, MD, Chair**
 - * Report of the House of Delegates Committee on Compensation of the Officers (F)
- 19. Resolutions**
 - 001 Support for the Decriminalization and Treatment of Suicide Attempts Amongst Military Personnel (Amendments to C&B)
 - 002 Living Organ Donation at the Time of Imminent Death (Amendments to C&B)
 - 003 Study of the Current Uses and Ethical Implications of Expanded Access Programs (Amendments to C&B)
 - 004 Addressing Patient Spirituality in Medicine (Amendments to C&B)
 - 005* No Compromise on AMA's Anti-Female Genital Mutilation Policy (Amendments to C&B)
 - 006* Effective Peer Review (Amendments to C&B)
 - 007* Fair Process for Employed Physicians (Amendments to C&B)
 - 201 Removing Restrictions on Federal Funding for Firearm Violence Research (B)
 - 202 Inclusion of Sexual Orientation and Gender Identity Information in Electronic Health Records (B)

203 Universal Prescriber Access to Prescription Drug Monitoring Programs (B)
 204 Seamless Conversion of Medicare Advantage Programs (B)
 205 AMA Study of the Affordable Care Act (B)
 206 Advocacy and Studies on Affordable Care Act Section 1332 (State Innovation Waivers) (B)
 207 Limitation on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care (B)
 208 MIPS and MACRA Exemption (B)
 209 Affordable Care Act Revisit (B)
 210 Automatic Enrollment into Medicare Advantage (B)
 211 Electronic Health Records (B)
 212 Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation (B)
 213 SOAP Notes and Chief Complaint (B)
 214 Firearm Related Injury and Death: Adopt a Call to Action (B)
 215 Parental Leave (B)
 216* Ending Medicare Advantage Auto-Enrollment (B)
 217* The Rights of Patients, Providers and Facilities to Contract for Non-Covered Services (B)
 218* Support for Prescription Drug Monitoring Programs (B)
 219* Protect Individualized Compounding in Physicians' Offices as Practice of Medicine (B)
 301 Expanding the Treatment of Opioid Dependence Using Medication-Assisted Treatment by Physicians in Residency Training Programs (C)
 302 Protecting the Rights of Breastfeeding Residents and Fellows (C)
 303 Primary Care and Mental Health Training in Residency (C)
 304 Improving Access to Care and Health Outcomes (C)
 305 Privacy, Personal Use and Funding of Mobile Devices (C)
 306 Formal Leadership Training During Medical Education (C)
 307 Inappropriate Uses of Maintenance of Certification (C)
 308 Promoting and Reaffirming Domestic Medical School Clerkship Education (C)
 309 Development of Alternative Competency Assessment Models (C)
 310 Maintenance of Certification and Insurance Plan Participation (C)
 311 Prevent Maintenance of Certification Licensure and Hospital Privileging Requirements (C)
 312* Eliminating the Tax Liability for Payment of Student Loans (C)
 602 Equality (F)
 603 Support a Study on the Minimum Competencies and Scope of Medical Scribe Utilization (F)
 604* Oppose Physician Gun Gag Rule Policy by Taking our AMA Business Elsewhere (F)
 801 Increasing Access to Medical Devices for Insulin-Dependent Diabetics (J)
 802 Eliminate "Fail First" Policy in Addiction Treatment (J)
 803 Reducing Perioperative Opioid Consumption (J)
 804 Parity in Reproductive Health Insurance Coverage for Same-Sex Couples (J)
 805 Health Insurance Companies Should Collect Deductible from Patients After Full Payments to Physicians (J)
 806 Pharmaceutical Industry Drug Pricing is a Public Health Emergency (J)
 807 Pharmacy Use of Medication Discontinuation Messaging Function (J)
 808 A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities (J)
 809 Addressing the Exploitation of Restricted Distribution Systems by Pharmaceutical Manufacturers (J)

- 810 Medical Necessity of Breast Reconstruction and Reduction Surgeries (J)
- 811 Opposition to CMS Mandating Treatment Expectations and Practicing Medicine (J)
- 812 Enact Rules and Payment Mechanisms to Encourage Appropriate Hospice and Palliative Care Usage (J)
- 813 Physician Payment for Information Technology Costs (J)
- 814* Addressing Discriminatory Health Plan Exclusions or Problematic Benefit Substitutions for Essential Health Benefits Under the Affordable Care Act (J)
- 815* Preservation of Physician-Patient Relationships and Promotion of Continuity of Patient Care (J)
- 816* Support for Seamless Physician Continuity of Patient Care (J)
- 901 Disclosure of Screening Test Risks and Benefits, Performed Without a Doctor's Order (K)
- 902 Removing Restrictions on Federal Public Health Crisis Research (K)
- 903 Prevention of Newborn Falls in Hospitals (K)
- 904 Improving Mental Health at Colleges and Universities for Undergraduates (K)
- 905 Chronic Traumatic Encephalopathy (CTE) Awareness (K)
- 906 Universal Color Scheme for Respiratory Inhalers (K)
- 907 Clinical Implications and Policy Considerations of Cannabis Use (K)
- 908 Faith and Mental Health (K)
- 909 Promoting Retrospective and Cohort Studies on Pregnant Women and Their Children (K)
- 910 Disparities in Public Education as a Crisis in Public Health and Civil Rights (K)
- 911 Importance of Oral Health in Medical Practice (K)
- 912 Neuropathic Pain Recognized as a Disease (K)
- 913 Improving Genetic Testing and Counseling Services in Hospitals and Healthcare Systems (K)
- 914 Needle / Syringe Disposal (K)
- 915 Women and Alzheimer's Disease (K)
- 916 Women and Pre-Exposure Prophylaxis (PrEP) (K)
- 917 Youth Incarceration in Adult Prisons (K)
- 918 Ensuring Cancer Patient Access to Pain Medication (K)
- 919 Coal-Tar Based Sealcoat Threat to Human Health and the Environment (K)
- 920 Haptenation and Hypersensitivity Disorders Communication (K)
- 921 Raise the Minimum Age of Legal Access to Tobacco to 21 Years (K)
- 922 Responsible Parenting and Access to Family Planning (K)
- 923 Reverse Onus in the Manufacture and Use of Chemicals (K)
- 924 AMA Advocacy for Environmental Sustainability and Climate (K)
- 925* Graphic Warning Label on all Cigarette Packages (K)

20. Resolutions not for consideration

- 601 Sexual Orientation and Gender Identity Demographic Collection by the AMA and Other Medical Organizations (Not for consideration)
- 605* Study of Models of Childcare Provided at Healthcare Institutions (Not for consideration)

*** Contained in Handbook Addendum**

**DECLARATION OF PROFESSIONAL RESPONSIBILITY:
MEDICINE'S SOCIAL CONTRACT WITH HUMANITY**

Preamble

Never in the history of human civilization has the well-being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all.

As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well-being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to:

1. Respect human life and the dignity of every individual.
2. Refrain from supporting or committing crimes against humanity and condemn all such acts.
3. Treat the sick and injured with competence and compassion and without prejudice.
4. Apply our knowledge and skills when needed, though doing so may put us at risk.
5. Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.
6. Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.
7. Educate the public and polity about present and future threats to the health of humanity.
8. Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.
9. Teach and mentor those who follow us for they are the future of our caring profession.

We make these promises solemnly, freely, and upon our personal and professional honor.

Adopted by the House of Delegates of the American Medical Association
in San Francisco, California on December 4, 2001

Delegate/Alternate Delegate Job Description, Roles and Responsibilities

At the 1999 Interim Meeting, the House of Delegates adopted as amended Recommendation 16 of the final report of the Special Advisory Committee to the Speaker of the House of Delegates. This recommendation included a job description and roles and responsibilities for delegates and alternate delegates. The description and roles and responsibilities were modified at the 2002 Annual Meeting by Recommendation 3 of the Joint Report of the Board of Trustees and Council on Long Range Planning and Development. The modified job description, qualifications, and responsibilities are listed below.

Delegates and Alternate Delegates should meet the following job description and roles and responsibilities:

Job Description and Roles and Responsibilities of AMA Delegates/Alternate Delegates

Members of the AMA House of Delegates serve as an important communications, policy, and membership link between the AMA and grassroots physicians. The delegate/alternate delegate is a key source of information on activities, programs, and policies of the AMA. The delegate/alternate delegate is also a direct contact for the individual member to communicate with and contribute to the formulation of AMA policy positions, the identification of situations that might be addressed through policy implementation efforts, and the implementation of AMA policies. Delegates and alternate delegates to the AMA are expected to foster a positive and useful two-way relationship between grassroots physicians and the AMA leadership. To fulfill these roles, AMA delegates and alternate delegates are expected to make themselves readily accessible to individual members by providing the AMA with their addresses, telephone numbers, and e-mail addresses so that the AMA can make the information accessible to individual members through the AMA web site and through other communication mechanisms. The qualifications and responsibilities of this role are as follows:

A. Qualifications

- AMA member.
- Elected or selected by the principal governing body or the membership of the sponsoring organization.
- The AMA encourages that at least one member of each delegation be involved in the governance of their sponsoring organization.

B. Responsibilities

- Regularly communicate AMA policy, information, activities, and programs to constituents so he/she will be recognized as the representative of the AMA.
- Relate constituent views and suggestions, particularly those related to implementation of AMA policy positions, to the appropriate AMA leadership, governing body, or executive staff.
- Advocate constituent views within the House of Delegates or other governance unit, including the executive staff.
- Attend and report highlights of House of Delegates meetings to constituents, for example, at hospital medical staff, county, state, and specialty society meetings.
- Serve as an advocate for patients to improve the health of the public and the health care system.
- Cultivate promising leaders for all levels of organized medicine and help them gain leadership positions.
- Actively recruit new AMA members and help retain current members.
- Participate in the AMA Membership Outreach Program.

SEATING ALLOCATION – 2016 INTERIM MEETING

ANESTHESIOLOGISTS - 11

American Society of Anesthesiologists - 11
Trustees (Ehrenfeld, McDade) - 2
Former Board Chair (Patchin) - 1
Delegates - 7
Resident and Fellow Section Delegate – 1

CARDIOLOGY - 8

American College of Cardiology - 5
Delegates - 4
Resident and Fellow Section Delegate - 1
American Society of Echocardiography - 1
Heart Rhythm Society - 1
Society for Cardiovascular Angiography and Interventions - 1

DERMATOLOGY - 8

American Academy of Dermatology - 4
American College of Mohs Surgery - 1
American Society for Dermatologic Surgery - 1
American Society of Dermatopathology - 1
Society for Investigative Dermatology - 1

EMERGENCY MEDICINE - 6

American College of Emergency Physicians - 6
Delegates - 5
Resident and Fellow Section Delegate – 1

FAMILY PHYSICIANS - 19

American Academy of Family Physicians - 19
Former Board Chair (Langston) - 1
Delegates - 18

GASTROENTEROLOGY - 2

American College of Gastroenterology - 2

GREAT LAKES - 104

Illinois - 23
Trustee (Kobler) - 1
Delegates - 11
Medical Student Regional Delegate - 1
Resident and Fellow Section Delegate - 1
American Acad of Facial Plastic and Reconstructive Surgery - 1
American College of Legal Medicine - 1
American College of Nuclear Medicine - 1
American College of Radiation Oncology - 1
American Medical Women’s Association - 1
American Society for Metabolic and Bariatric Surgery - 1
American Society of Cytopathology - 1
American Thoracic Society - 1
Society of Nuclear Medicine and Molecular Imaging - 1
Indiana - 8
Former Board Chair (Steen) - 1
Delegates - 5
Medical Student Regional Delegate - 1
National Medical Association - 1

Michigan - 14

Delegates - 12
Medical Student Regional Delegate - 1
American Roentgen Ray Society - 1

New York - 30

Former President (Nielsen) - 1
Former Board Chair (Cady) - 1
Delegates - 19
Medical Student Regional Delegates - 2
American Association of Hip and Knee Surgeons - 1
American Society for Gastrointestinal Endoscopy - 1
American Society of Addiction Medicine - 1
American Society of Neuroradiology – 1
Society of Amer Gastrointestinal Endoscopic Surgeons - 1
Society of Hospital Medicine - 1
Society of Interventional Radiology - 1

Ohio - 12

Delegates - 10
Medical Student Regional Delegate - 1
Amer Assoc of Neuromuscular & Electrodiagnostic Med - 1

Pennsylvania - 17

Trustee (Sirio) - 1
Delegates - 13
Medical Student Regional Delegate - 1
American College of Medical Genetics and Genomics - 1
American Osteopathic Association - 1

HAND SURGEONS - 2

American Association for Hand Surgery - 1
American Society for Surgery of the Hand - 1

HEART OF AMERICA - 22

Arkansas - 3
Kansas - 5
Delegates - 3
American Society of Neuroimaging – 1
College of American Pathologists (1 of 4)
Missouri - 6
Oklahoma - 8
Delegates – 4
Medical Student Regional Delegate - 1
American College of Chest Physicians (CHEST) - 1
American College of Phlebology - 1
American Medical Group Association - 1

INTERNAL MEDICINE - 13

American College of Physicians - 13

NEUROSCIENCES - 22

Former President (Carmel) - 1
American Academy of Child and Adolescent Psychiatry - 1
American Academy of Neurology - 3
American Academy of Pain Medicine - 1
American Academy of Psychiatry and the Law - 1
American Association for Geriatric Psychiatry - 1
American Association of Neurological Surgeons - 2
Delegates - 1
Resident and Fellow Section Delegate - 1
American Psychiatric Association - 9
Delegates - 8
Resident and Fellow Section Delegate - 1
Congress of Neurological Surgeons - 1
GLMA - 1
Spine Intervention Society - 1

NEW ENGLAND - 28

Connecticut - 5
Delegates - 4
Resident and Fellow Section Delegate - 1
Maine - 3
Former President (McAfee) - 1
Delegates - 2
Massachusetts - 13
Delegates - 9
Medical Student Regional Delegate - 2
Resident and Fellow Section Delegate - 1
American Society of Abdominal Surgeons - 1
New Hampshire - 2
Trustee (Tuttle) - 1
Delegates - 1
Rhode Island – 2
Vermont - 3
Delegates – 1
Medical Student Regional Delegate - 1
Resident and Fellow Section Delegate - 1

NORTH CENTRAL - 27

Iowa - 4
Delegates - 3
International Academy of Independent Medical Evaluators- 1
Minnesota - 8
Trustee (Babu) - 1
Delegates – 5
Medical Student Regional Delegate - 1
AMDA–The Soc. for Post-Acute & Long-Term Care Medicine-1
Nebraska - 2
North Dakota - 1
South Dakota – 2
Delegates – 1
Medical Student Regional Delegation - 1
Wisconsin - 10
Former Board Chair (Flaherty) - 1
Delegates - 5
Medical Student Regional Delegate - 1
Resident and Fellow Section Delegate - 1
Radiological Society of North America - 1
Undersea and Hyperbaric Medical Society - 1

OBSTETRICIANS AND GYNECOLOGISTS - 14

American Congress of Obstetricians and Gynecologists - 14
Former President (Wah) - 1
Former Board Chair (Heyman) - 1
Delegates - 12

ONCOLOGY - 3

American Society of Clinical Oncology - 3
Delegates - 2
Resident and Fellow Section Delegate - 1

ORTHOPAEDIC SURGEONS - 5

American Academy of Orthopaedic Surgeons - 5

PACIFIC RIM - 44

Alaska - 1
California - 31
Former Presidents (Bristow, Corlin, Plested) - 3
Delegates - 21
Medical Student Regional Delegates - 2
American Clinical Neurophysiology Society - 1
American Society of Interventional Pain Physicians - 2
Delegates - 1
Resident and Fellow Section Delegate - 1
Infectious Diseases Society of America - 1
The Triological Society - 1
Hawaii - 2
Oregon - 3
Former President (Reardon) - 1
Delegates - 2
Washington - 7
Delegates - 4
Resident and Fellow Section Delegate - 1
American Society for Radiation Oncology - 1
National Association of Medical Examiners - 1

PEDIATRICS - 7

American Academy of Pediatrics - 7

PHYSICAL MEDICINE AND REHABILITATION - 2

American Academy of Physical Med & Rehabilitation - 2

PREVENTIVE MEDICINE - 6

Aerospace Medical Association - 1
American Academy of Insurance Medicine - 1
American Association of Public Health Physicians - 1
American College of Medical Quality - 1
American College of Occupational & Environmental Med - 1
American College of Preventive Medicine - 1

RADIOLOGY - 8

American College of Radiology - 8
Delegates - 7
Resident and Fellow Section Delegate - 1

RHEUMATOLOGY - 2

American College of Rheumatology - 2

SECTIONS - 11

Academic Physicians Section - 1
Integrated Physician Practice Section - 1
International Medical Graduates Section - 1
Medical Student Section - 2
Trustee (Maniya) - 1
Delegates - 1
Minority Affairs Section - 1
Organized Medical Staff Section - 1
Resident and Fellow Section – 1
Senior Physicians Section - 1
Women Physicians Section -1
Young Physicians Section - 1

SERVICES - 6

Air Force - 1
Army - 1
Association of Military Surgeons of the United States - 1
Navy - 1
Public Health Service - 1
Veterans Affairs - 1

SOUTHEASTERN - 115

Alabama - 7
Delegates - 4
Medical Student Regional Delegate - 1
American Geriatrics Society - 1
United States and Canadian Academy of Pathology - 1

SOUTHEASTERN (cont’d)

Delaware - 4
Trustee (Permut) - 1
Delegates - 1
Resident and Fellow Section Delegate - 1
Society of Critical Care Medicine - 1
District of Columbia - 3
Former Board Chair (Scalettar) - 1
Delegates - 2
Florida - 21
Former Presidents (Coble, Wilson) - 2
Delegates - 14
Medical Student Regional Delegate - 1
American Academy of Hospice and Palliative Medicine - 1
American Academy of Sleep Medicine - 1
American Society for Reproductive Medicine - 1
The Endocrine Society - 1
Georgia - 7
Delegates - 5
American Society for Clinical Pathology - 1
Association of University Radiologists - 1
Kentucky –5
Former President (Hoven) - 1
Delegates (minus Vice Speaker) - 5
Louisiana - 9
Former Presidents (Johnson, Palmisano) - 2
Delegates - 4
Medical Student Regional Delegate - 1
Resident and Fellow Section Delegate – 1
College of American Pathologists (1 of 4)

Maryland – 11

Trustee (Edwards) - 1
Former Board Chair (Lewers) - 1
Delegates - 5
Medical Student Regional Delegate - 1
Academy of Physicians in Clinical Research - 1
American Gastroenterological Association – 1
Renal Physicians Association - 1

Mississippi - 4

Former President (Hill) - 1
Delegates - 3

New Jersey - 9

Delegates - 7
Medical Student Regional Delegate - 1
American Orthopaedic Association - 1

North Carolina - 7

Trustee (Osbahr) - 1
Delegates - 6

Puerto Rico - 2

South Carolina - 6

Former President (Smoak) - 1
Delegates - 4
Medical Student Regional Delegate - 1

Tennessee - 9

Trustee (Williams) - 1
Delegates - 5
Medical Student Regional Delegate - 1
American Association of Physicians of Indian Origin - 1
International Society for the Advancement of Spine Surgery - 1
Virginia - 9
Former President (Wootton) - 1
Delegates - 7
Medical Student Regional Delegate - 1
West Virginia - 2

SURGEONS - 36

American Academy of Cosmetic Surgery - 1
American Academy of Ophthalmology - 4
American Academy of Otolaryngic Allergy - 1
Amer Acad of Otolaryngology - Head & Neck Surgery - 3
American Association for Thoracic Surgery - 1
American Association of Plastic Surgeons - 1
American College of Surgeons - 6
American Orthopaedic Foot and Ankle Society - 1
American Society for Aesthetic Plastic Surgery - 1
American Society of Breast Surgeons - 1
American Society of Cataract and Refractive Surgery - 1
American Society of Colon and Rectal Surgeons - 1
American Society of General Surgeons - 1
American Society of Maxillofacial Surgeons – 1
Amer Soc of Ophthalmic Plastic & Reconstructive Surg - 1
American Society of Plastic Surgeons - 3
Delegates - 2
Resident and Fellow Section Delegate - 1

SURGEONS (cont’d)

American Society of Retina Specialists - 1
Contact Lens Association of Ophthalmologists - 1
International College of Surgeons - US Section - 1
North American Spine Society - 1
Society for Vascular Surgery - 1
Society of Laparoendoscopic Surgeons - 1
Society of Thoracic Surgeons - 2

TERRITORIES - 2

Guam - 1
Virgin Islands - 1

TEXAS - 28

Trustee (Kridel) - 1
Former Presidents (Dickey, Painter, Rohack) - 3
Delegates (minus Speaker) - 18
Medical Student Regional Delegate - 2
Resident and Fellow Section Delegate - 1
American Association of Clinical Endocrinologists - 1
American Association of Gynecologic Laparoscopists - 1
American College of Allergy, Asthma and Immunology - 1
College of American Pathologists (1 of 4)

UROLOGY - 4

American Association of Clinical Urologists - 1
American Urological Association - 3
Delegates -2
Resident and Fellow Section Delegate - 1

WESTERN MOUNTAIN - 28

Arizona - 7
Delegates - 5
Medical Student Regional Delegate - 1
American Institute of Ultrasound in Medicine - 1
Colorado - 8
Former President (Lazarus) - 1
Delegates - 4
Resident and Fellow Section Delegate - 1
College of American Pathologists (1 of 4)
Obesity Medicine Association - 1
Idaho - 1
Montana - 1
Nevada - 2
New Mexico - 4
Trustee (McAneny) - 1
Delegates - 2
American Academy of Allergy, Asthma & Immunology - 1
Utah - 4
Former Presidents (A. Nelson, J. Nelson) - 2
Delegates - 2
Wyoming - 1

OFFICIAL OBSERVERS - 27

Accreditation Association for Ambulatory Health Care
Alliance for Continuing Education in the Health Professions
Alliance for Regenerative Medicine
Ambulatory Surgery Center Association
American Academy of Physician Assistants
American Association of Medical Assistants
American Board of Medical Specialties
American Dental Association
American Health Quality Association
American Hospital Association
American Nurses Association
American Public Health Association
Association of periOperative Registered Nurses
Association of State and Territorial Health Officials
Commission on Graduates of Foreign Nursing Schools
Council of Medical Specialty Societies
Educational Commission for Foreign Medical Graduates
Federation of State Medical Boards
Federation of State Physician Health Programs
Medical Group Management Association
National Association of County and City Health Officials
National Commission on Correctional Health Care
National Council of State Boards of Nursing
National Indian Health Board
PIAA
Society for Academic Continuing Medical Education
US Pharmacopeia

Tellers - 8

Chairs of AMA Councils - 10

HOUSE OF DELEGATES - 2016 INTERIM MEETING

STAGE

Reserved Seating for
Alternate Delegates

644 Delegate Chairs



Microphone

T Teller

Each state has been allotted seats for its Delegates, AMA Trustees not on the platform, Former Presidents and Former Chairs of the Board.

Specialty Society Delegates have been seated with state delegations according to their state of residence, unless otherwise requested. Specialties with more than one delegate are seated together, not within state delegations, or, if requested, seated by specialty designation, e.g., radiology, (see preceeding page).

Chair / Chair-elect of AMA Councils (10)																		
1	T	T	<									>	T	T				
OBGYN - 14							Anesthesiologists - 11											
2	<						>	<						>				
OBGYN							Arkansas - 3			Anesthesiologists								
3	<						>	<			>	<			>			
Sections - 11							Oklahoma - 8			Kansas - 5								
4	<						>	<			>	<			>			
Urology - 4				Sections				Oklahoma										
5	<					>	<				>	<			>			
PM&R - 2			Preventive Medicine - 6						Missouri - 6									
		<						>	<						>			
Nebraska - 2			Iowa - 4				Cardiology - 8											
		<						>	<						>			
Wisconsin - 10							Dermatology - 8											
8	<						>	<							>			
Wisconsin			ND - 1		South Dakota - 2			Connecticut - 5			NH - 2							
9	<						>	<				>	<		>			
Minnesota - 8							Vermont - 3			Maine - 3								
10	<							>	<				>	<		>		
Oregon - 3		AK - 1		Hawaii - 2			Massachusetts - 13											
11	<						>	<				>	<			>		
California - 31							Massachusetts					RI - 2						
12	<							>	<				>	<		>		
California							Oncology - 3			Gastro - 2		Rheum - 2						
13	<							>	<				>	<		>		
California							Radiology - 8											
		<						>	<							>		
California							Emergency Medicine - 6											
		<						>	<							>		
California			Washington - 7				Surgeons - 36											
16	<							>	<							>		
Territories - 2			Washington				Surgeons											
17	<							>	<							>		
Family Physicians - 19							Surgeons											
18	<							>	<							>		
Family Physicians							Surgeons											
19	<							>	<							>		
Pediatrics - 7				Family Physicians				Surgeons			Ortho Surgeons - 5							
20	<							>	<				>	<		>		
Pediatrics			Internal Medicine - 13						Surgeons			Ortho Surgeons						
21	<							>				<			>	<		>
Internal Medicine							Surgeons					Hand Surg - 2						
22	<							>				<			>	<		>
Official Observers																		
23	<															>		

Illinois - 23

Michigan - 14

1	T	T	<									>	T	T	
2	Illinois								Michigan						
3	Illinois								Michigan			Pennsylvania - 17			
4	Illinois				New York - 30				Pennsylvania						
5	New York				Pennsylvania										
6	New York				Louisiana - 9										
7	New York				La.			Maryland - 11							
8	New York				Ind. - 8			Maryland			West Va. - 2				
9	Indiana				Tennessee - 9										
10	Ohio - 12				Tennessee			Mississippi - 4							
11	Ohio		Neurosciences - 22				New Jersey - 9								
12	Neurosciences				New Jersey		Puerto Rico - 2		District of Columbia - 3						
13	Neurosciences				Virginia - 9										
14	Neurosciences				Texas - 28			Virginia		Delaware - 4					
15	Texas				Alabama - 7										
16	Texas				North Carolina - 7										
17	Texas				Florida - 21										
18	Texas		MT - 1		ID - 1		WY - 1		Florida						
19	Arizona - 7				Florida										
20	Colorado - 8				South Carolina - 6										
21	Utah - 4		Nevada - 2		NM - 4		Georgia - 7								
22	Services - 6				New Mexico			Kentucky - 5							
23	Official Observers														

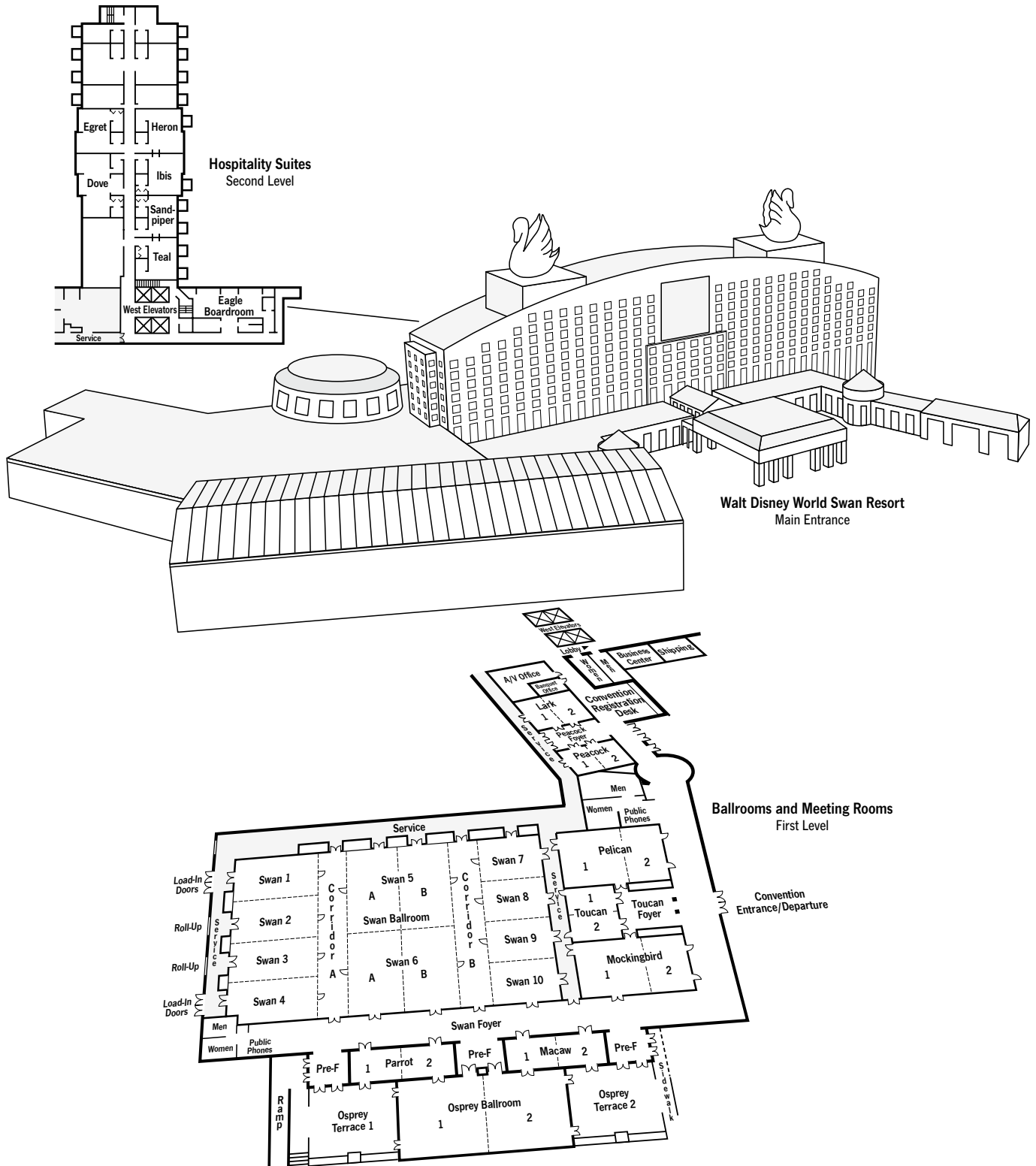
Reserved
Seating for
Press

Former Trustees

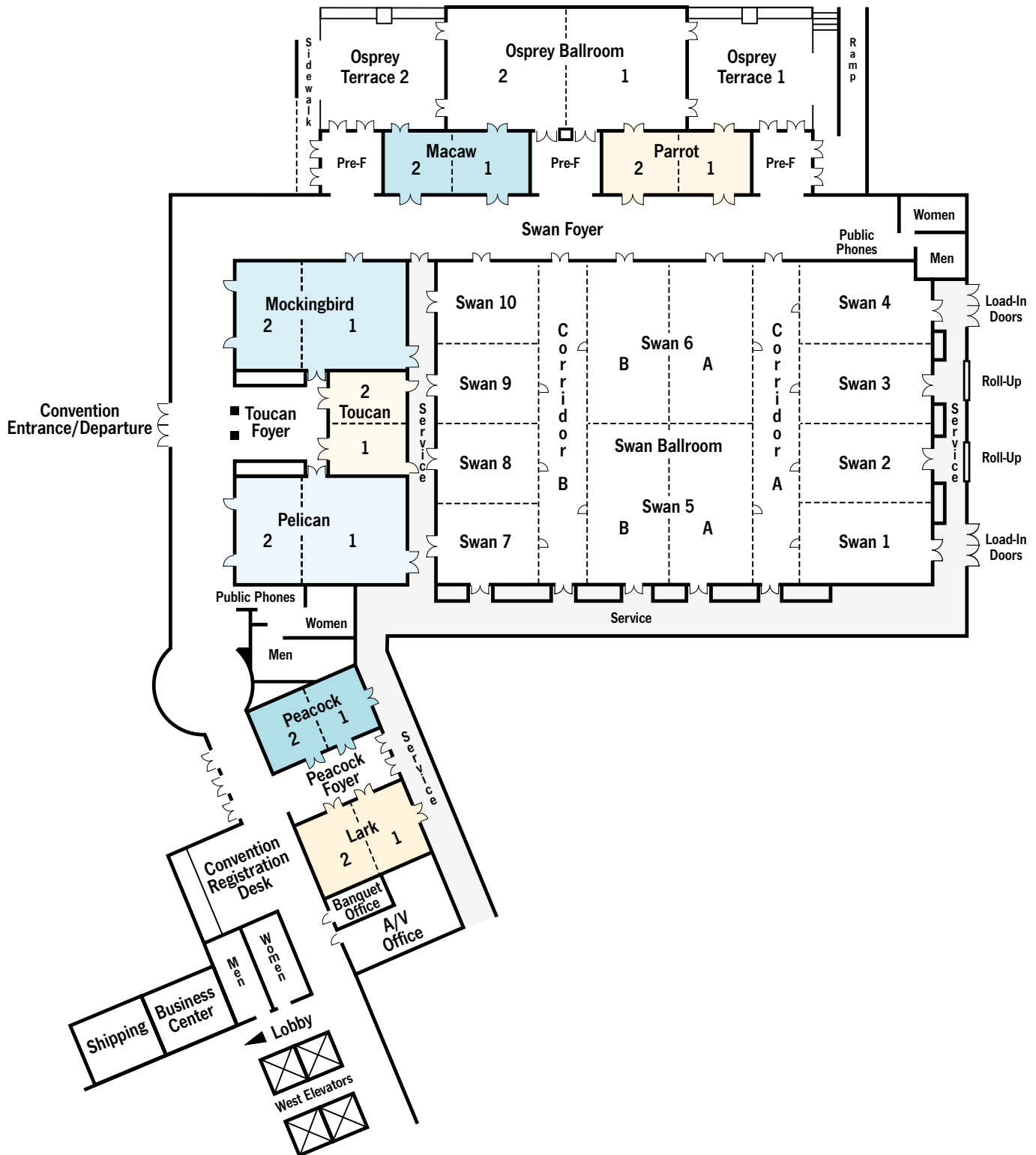
Reserved Seating for
Alternate Delegates

WALT DISNEY WORLD SWAN RESORT

Meeting Space Aerial View



First Level

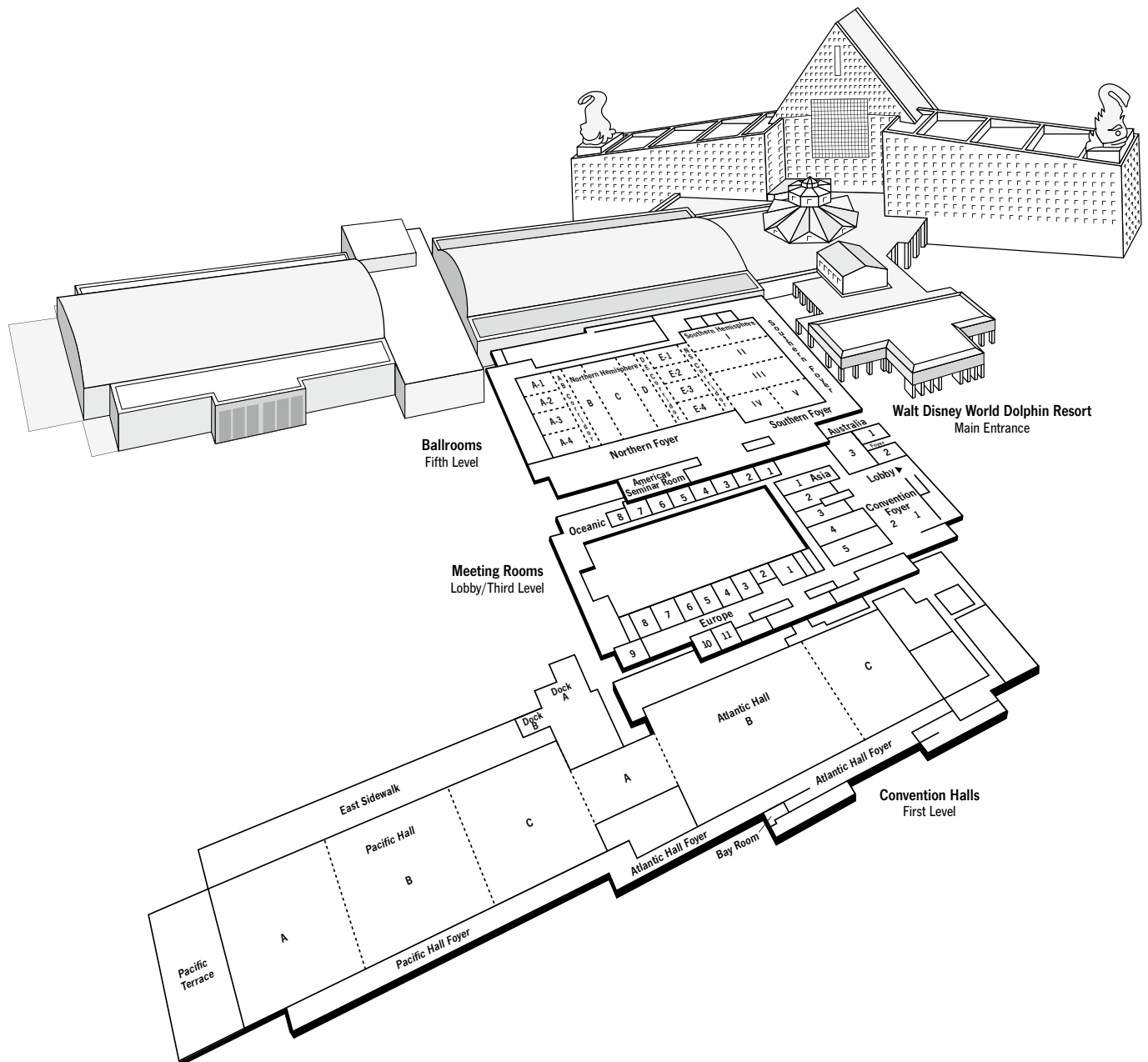


Second Level

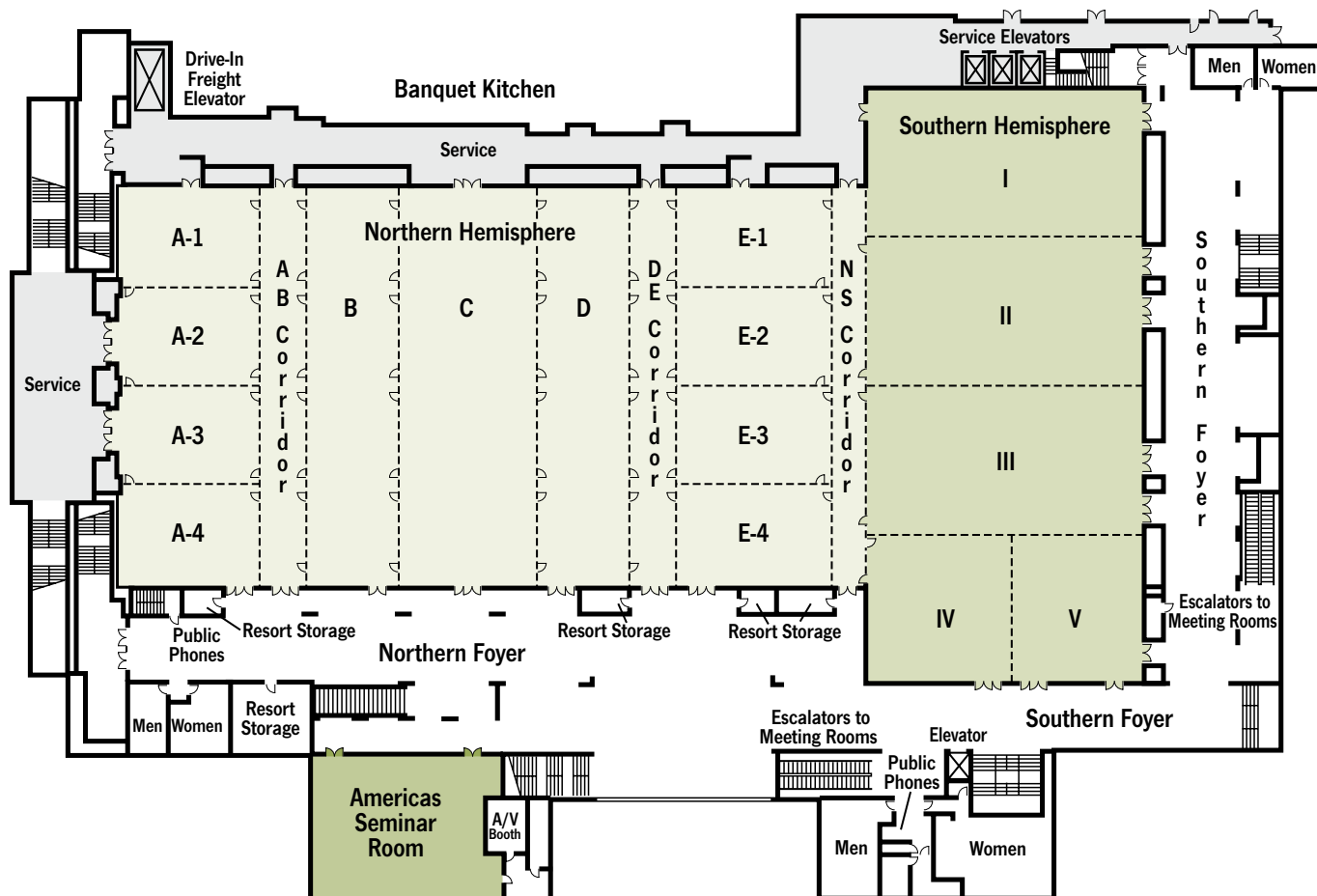


WALT DISNEY WORLD DOLPHIN RESORT

Meeting Space Aerial View



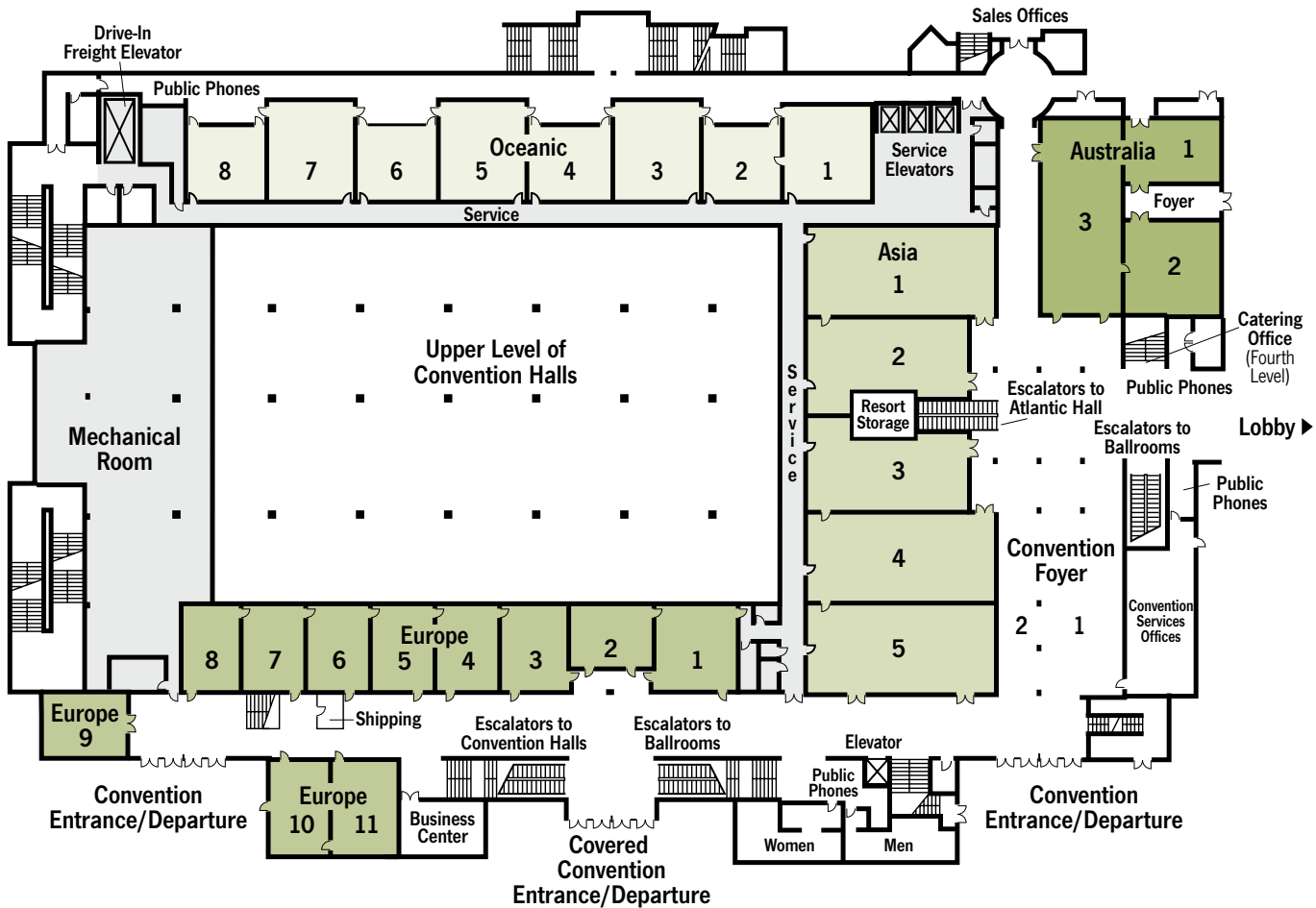
Fifth Level



FEATURES:

- 10,000 square foot sound booth running along the side of both ballrooms
- Programmable lighting and hang points in ceiling
- Extensive ventilation system permitting indoor pyrotechnics
- Drive-in freight elevator: 23'L x 10'W x 12'H; load limit: 12,000 lbs.
- Fully scalable DS-3 class Internet service, delivered via our fiber-optic and Ethernet backbone, available in the ballrooms and foyers
- Wireless access available throughout the ballrooms and foyers
- Salon B and Salon D in the Hemispheres Ballroom cannot stand alone
- Built-in A/V booth in Americas Seminar Room
- Complimentary house phone in Americas Seminar Room
- Convention network infrastructure managed by on-site technicians
- On-site audio/visual services department

Lobby/Third Level



FEATURES:

- Both fluorescent and incandescent adjustable lighting
- Simultaneous recording of presentation through a central audio mixer
- Each room includes four solid walls with bulletin board wall to maximize sound proofing, built-in A/V screen, and patches for microphone and video
- Drive-in freight elevator: 23'L x 10'W x 12'H; load limit: 12,000 lbs.
- Fully scalable DS-3 class Internet service, delivered via our fiber-optic and Ethernet backbone, available in all meeting rooms and foyers
- Wireless access available throughout all meeting rooms and foyers
- Complimentary house phone in meeting rooms
- Australia Boardroom
 - Projection display system and upgraded A/V system with touchpad control
 - Warm, modern décor with luxurious blonde wood paneling
 - Executive board table for 16 with over-sized ergonomic leather chairs
 - Private entry area
 - Connected his/hers lavatories

REFERENCE COMMITTEE HEARING LOCATIONS

SUNDAY, NOVEMBER 13
8:30am-Noon

Ref Cmte Amendments to C&B	Northern Hemisphere E3-4
Reference Committee B	Southern Hemisphere 2
Reference Committee C	Southern Hemisphere 4-5
Reference Committee F	Pacific A-B
Reference Committee J	Southern Hemisphere 3
Reference Committee K	Southern Hemisphere 1

2016 INTERIM MEETING OF THE AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Official Call to the Officers and Members of the American Medical Association to attend the Interim Meeting of the House of Delegates in Orlando, Florida, November 12-15, 2016.

The House of Delegates will convene at 2 p.m. on November 12, at the Walt Disney World Swan and Dolphin Resort, Orlando, Florida.

STATE ASSOCIATION REPRESENTATION IN THE HOUSE OF DELEGATES

Alabama 4	Georgia 5	Maryland 5	New Mexico 2	South Dakota 1
Alaska 1	Guam 1	Massachusetts 9	New York 19	Tennessee 5
Arizona 5	Hawaii 2	Michigan 12	North Carolina 6	Texas 18
Arkansas 3	Idaho 1	Minnesota 5	North Dakota 1	Utah 2
California 21	Illinois 11	Mississippi 3	Ohio 10	Vermont 1
Colorado 4	Indiana 5	Missouri 6	Oklahoma 4	Virgin Islands 1
Connecticut 4	Iowa 3	Montana 1	Oregon 2	Virginia 7
Delaware 1	Kansas 3	Nebraska 2	Pennsylvania 13	Washington 4
District of Columbia 2	Kentucky 5	Nevada 2	Puerto Rico 2	West Virginia 2
Florida 14	Louisiana 4	New Hampshire 1	Rhode Island 2	Wisconsin 5
	Maine 2	New Jersey 7	South Carolina 4	Wyoming 1

SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES

American Academy of Dermatology 4	American College of Physicians 13
American Academy of Family Physicians 18	American College of Radiology 7
American Academy of Neurology 3	American College of Rheumatology 2
American Academy of Ophthalmology 4	American College of Surgeons 6
American Academy of Orthopaedic Surgeons 5	American Congress of Obstetricians and Gynecologists 12
American Academy of Otolaryngology - Head and Neck Surgery 3	American Psychiatric Association 8
American Academy of Pediatrics 7	American Society of Anesthesiologists 7
American Academy of Physical Med. & Rehabilitation 2	American Society of Clinical Oncology 2
American College of Cardiology 4	American Society of Plastic Surgeons 2
American College of Emergency Physicians 5	American Urological Association 2
American College of Gastroenterology 2	College of American Pathologists 4
	Society of Thoracic Surgeons 2

Remaining eligible national medical specialty societies (95) are entitled to one delegate each.

The Academic Physicians Section, Integrated Physician Practice Section, International Medical Graduates Section, Medical Student Section, Minority Affairs Section, Organized Medical Staff Section, Resident and Fellow Section, Senior Physicians Section, Women Physicians Section, Young Physicians Section, Army, Navy, Air Force, Public Health Service, Department of Veterans Affairs, Professional Interest Medical Associations, AMWA, AOA and NMA are entitled to one delegate each.

State Medical Associations	266
National Medical Specialty Societies	219
Professional Interest Medical Associations	2
Other National Societies (AMWA, AOA, NMA)	3
Medical Student Regional Delegates	27
Resident and Fellow Delegate Representatives	20
Sections	10
Services	5
Total Delegates	552

Registration facilities will be maintained at the Walt Disney World Swan and Dolphin Resort, Orlando, Florida in the Dolphin Hotel Convention Foyer (lobby level).

Andrew W. Gurman, MD
President

Susan R. Bailey, MD
Speaker, House of Delegates

Patrice A. Harris, MD
Secretary

2016-2017

OFFICIALS OF THE ASSOCIATION

BOARD OF TRUSTEES (OFFICERS)

President - Andrew W. Gurman..... Hollidaysburg, Pennsylvania
President-Elect - David O. Barbe..... Mountain Grove, Missouri
Immediate Past President - Steven J. Stack..... Lexington, Kentucky
Secretary - Jack Resneck, Jr. San Rafael, California
Speaker, House of Delegates - Susan R. Bailey..... Fort Worth, Texas
Vice Speaker, House of Delegates - Bruce A. Scott, MD Louisville, Kentucky

Maya A. Babu (2017)..... Rochester, Minnesota
Willarda V. Edwards (2020) Baltimore, Maryland
Jesse M. Ehrenfeld (2018)..... Nashville, Tennessee
Gerald E. Harmon, *Chair-Elect* (2017)..... Pawleys Island, South Carolina
Patrice A. Harris, *Chair* (2019)..... Atlanta, Georgia
William E. Kobler (2020) Rockford, Illinois
Russell W.H. Kridel (2018) Houston, Texas
Omar Z. Maniya (2017) Princeton Junction, New Jersey
Barbara L. McAneny (2018)..... Albuquerque, New Mexico
William A. McDade (2020) Metairie, Louisiana
Albert J. Osbahr, III (2019)..... Hickory, North Carolina
Stephen R. Permut (2018)..... Wilmington, Delaware
Carl A. Sirio (2018) Pittsburgh, Pennsylvania
Georgia A. Tuttle (2019)..... Lebanon, New Hampshire
Kevin W. Williams (2020)..... Nashville, Tennessee

COUNCILS OF THE AMA

COUNCIL ON CONSTITUTION AND BYLAWS

Colette R. Willins, *Chair*, Westlake, Ohio (2019); Jerome C. Cohen, *Vice Chair*, Binghamton, New York (2017);
Naiim S. Ali, Burlington, Vermont (Resident (2018)); Patricia L. Austin, Alamo, California (2018); Madelyn E. Butler,
Tampa, Florida (2018); Pino D. Colone, Howell, Michigan (2020); Cyndi J. Yag-Howard, Naples, Florida (2018); Joy Lee,
Washington, DC (Student (2017)). Ex Officio, without vote: Susan R. Bailey, Fort Worth, Texas; Bruce A. Scott, MD,
Louisville, Kentucky. Secretary: Janice Robertson, Chicago, Illinois.

COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

Ronald J. Clearfield, Bonita Springs, Florida, *Chair* (2017); Dennis S. Agliano, Tampa, Florida *Vice Chair* (2018);
Marc Mendelsohn, Brooklyn, New York (Resident (2018)); Kathryn L. Moseley, Ann Arbor, Michigan (2020);
Alexander M. Rosenau, Allentown, Pennsylvania (2022); James E. Sabin, Boston, Massachusetts (2019);
Peter A. Schwartz, Reading, Pennsylvania (2023); Monique A. Spillman, Dallas, Texas (2021); Kimberly A. Swartz,
Gainesville, Florida (Student (2017)). Secretary: Bette Crigger, Chicago, Illinois.

COUNCIL ON LEGISLATION

E. Coy Irvin, Florence, South Carolina, *Chair* (2017); E. Scott Ferguson, West Memphis, Arkansas, *Vice Chair* (2017);
Jack J. Beller, Norman, Oklahoma, Immediate Past *Chair* (2017); Seyed H. Aleali, Bridgeport, Connecticut (2017);
John R. Corker, Dallas, Texas (Resident (2017)); Mary S. Carpenter, Winner, South Dakota (2017); Jacob R. Burns,
Gainesville, Florida (Student (2017)); Marilyn J. Heine, Dresher, Pennsylvania (2017); Beth Irish, Portland, Oregon
(Alliance Liaison (2017)); Jerry D. Kennett, Columbia, Missouri (2017); Vidya Kora, Michigan City, Indiana (AMPAC
Observer (2017)); Heather A. Smith, New York, New York (2017); David T. Tayloe, Jr., Goldsboro, North Carolina
(2017); Willie Underwood, III, Buffalo, New York (2017). Secretary: George Cox, Washington, DC.

COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

Mary T. Herald, Summit, New Jersey, *Chair* (2018); Glenn A. Loomis, LaGrangeville, New York, *Vice Chair* (2019); Clifford K. Moy, Frisco, Texas (2017); Gamini S. Soori, Omaha, Nebraska (2017); James Goodyear, North Wales, Pennsylvania (2017); Alfred Herzog, Hartford, Connecticut (2019); Shannon Pryor, Washington, DC (2020); Clarence Chou, Milwaukee, WI (2020); Rohil Shekhar (Student) (2017); Matthew Lecuyer, Providence, RI (Resident) (2019). Secretary: Susan Close, Chicago, Illinois.

COUNCIL ON MEDICAL EDUCATION

Patricia L. Turner, Chicago, Illinois, *Chair* (2019); Lynne M. Kirk, Dallas, Texas, *Chair-elect* (2019); Jacqueline A. Bello, Bronx, New York (2017); Carol D. Berkowitz, Torrance, California (2019) *Member-at-large*; Cynthia A. Jumper, Lubbock, Texas (2020); Darlyne Menscer, Charlotte, North Carolina, *Past Chair* (2017); Trishna H. Narula, MPH, Stanford, California (Student (2017)); Richard S. Pieters, Worcester, Massachusetts (2017); Liana Puscas, Durham, North Carolina (2017); Niranjan V. Rao, New Brunswick, New Jersey (2018); Luke Selby, Denver, Colorado (Resident (2017)); John P. Williams, Pittsburgh, Pennsylvania (2019). Secretary: Carrie Radabaugh, Chicago, Illinois.

COUNCIL ON MEDICAL SERVICE

Peter S. Lund, Erie, Pennsylvania, *Chair* (2018); Paul A. Wertsch, Madison, Wisconsin, *Chair-elect* (2018); Lisa Egbert, Dayton, Ohio (2017); Laura Faye Gephart, Tampa, Florida (Resident (2019)); W. Alan Harmon, Jacksonville, Florida (2020); James G. Hinsdale, San Jose, California (2019); Lynn Jeffers, Camarillo, California (2020); Peter Lavine, Washington, DC (2018); Asa Lockhart, Tyler, Texas (2018); Thomas Madejski, Medina, New York (2019); Karthik Sarma, Los Angeles, California (Student (2017)); Lynda M. Young, Worcester, Massachusetts (2017). Secretary: Val Carpenter, Chicago, Illinois.

COUNCIL ON SCIENCE AND PUBLIC HEALTH

S. Bobby Mukkamala, Flint, Michigan, *Chair* (2017); Robert A. Gilchick, Los Angeles, California, *Chair-elect* (2018); Robyn F. Chatman, Cincinnati, Ohio (2019); Noel N. Deep, Antigo, Wisconsin (2019); Alex Ding, Belmont, California (2020); Adam Dougherty, Sacramento, California (Resident (2017)); Kira A. Geraci-Ciardullo, Mamaroneck, New York (2018); Christina Kratschmer, Brooklyn, New York (Student (2017)); Ilse R. Levin, Silver Spring, Maryland (2017); Michael M. Miller, Madison, Wisconsin (2018); Bruce M. Smoller, Chevy Chase, Maryland (2019); David J. Welsh, Batesville, IN (2020). Secretary: Barry Dickinson, Chicago, Illinois.

AMERICAN MEDICAL ASSOCIATION POLITICAL ACTION COMMITTEE

Robert Puchalski, Waxhaw, North Carolina, *Chair*; Vidya S. Kora, Michigan City, Indiana, *Secretary*; Justin M. Bishop, Lubbock, Texas (Student); Kay C. Brada, Lawrence, Kansas (Alliance Representative); Steven J. Fleischman, New Haven, Connecticut; Linda B. Ford, Bellevue, Nebraska; Benjamin Z. Galper, Boston, Massachusetts (Resident); Dev A. GnanaDev, Colton, California; Stephen A. Imbeau, Florence, South Carolina; James L. Milam, Libertyville, Illinois; John W. Poole, Ridgewood, New Jersey; Lyle Thorstenson, Nacogdoches, Texas. *Executive Director and Treasurer*: Kevin Walker, Washington, DC.

EX OFFICIO MEMBERS OF THE HOUSE OF DELEGATES

The Former Presidents and Former Trustees of the Association, the Chairs of the Councils of the AMA and the current General Officers, with the exception of the Speaker and Vice Speaker of the House of Delegates, are ex officio, nonvoting members of the House of Delegates.

FORMER PRESIDENTS

Lonnie R. Bristow	1995-1996	Jeremy A. Lazarus	2012-2013	Thomas R. Reardon	1999-2000
Peter W. Carmel	2011-2012	Robert E. McAfee	1994-1995	J. James Rohack	2009-2010
Yank D. Coble, Jr.	2002-2003	Alan R. Nelson	1989-1990	Randolph D. Smoak, Jr.	2000-2001
Richard F. Corlin	2001-2002	John C. Nelson	2004-2005	Cecil B. Wilson	2010-2011
Nancy W. Dickey	1998-1999	Nancy H. Nielsen	2008-2009	Robert M. Wah	2014-2015
J. Edward Hill	2005-2006	Joseph T. Painter	1993-1994	Percy Wootton	1997-1998
Ardis D. Hoven	2013-2014	Donald J. Palmisano	2003-2004		
Daniel H. Johnson, Jr.	1996-1997	William G. Plested, III	2006-2007		

FORMER TRUSTEES

Herman I. Abromowitz	1997-2005	D. Ted Lewers	1993-2002
Susan Hershberg Adelman	1998-2002	W. J. Lewis	1979-1984
Kendall S. Allred	2008-2009	Audrey J. Ludwig	1990-1991
Raj S. Ambay	2009-2011	Justin B. Mahida	2009-2010
Joseph P. Annis	2006-2014	Robert E. McAfee	1984-1993
John H. Armstrong	2002-2006	Mary Anne McCaffree	2008-2016
Timothy E. Baldwin	1987-1989	Joe T. McDonald	2005-2006
Regina M. Benjamin	1995-1998	Samuel J. Mackenzie	2014-2015
Scott L. Bernstein	1991-1992	Robert R. McMillan	2002-2008
Stefano M. Bertozzi	1986-1988	Sandeep "Sunny" Mistry	2000-2001
David J. Brailer	1985-1986	Alan R. Nelson	1980-1988
Lonnie R. Bristow	1985-1994	John C. Nelson	1994-2003
Rufus K. Broadaway	1982-1991	Nancy H. Nielsen	2005-2007
Duane M. Cady	1999-2007	Joseph T. Painter	1984-1992
Peter Carmel	2002-2010	Donald J. Palmisano	1996-2002
Alice A. Chenault	1984-1985	Rebecca J. Patchin	1988-1989
Yank D. Coble	1994-2001	Rebecca J. Patchin	2003-2011
David S. Cockrum	1993-1994	Pamela Petersen-Crair	1996-1998
MaryAnn Contogiannis	1989-1993	Dina Marie Pitta	2015-2016
Malini Daniel	2012-2013	William G. Plested, III	1998-2005
Christopher M. DeRienzo	2006-2008	Stephen Pool	1995-1996
Nancy W. Dickey	1989-1997	Liana Puscas	1999-2001
Alexander Ding	2011-2013	Thomas R. Reardon	1990-1998
William A. Dolan	2007-2011	Kevin C. Reilly	2003-2005
F. William Dowda	1982-1985	Ryan J. Ribeira	2013-2014
Timothy T. Flaherty	1994-2003	Joseph A. Riggs	1999-2003
Palma E. Formica	1990-1999	J. James Rohack	2001-2008
Melissa J. Garretson	1992-1993	David A. Rosman	2002-2004
Michael S. Goldrich	1993-1997	Samantha L. Rosman	2005-2009
Julie K. Goonewardene	2012-2016	Raymond Scalettar	1985-1994
Alan C. Hartford	1989-1990	Bruce A. Scott	1998-2002
William A. Hazel, Jr.	2004-2009	P. John Seward	1990-1995
Cyril M. Hetsko	2003-2011	Randolph D. Smoak, Jr.	1992-1999
Joseph M. Heyman	2002-2010	Lowell H. Steen	1975-1982
J. Edward Hill	1996-2004	Michael Suk	1994-1995
Ardis D. Hoven	2005-2012	Andrew M. Thomas	1997-1999
William E. Jacott	1989-1998	Jeffrey A. Towson	1998-1999
Hillary D. Johnson	2001-2002	Jordan M. VanLare	2011-2012
Matthew D. Kagan	1999-2000	Robert M. Wah	2005-2013
Christopher K. Kay	2008-2012	Peter Y. Watson	2001-2003
Robert T. Kelly	1980-1983	Monica C. Wehby	2011-2013
Edward L. Langston	2003-2011	Meredith C. Williams	2010-2011
Matthew C. Lawyer	2004-2005	Cecil B. Wilson	2002-2009
Jeremy A. Lazarus	2005-2011	Percy Wootton	1991-1996

SPECIALTY AND SERVICE SOCIETY REPRESENTATIVES

(The following are not members of the House of Delegates, but are representatives of the following societies which are represented in the SSS.)

American Academy of Emergency Medicine	Joseph Wood, MD, JD
American Society of Nuclear Cardiology	David Winchester, MD
Society of Gynecologic Oncologists	Carol Brown, MD
American Society of Transplant Surgeons	Thomas Peters, MD
National Lipid Association	Michael Davidson, MD
Society of Cardiovascular Computed Tomography	Vinay Malhotra, MD
Korean American Medical Association	John Yun, MD
Association of Professors of Dermatology	Christopher R. Shea, MD
American Society for Reconstructive Microsurgery	Gregory R. D. Evans, MD
American Rhinological Society	Joseph B. Jacobs, MD
North American Neuromodulation Society	Haroon Hameed, MD
North American Neuro-Ophthalmology Society	Nicholas J. Volpe, MD
American Society of Hematology	Gamini Soori, MD
International Society of Hair Restoration Surgery	Carlos Puig, MD
American Association of Endocrine Surgeons	Steven De Jong, MD
American College of Medical Toxicology	Charles McKay, MD

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The following is a list of delegates and alternate delegates to the House of Delegates
as reported to the Executive Vice President

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Beverly F Jordan, Enterprise AL
George C Smith, Lineville AL

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B Jerry Harrison, Hayleyville AL
Mark H LeQuire, Montgomery AL
Bill Schneider, Huntsville AL

Regional Medical Student Delegate(s)

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Delegate(s)

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Alternate Delegate(s)

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Thomas H Hicks, Tucson AZ
M Zuhdi Jasser, Phoenix AZ

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Ross Goldberg, Phoenix AZ
Michael Hamant, Tucson AZ
Marc Leib, Phoenix AZ

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Katie Marsh, Tucson AZ

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Delegate(s)

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James J Strebig, Irvine CA
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Gordon Fung, San Francisco CA
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Poyin Huang, Los Angeles CA
Scott Richard Karlan, West Hollywood CA
Nikan Khatibi, Laguna Niguel CA

This list does not reflect temporary changes for this meeting.

California Medical Association

Alternate Delegate(s)

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Maria T Lymberis, Santa Monica CA
Ramin Manshadi, Stockton CA
Theodore Mazer, San Diego CA
Lisa S Miller, San Diego CA
Helene Nepomuceno, Orange CA
Anum Syed, Sylmar CA
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Jan Kief, Highlands Ranch CO
Katie Lozano, Centennial CO
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Medical Society of Delaware

Alternate Delegate(s)

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Alan B Pillersdorf, Lake Worth FL
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Thomas G Peters, Jacksonville FL
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Sergio B Seoane, Lakeland FL
Aaron Sudbury, Bradenton FL
Michael Zimmer, St Petersburg FL

This list does not reflect temporary changes for this meeting.

Florida Medical Association

Regional Medical Student Delegate(s)

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Hunter Pattison, Gainesville FL

Anna Beth West, Gainesville FL

Medical Association of Georgia

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Alternate Delegate(s)

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Brent Mohr, South Bend IN

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Regional Medical Student Alternate Delegate(s)

Ashtin Jeney, Arlington VA

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Alain A Chaoui, Boxford MA
Ronald Dunlap, Norwell MA

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Rose M Ramirez, Belmont MI
Venkat K Rao, Flint MI

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Kathryn Lombardo, Rochester MN
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William Nicholson, White Bear Lake MN
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Jennifer Bryan, Flowood MS
J Clay Hays, Jackson MS

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Daniel P Edney, Vicksburg MS
Lee Voulters, Gulfport MS

This list does not reflect temporary changes for this meeting.

Missouri State Medical Association

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Lent Johnson, Hannibal MO

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Nathaniel Murdock, St Louis MO
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Charles W Van Way, Kansas City MO

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Jared Lammert, Columbia MO

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Alternate Delegate(s)

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Regional Medical Student Alternate Delegate(s)

Karen Dionesotes, Omaha NE

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Nevada State Medical Association

Alternate Delegate(s)

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Alternate Delegate(s)

Stuart Glassman, Concord NH

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Regional Medical Student Alternate Delegate(s)

Arjun Gupta, East Hanover NJ

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Stephen P Lucero, Santa Fe NM

Alternate Delegate(s)

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William Ritchie, Albuquerque NM

Medical Society of the State of New York

Delegate(s)

Jerome C Cohen, Binghamton NY
Frank G Dowling, Islandia NY

This list does not reflect temporary changes for this meeting.

Medical Society of the State of New York

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John J Kennedy, Schenectady NY
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Charles Rothberg, Patchogue NY
Joseph Sellers, Cobleskill NY
Jocelyn Young, Rochester NY
Daniel M Young, Windsor NY

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Pratistha Koirala, Bronx NY
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Abdul Rehman, Staten Island NY
Corliss Varnum, Oswego NY
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Richard Vienne, Buffalo NY

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North Carolina Medical Society

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Alternate Delegate(s)

A Michael Booth, Bismarck ND

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Charles J Hickey, Dublin OH
Gary R Katz, Dublin OH
William C. Sternfeld, Toledo OH
Donna A Woodson, Toledo OH

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Denise L Bobovnyik, Canfield OH
David O Griffith, Troy OH
Samantha King, Columbus OH
Deepak Kumar, Dayton OH
Andrew Rudawsky, Stow OH
Carl S Wehri, Delphos OH
Regina Whitfield-Kekessi, West Chester OH

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Kevin Qin, Toledo OH

Regional Medical Student Alternate Delegate(s)

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Brandon E Tabman, Columbus OH

This list does not reflect temporary changes for this meeting.

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Jay A Gregory, Muskogee OK
Bruce Storms, Chickasha OK

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Jenny Boyer, Tulsa OK
Julie Hager, Oklahoma City OK
Woody Jenkins, Stillwater OK

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John Carradini, Tulsa OK

Regional Medical Student Alternate Delegate(s)

Brady Iba, Oklahoma City OK

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Sylvia Ann Emory, Eugene OR

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Ralph Schmeltz, Pittsburgh PA
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Mark Friedlander, Nabeth PA
Kevin Owen Garrett, Allison Park PA

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Jill M Owens, Bradford PA
Evan Pollack, Bryn Mawr PA
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Scott E Shapiro, Lower Gwynedd PA
John Michael Vasudevan, Philadelphia PA
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Regional Medical Student Alternate Delegate(s)

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Alternate Delegate(s)

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Jose Luis Romany Rodriguez, San Juan PR

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Peter A Hollmann, Cranston RI

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Sarah Fessler, Riverside RI

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Terry Dodge, Rock Hill SC
Richard Osman, Myrtle Beach SC
Bruce A Snyder, Greenville SC

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Jayme Looper, West Columbia SC

This list does not reflect temporary changes for this meeting.

South Carolina Medical Association

Regional Medical Student Alternate Delegate(s)

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Delegate(s)

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Alternate Delegate(s)

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John J Ingram, Alcoa TN

Lee R Morisy, Memphis TN

BW Ruffner, Signal Mountain TN

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James D King, Selmer TN

J. Fred Ralston, Jr, Fayetteville TN

Wiley T Robinson, Memphis TN

Christopher E Young, Signal Mtn TN

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A Tomas Garcia, Houston TX

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Robert T Gunby, Dallas TX

David N Henkes, San Antonio TX

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Asa C Lockhart, Tyler TX

Kenneth L Mattox, Houston TX

Kevin H McKinney, Galveston TX

Clifford K. Moy, Frisco TX

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Lyle S Thorstenson, Nacogdoches TX

E Linda Villarreal, Edinburg TX

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John G Flores, Little Elm TX

Gregory M Fuller, Keller TX

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Cynthia Jumper, Lubbock TX

Jerry D McLaughlin, Longview TX

Jennifer Nordhauser, San Antonio TX

Christopher Plummer, San Antonio TX

Jayesh Shah, San Antonio TX

Elizabeth Torres, Sugar Land TX

Roxanne Tyroch, El Pasco TX

Arlo F Weltge, Bellaire TX

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Jared Bell, Santa Teresa NM

Jerome Jeevarajan, Dallas TX

Regional Medical Student Alternate Delegate(s)

Carlos Martinez, Lubbock TX

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Delegate(s)

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Sharon Richens, St. George UT

Alternate Delegate(s)

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D Glenn Morrell, Layton UT

Vermont Medical Society

Delegate(s)

Robert Tortolani, Brattleboro VT

Alternate Delegate(s)

Robert Block, Bennington VT

This list does not reflect temporary changes for this meeting.

Vermont Medical Society

Resident and Fellow Sectional Delegate(s)

Naiim Ali, Burlington VT

Regional Medical Student Delegate(s)

Kelsey Sullivan, Colchester VT

Medical Society of Virginia

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Thomas W Eppes, Forest VA

Randolph J Gould, Norfolk VA

Hazle S Konerding, Richmond VA

Mitchell B Miller, Virginia Beach VA

Lawrence K Monahan, Roanoke VA

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Bhushan H Pandya, Danville VA

Sterling N Ransone, Deltaville VA

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Alternate Delegate(s)

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Tosha Wetterneck, Madison WI

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Barbara Hummel, Milwaukee WI

George Melvin Lange, Milwaukee WI

Kashni Ramnanan, Summit WI

Claudia L Reardon, Madison WI

Resident and Fellow Sectional Delegate(s)

Casey Melcher, Milwaukee WI

Resident and Fellow Sectional Alternate Delegate(s)

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Delegate(s)

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American Academy of Pediatrics

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Melissa J Garretson, Fort Worth TX

Samantha Rosman, Jamaica Plain MA

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Jonathan Klein, Elk Grove Village IL

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Delegate(s)

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Leon Reinstein, Baltimore MD

Alternate Delegate(s)

Mohammad Agha, Columbia MO

Carlo Milani, Seattle WA

American Academy of Psychiatry and the Law

Delegate(s)

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Alternate Delegate(s)

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American Academy of Sleep Medicine

Delegate(s)

Alejandro Chediak, Miami FL

Alternate Delegate(s)

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This list does not reflect temporary changes for this meeting.

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Alternate Delegate(s)

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American Association for Hand Surgery

Delegate(s)

Peter C Amadio, Rochester MN

Alternate Delegate(s)

Nicholas B Vedder, Seattle WA

American Association for Thoracic Surgery

Delegate(s)

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American Association of Clinical Endocrinologists

Delegate(s)

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American Association of Clinical Urologists

Delegate(s)

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American Association of Gynecologic Laparoscopists

Delegate(s)

Joseph M Maurice, Chicago IL

American Association of Hip and Knee Surgeons

Delegate(s)

Chris Dangles, Champaign IL

Alternate Delegate(s)

Edward Tanner III, Rochester NY

American Association of Neurological Surgeons

Delegate(s)

Kenneth S Blumenfeld, San Jose CA

Alternate Delegate(s)

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American Association of Physicians of Indian Origin

Delegate(s)

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Delegate(s)

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Alternate Delegate(s)

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American Association of Public Health Physicians

Delegate(s)

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Alternate Delegate(s)

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Delegate(s)

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American College of Allergy, Asthma and Immunology

Delegate(s)

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Alternate Delegate(s)

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American College of Cardiology

Delegate(s)

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Suma Thomas, Cleveland OH

L Samuel Wann, Whitefish Bay WI

Kim Allan Williams, Chicago IL

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Delegate(s)

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American Society for Dermatologic Surgery

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Alternate Delegate(s)

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American Society of Cytopathology

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Army

Delegate(s)

Michael R Nelson, Olney MD

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Alternate Delegate(s)

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GLMA

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Alternate Delegate(s)

Desiray Bailey, Des Moines WA

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Delegate(s)

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Alternate Delegate(s)

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Alternate Delegate(s)

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Alternate Delegate(s)

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Alternate Delegate(s)

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National Association of Medical Examiners

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Alternate Delegate(s)

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National Medical Association

Delegate(s)

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Alternate Delegate(s)

Sandra L Gadson, Merrillville IN

Navy

Delegate(s)

Mae Pouget, Falls Church VA

Alternate Delegate(s)

Christopher Culp, Honolulu HI

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Delegate(s)

R Dale Blasier, Little Rock AR

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Obesity Medicine Association**Delegate(s)**

Ethan Lazarus, Greenwood Village CO

Alternate Delegate(s)

Carolynn Francavilla, Lakewood CO

Resident and Fellow Sectional Alternate Delegate(s)

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Alternate Delegate(s)

Kevin C Reilly, Elizabethtown KY

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Alternate Delegate(s)

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Alternate Delegate(s)

Clifford Kavinsky, Chicago IL

Society for Investigative Dermatology**Delegate(s)**

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Alternate Delegate(s)

Paul R Bergstesser, Dallas TX

Society for Vascular Surgery**Delegate(s)**

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Paresh Shah, New York NY

Alternate Delegate(s)

Eli Lerner, Jacksonville FL

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Alternate Delegate(s)

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Society of Hospital Medicine**Delegate(s)**

Brad Flansbaum, New York NY

Society of Interventional Radiology**Delegate(s)**

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Alternate Delegate(s)

Terence Matalon, Philadelphia PA

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Society of Nuclear Medicine and Molecular Imaging**Delegate(s)**

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Alternate Delegate(s)

Hazem H Chehabi, Newport Beach CA

Society of Thoracic Surgeons**Delegate(s)**

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Robert M Vanecko, Chicago IL

Spine Intervention Society**Delegate(s)**

Claire Tibiletti, Tyler TX

Alternate Delegate(s)

Kieran Slevin, Voorhees NJ

This list does not reflect temporary changes for this meeting.

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Delegate(s)

Michael E Hoffer, San Diego CA

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Delegate(s)

Laurie Gesell, Brookfield WI

US and Canadian Academy of Pathology

Delegate(s)

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Alternate Delegate(s)

Daniel Zedek, Chapel Hill NC

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Delegate(s)

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Alternate Delegate(s)

John K Iskander, Atlanta GA

Veterans Affairs

Delegate(s)

Carolyn M Clancy, Washington DC

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Academic Physicians Section

Delegate(s)

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Alternate Delegate(s)

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Delegate(s)

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Delegate(s)

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Alternate Delegate(s)

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Delegate(s)

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Alternate Delegate(s)

William Estes, Temple TX

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Delegate(s)

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Alternate Delegate(s)

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Alternate Delegate(s)

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Alternate Delegate(s)

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Delegate(s)

Josephine Nguyen, Gig Harbor WA

Alternate Delegate(s)

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Delegate(s)

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Alternate Delegate(s)

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Sherri Baker, MD, Oklahoma

* Alternate Delegate

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

2016 Interim Meeting Notes on Orders of Business

FIRST SESSION, Saturday, November 12, 2:00 – 6:00 pm

SECOND SESSION, Sunday, November 13, 8:00 – 8:30 am

THIRD SESSION, Monday, November 14, 2:00 – 6:00 pm

FOURTH SESSION, Tuesday, November 15, 8:30 am – noon

SUMMARY OF FISCAL NOTES (I-16)

BOT Report(s)

- 01 2016 AMA Advocacy Efforts: Informational report
- 02 AMA Support for State Medical Societies' Efforts to Implement MICRA-Type Legislation: Modest
- 03 Model State Legislation Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid Prescribing: Modest
- 04 Redefining the AMA's Position on the ACA and Healthcare Reform - Update: Informational report
- 05 IOM "Dying in America" Report: Minimal
- 06 Designation of Specialty Societies for Representation in the House of Delegates: Minimal
- 07 Supporting Autonomy for Patients with Differences of Sex Development: Minimal
- 08 Medical Reporting for Safety Sensitive Positions: Minimal
- 09 Product-Specific Direct-to-Consumer Advertising of Prescription Drugs: Minimal
- 10 AMA Initiatives on Pharmaceutical Costs: Informational report
- 11 2017 Strategic Plan: Informational report

CC&B Report(s)

- 01 Membership and Representation in the Organized Medical Staff Section - Updated Bylaws: Minimal
- 02 Bylaw Amendments Pertaining to Late Resolutions and Emergency Business: Minimal

CEJA Opinion(s)

- 01 Modernized Code of Medical Ethics: Informational Report
- 02 Ethical Practice in Telemedicine: Informational Report

CEJA Report(s)

- 01 Collaborative Care: Minimal
- 02 Competence, Self-Assessment and Self Awareness: Minimal
- 03 CEJA and House of Delegates Collaboration: Informational Report
- 04 Ethical Physician Conduct in the Media: Informational Report

CLRPD Report(s)

- 01 Minority Affairs Section and Integrated Physician Practice Section, Five-Year Reviews: Minimal

CME Report(s)

- 01 Access to Confidential Health Services for Medical Students and Physicians: Minimal

CMS Report(s)

- 01 Infertility Benefits for Veterans: Minimal
- 02 Health Care While Incarcerated: Minimal
- 03 Providers and the Annual Wellness Visit: Minimal
- 04 Concurrent Hospice and Curative Care: Minimal
- 05 Incorporating Value into Pharmaceutical Pricing: Minimal
- 06 Integration of Mobile Health Applications and Devices into Practice: Modest
- 07 Hospital Discharge Communications: Minimal

SUMMARY OF FISCAL NOTES (I-16)

CSAPH Report(s)

- 01 Urine Drug Testing: \$30,000
- 02 National Drug Shortages: Update: Informational Report
- 03 Genome Editing and its Potential Clinical Use: Minimal
- 04 Hormone Therapies: Off-Label Uses and Unapproved Formulations: Minimal

HOD Comm on Compensation of the Officers

- * Report of the House of Delegates Committee on Compensation of the Officers: \$80,000 - see report.

Resolution(s)

- 001 Support for the Decriminalization and Treatment of Suicide Attempts Amongst Military Personnel: Minimal
- 002 Living Organ Donation at the Time of Imminent Death: Modest
- 003 Study of the Current Uses and Ethical Implications of Expanded Access Programs: Modest
- 004 Addressing Patient Spirituality in Medicine: Minimal
- 005* No Compromise on AMA's Anti-Female Genital Mutilation Policy: Modest
- 006* Effective Peer Review: Modest
- 007* Fair Process for Employed Physicians: Minimal
- 201 Removing Restrictions on Federal Funding for Firearm Violence Research: Modest
- 202 Inclusion of Sexual Orientation and Gender Identity Information in Electronic Health Records: Minimal
- 203 Universal Prescriber Access to Prescription Drug Monitoring Programs: Minimal
- 204 Seamless Conversion of Medicare Advantage Programs: Modest
- 205 AMA Study of the Affordable Care Act: Modest
- 206 Advocacy and Studies on Affordable Care Act Section 1332 (State Innovation Waivers): Modest
- 207 Limitation on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care: Modest
- 208 MIPS and MACRA Exemption: Modest
- 209 Affordable Care Act Revisit: Modest
- 210 Automatic Enrollment into Medicare Advantage: Modest
- 211 Electronic Health Records: Minimal
- 212 Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation: Minimal
- 213 SOAP Notes and Chief Complaint: Minimal
- 214 Firearm Related Injury and Death: Adopt a Call to Action: Minimal
- 215 Parental Leave: Estimated cost of \$31,000 to conduct a detailed literature review of the impact of various forms of leave on patient health. Evaluate relevant studies and identify data sources needed to provide estimates. Estimate impacts and write-up results.
- 216* Ending Medicare Advantage Auto-Enrollment: Modest
- 217* The Rights of Patients, Providers and Facilities to Contract for Non-Covered Services: Modest
- 218* Support for Prescription Drug Monitoring Programs: Minimal
- 219* Protect Individualized Compounding in Physicians' Offices as Practice of Medicine: Modest
- 301 Expanding the Treatment of Opioid Dependence Using Medication-Assisted Treatment by Physicians in Residency Training Programs: Minimal
- 302 Protecting the Rights of Breastfeeding Residents and Fellows: Modest
- 303 Primary Care and Mental Health Training in Residency: Minimal
- 304 Improving Access to Care and Health Outcomes: Minimal
- 305 Privacy, Personal Use and Funding of Mobile Devices: Minimal

SUMMARY OF FISCAL NOTES (I-16)

Resolution(s)

- 306 Formal Leadership Training During Medical Education: Modest
- 307 Inappropriate Uses of Maintenance of Certification: Modest
- 308 Promoting and Reaffirming Domestic Medical School Clerkship Education: Modest
- 309 Development of Alternative Competency Assessment Models: Minimal
- 310 Maintenance of Certification and Insurance Plan Participation: Minimal
- 311 Prevent Maintenance of Certification Licensure and Hospital Privileging Requirements: Modest
- 312* Eliminating the Tax Liability for Payment of Student Loans: Modest
- 602 Equality: No significant fiscal impact
- 603 Support a Study on the Minimum Competencies and Scope of Medical Scribe Utilization: Moderate
- 604* Oppose Physician Gun Gag Rule Policy by Taking our AMA Business Elsewhere: Minimal
- 801 Increasing Access to Medical Devices for Insulin-Dependent Diabetics: Modest
- 802 Eliminate "Fail First" Policy in Addiction Treatment: Minimal
- 803 Reducing Perioperative Opioid Consumption: Minimal
- 804 Parity in Reproductive Health Insurance Coverage for Same-Sex Couples: Minimal
- 805 Health Insurance Companies Should Collect Deductible from Patients After Full Payments to Physicians: Modest
- 806 Pharmaceutical Industry Drug Pricing is a Public Health Emergency: Minimal
- 807 Pharmacy Use of Medication Discontinuation Messaging Function: Modest
- 808 A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities: Modest
- 809 Addressing the Exploitation of Restricted Distribution Systems by Pharmaceutical Manufacturers: Minimal
- 810 Medical Necessity of Breast Reconstruction and Reduction Surgeries: Minimal
- 811 Opposition to CMS Mandating Treatment Expectations and Practicing Medicine: Modest
- 812 Enact Rules and Payment Mechanisms to Encourage Appropriate Hospice and Palliative Care Usage: Minimal
- 813 Physician Payment for Information Technology Costs: Modest
- 814* Addressing Discriminatory Health Plan Exclusions or Problematic Benefit Substitutions for Essential Health Benefits Under the Affordable Care Act: Modest
- 815* Preservation of Physician-Patient Relationships and Promotion of Continuity of Patient Care: Minimal
- 816* Support for Seamless Physician Continuity of Patient Care: Modest
- 901 Disclosure of Screening Test Risks and Benefits, Performed Without a Doctor's Order: Modest
- 902 Removing Restrictions on Federal Public Health Crisis Research: Minimal
- 903 Prevention of Newborn Falls in Hospitals: Minimal
- 904 Improving Mental Health at Colleges and Universities for Undergraduates: Minimal
- 905 Chronic Traumatic Encephalopathy (CTE) Awareness: Modest
- 906 Universal Color Scheme for Respiratory Inhalers: Estimated cost of 22,000 (includes staffing and meeting costs) to convene a series of meetings with stakeholders, including the FDA, providers, and industry organizations, to develop consensus on a color scheme for inhalers. Encourage manufacturers to adopt the color scheme.
- 907 Clinical Implications and Policy Considerations of Cannabis Use: Minimal
- 908 Faith and Mental Health: Modest
- 909 Promoting Retrospective and Cohort Studies on Pregnant Women and Their Children: Modest
- 910 Disparities in Public Education as a Crisis in Public Health and Civil Rights: Minimal
- 911 Importance of Oral Health in Medical Practice: Minimal
- 912 Neuropathic Pain Recognized as a Disease: Minimal
- 913 Improving Genetic Testing and Counseling Services in Hospitals and Healthcare Systems: Minimal

SUMMARY OF FISCAL NOTES (I-16)

Resolution(s)

- 914 Needle / Syringe Disposal: Minimal
- 915 Women and Alzheimer's Disease: Modest
- 916 Women and Pre-Exposure Prophylaxis (PrEP): Estimated cost of \$41,000 for a social media campaign for PrEP Awareness
- 917 Youth Incarceration in Adult Prisons: Modest
- 918 Ensuring Cancer Patient Access to Pain Medication: Minimal
- 919 Coal-Tar Based Sealcoat Threat to Human Health and the Environment: Modest
- 920 Haptenation and Hypersensitivity Disorders Communication: Modest
- 921 Raise the Minimum Age of Legal Access to Tobacco to 21 Years: Minimal
- 922 Responsible Parenting and Access to Family Planning: Minimal
- 923 Reverse Onus in the Manufacture and Use of Chemicals: Minimal
- 924 AMA Advocacy for Environmental Sustainability and Climate: Modest
- 925* Graphic Warning Label on all Cigarette Packages: Modest

Resolutions not for consideration

- 601 Sexual Orientation and Gender Identity Demographic Collection by the AMA and Other Medical Organizations: Minimal
- 605* Study of Models of Childcare Provided at Healthcare Institutions: Modest

*** contained in Handbook Addendum**

Minimal - less than \$1,000

Modest - between \$1,000 - \$5,000

Moderate - between \$5,000 - \$10,000

Reference Committee on Amendments to Constitution and Bylaws

BOT Report(s)

- 05 IOM "Dying in America" Report
- 06 Designation of Specialty Societies for Representation in the House of Delegates
- 07 Supporting Autonomy for Patients with Differences of Sex Development
- 08 Medical Reporting for Safety Sensitive Positions

CC&B Report(s)

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- 02 Bylaw Amendments Pertaining to Late Resolutions and Emergency Business

CEJA Report(s)

- 01 Collaborative Care
- 02 Competence, Self-Assessment and Self Awareness

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- 001 Support for the Decriminalization and Treatment of Suicide Attempts Amongst Military Personnel
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- 004 Addressing Patient Spirituality in Medicine
- 005* No Compromise on AMA's Anti-Female Genital Mutilation Policy
- 006* Effective Peer Review
- 007* Fair Process for Employed Physicians

* contained in Handbook Addendum

REPORT OF THE BOARD OF TRUSTEES

BOT Report 5-I-16

Subject: IOM “Dying in America” Report
(Resolution 6-I-15)

Presented by: Patrice A. Harris, MD, MA, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

At its 2015 Interim Meeting, the American Medical Association (AMA) House of Delegates referred to the Board of Trustees Resolution 6-I-15, “IOM ‘Dying in America’ Report,” introduced by the Medical Association of Georgia. Resolution 6 asked our AMA to “support and advocate for the recommendations of the Institute of Medicine ‘Dying in America’ report, which will improve the quality of end-of-life care received by all patients.”

Testimony for this resolution supported the spirit of the IOM report in light of the recognized need to improve quality of care at the end of life. However, testimony noted that the AMA had not had the opportunity to vet the report thoroughly in light of existing AMA policies on relevant issues and noted that endorsing the report in its entirety could have unintended consequences for AMA.

BACKGROUND

The overarching goal of *Dying in America* is to ensure that all patients “with advanced serious illness who are nearing the end of life” have round-the-clock access to comprehensive care provided by appropriately trained personnel in appropriate settings, in keeping with individuals’ values, goals, and preferences.

The report identifies five key domains in which action is needed: financing for comprehensive care; quality measurement; professional education, licensure, and credentialing; interoperable electronic health records; and public education about end-of-life care and advance care planning. In each of these areas, the report recommends specific activities and defines accountability among key stakeholders. (See Appendix A.)

Financing for Comprehensive Care

Dying in America calls for public and private payers to cover provision of comprehensive, high-quality consistently accessible care that is “patient centered and family oriented”; consistent with individuals’ values, goals, and preferences; and delivered by appropriately trained personnel (Recommendation 1). Such care should include access to interdisciplinary palliative care. The report further recommends that federal, state, and private insurance and health care delivery programs “integrate the financing of medical and social services,” by supporting coordination of care and use of financial incentives to decrease use of inappropriate emergency department or acute care services, among other initiatives (Recommendation 4).

1 *Quality Measurement*

2
3 *Dying in America* recommends that organizations that deliver health care publicly report aggregate
4 measures of quality and cost for the full range of end-of-life care (Recommendation 1). The report
5 urges professional societies and other organizations to establish, and payers and health care
6 systems to adopt, quality standards specifically relating to patient-clinician communication and
7 advance care planning, toward the goal of ensuring that all individuals have an opportunity to
8 participate in decisions about their care and receive services consistent with their values, goals, and
9 preferences (Recommendation 2). It further calls on the federal government to require public
10 reporting of quality measures, outcomes and costs, for all programs it funds or administers, and to
11 encourage all other payment and delivery systems to do so as well (Recommendation 4).
12

13 *Professional Education, Licensure and Credentialing*

14
15 *Dying in America* recommends that all clinicians who provide care for patients with advanced
16 serious illness should be competent in basic palliative care and that educational institutions and
17 professional societies provide opportunities for lifelong learning in this area (Recommendation 3).
18 Accrediting organizations, certifying bodies, health systems, and regulatory agencies should
19 include training in palliative care in licensure requirements for health care professionals who
20 provide care for patients nearing the end of life, and resources should be committed to increase the
21 number of available training positions for specialty-level training in palliative care.
22

23 *Interoperable Electronic Health Records*

24
25 *Dying in America* identifies the need for “coordinated, efficient, interoperable” transfer of
26 information among all providers and settings of care to support high quality, integrated,
27 comprehensive care (Recommendation 1). It further calls for electronic health records that
28 document advance care planning to improve communication across providers and settings over
29 time, including providing for documentation of designation of a surrogate; patient values, goals,
30 and preferences; the patient’s advance directive (when the patient has one); and medical orders for
31 life-sustaining treatment (Recommendation 4). The report also urges states to develop and
32 implement Physician Orders for Life-Sustaining Treatment (POLST) programs “in accordance with
33 nationally standardized requirements.”
34

35 *Public Education about End of Life and Advance Care Planning*

36
37 Finally, *Dying in America* urges civic leaders, government entities, health care professionals, and
38 other stakeholders to collaborate in developing and disseminating evidence-based information
39 about care and the end of life and advance care planning to counter misinformation and encourage
40 meaningful dialogue (Recommendation 5). The report calls on stakeholders to support research to
41 assess public perceptions and actions, developing and testing effective messaging tailored to target
42 audiences, and measuring progress and results.
43

44 *AMA POLICY*

45
46 AMA has extensive policy relevant to end-of-life care and to support the ultimate goals of the
47 *Dying in America* report in all of the domains noted above. (See Appendix B.)
48

49 The AMA *Code of Medical Ethics* has strong, well-established guidance that recognizes the
50 importance of engaging patients in advance care planning so that patients’ values, goals, and
51 preferences can inform care planning (Opinions 5.1, 5.2). The *Code* calls on physicians to respect

patients' decisions about care at the end of life, including decisions to forgo or withdraw life-sustaining interventions (Opinions 5.3, 5.4). The *Code* encourages physicians to engage pediatric patients (Opinion 2.2.1) and adult patients with compromised decision-making capacity to participate in treatment decisions to the extent possible, and recognizes the important role that surrogate decision makers play when patients lack decision-making capacity (Opinion 2.1.2). The *Code* further provides for the use of sedation to unconsciousness as an intervention of last resort for terminally ill patients when distressing symptoms are refractory to appropriate, symptom-specific palliative care (Opinion 5.6).

Policies of the AMA House of Delegates similarly promote advance care planning and patient-centered decision making at the end of life (H-85.956, H-85.957, H-140.845, H-140.966, H-140.970, H-140.989, D-140.968). House policies also encourage palliative care and hospice for patients nearing the end of life and support education across the professional lifespan in these areas (H-70.915, H-85.955, H-295.875), as well as in areas of medical specialization in which end-of-life decision making can play a central role, such as geriatrics (H-295.981, D-295.969).

In addition, the AMA has adopted policy calling for affordable, interoperative electronic medical records and medical devices to promote more effective coordination of care (D-478.994, D-478.995, D-478.996), as well as policy that addresses essential frameworks for physician maintenance of licensure and maintenance of certification (H-275.917, H-275.924). However, AMA policy opposes tying physician licensure to mandated, content-specific continuing medical education (H-275.973, H-295.921, H-300.953).

AMA PROGRAMS & ACTIVITIES

In addition to extensive policy, the AMA is (or has been) involved in numerous activities and programs designed to improve care at the end of life consistent with the broad recommendations of *Dying in America*. For example, the AMA was instrumental in the development of Education in Palliative and End-of-Life Care (EPEC), a program designed to educate practicing physicians from all specialties in palliative care, which is now offered by Northwestern University Feinberg School of Medicine ([EPEC](#)). Journals in the [JAMA Network](#) offer a variety of online CME modules in palliative care and pain management and live educational events at AMA meetings in recent years have addressed communicating with patients for advance care planning [1].

Through its participation in the Liaison Committee on Medical Education (LCME) and Accreditation Committee for Graduate Medical Education (ACGME), the AMA works to promote comprehensive education for physician trainees to ensure that they acquire the knowledge and skills to provide high quality, patient-centered care for a diverse patient population [2, 3]. Through the Physician Consortium for Performance Improvement ([PCPI](#)), the AMA has contributed to efforts to define and measure quality in end of life care.

With the American Bar Association, the American Hospital Association, the American Academy of Hospice and Palliative Medicine and numerous other medical specialty societies, the AMA annually supports [National Health Decisions Day](#), an initiative to provide information and resources on advance care planning for both patients and health care professionals.

The AMA has argued for legal recognition of patients' right to control decisions about their care at the end of life, including the right to refuse unwanted life-sustaining treatment [4]. The AMA has advocated for legislative support of advance care planning and advance directives. The AMA's efforts were instrumental in the decision by the Centers for Medicare & Medicaid Services to

1 include payment for AMA-developed CPT codes for advance care planning services in the [2016](#)
2 [Medicare Physician Fee Schedule \(PFS\) Final Rule](#).

3
4 The AMA's innovative STEPS Forward program of interactive, online educational modules
5 recently launched a new module, [Planning for End-of-Life Decisions with Your Patients](#), to help
6 physicians help patients convey their wishes about end of life care. The AMA is also a strong
7 advocate for improving the usability of electronic health records, and is collaborating with key
8 stakeholders in digital health to this end ([Digital Health](#)).

9
10 RECOMMENDATION

11
12 The Board of Trustees recommends that the following be adopted in lieu of Resolution 6-I-15 and
13 the remainder of this report be filed:

14
15 That our AMA reaffirm the following policies, which collectively promote high-quality,
16 patient-centered care for all patients at the end of life:

- 17
18 • H-70.915, Good Palliative Care
19 • H-85.955, Hospice Care
20 • H-85.956, Educating Physicians About Advance Care Planning
21 • H-85.957, Encouraging Standardized Advance Directive Forms within States
22 • H-140.845, Encouraging the Use of Advance Directives and Health Care Powers of
23 Attorney
24 • H-140.966, Decisions Near the End of Life
25 • H-140.970, Decisions to Forgo Life-Sustaining Treatment for Incompetent Patients
26 • H-140.989, Informed Consent and Decision-Making in Health Care
27 • H-275.917, Licensure by Specialty
28 • H-275.924, Maintenance of Certification
29 • H-295.875, Palliative Care and End-of-Life Care
30 • H-295.981, Geriatric Medicine
31 • H-480.953, Interoperability of Medical Devices
32 • D-140.968, Standardized Advanced Directives
33 • D-295.969, Geriatric and Palliative Training for Physicians
34 • D-478.994, Health Information Technology
35 • D-478.995, National Health Information Technology
36 • D-478.996, Information Technology Standards and Costs

37
38 (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

REFERENCES

1. Council on Ethical and Judicial Affairs. [*Resources in Advance Care Planning*](#). November 2010.
2. Liaison Committee on Medical Education. [*Functions and Structure of a Medical School: Standards for Accreditation of Medical Education Programs Leading to the MD Degree*](#). March 2016.
3. Accreditation Committee for Graduate Medical Education. [*Requirements for Graduate Medical Education in Hospice and Palliative Medicine*](#). February 2015.
4. Brief for the Am. Med. Ass'n et al. as Amici Curiae Supporting Petitioner, *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261 (1990) (No. 88-1503).

APPENDIX A¹

Recommendations of the Institute of Medicine

Recommendation 1. Government health insurers and care delivery programs as well as private health insurers should cover the provision of comprehensive care for individuals with advanced serious illness who are nearing the end of life.

Comprehensive care should

- be seamless, high-quality, integrated, patient-centered, family-oriented, and consistently accessible around the clock;
- consider the evolving physical, emotional, social, and spiritual needs of individuals approaching the end of life, as well as those of their family and/or caregivers;
- be competently delivered by professionals with appropriate expertise and training;
- include coordinated, efficient, and interoperable information transfer across all providers and all settings; and
- be consistent with individuals' values, goals, and informed preferences.

Health care delivery organizations should take the following steps to provide comprehensive care:

- All people with advanced serious illness should have access to skilled palliative care or, when appropriate, hospice care in all settings where they receive care (including health care facilities, the home, and the community).
- Palliative care should encompass access to an interdisciplinary palliative care team, including board-certified hospice and palliative medicine physicians, nurses, social workers, and chaplains, together with other health professionals as needed (including geriatricians). Depending on local resources, access to this team may be on site, via virtual consultation, or by transfer to a setting with these resources and this expertise.
- The full range of care that is delivered should be characterized by transparency and accountability through public reporting of aggregate quality and cost measures for all aspects of the health care system related to end-of-life care. The committee believes that informed individual choices should be honored, including the right to decline medical or social services.

Recommendation 2. Professional societies and other organizations that establish quality standards should develop standards for clinician-patient communication and advance care planning that are measurable, actionable, and evidence-based. These standards should change as needed to reflect the evolving population and health system needs and be consistent with emerging evidence, methods, and technologies. Payers and health care delivery organizations should adopt these standards and their supporting processes, and integrate them into assessments, care plans, and the reporting of health care quality. Payers should tie such standards to reimbursement, and professional societies should adopt policies that facilitate tying the standards to reimbursement, licensing, and credentialing to encourage

- all individuals, including children with the capacity to do so, to have the opportunity to participate actively in their health care decision making throughout their lives and as they approach death, and receive medical and related social services consistent with their values, goals, and informed preferences;

¹ Institute of Medicine. *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*. Washington, DC: National Academies Press; 2015.

- clinicians to initiate high-quality conversations about advance care planning, integrate the results of these conversations into the ongoing care plans of patients, and communicate with other clinicians as requested by the patient; and
- clinicians to continue to revisit advance care planning discussions with their patients because individuals' preferences and circumstances may change over time.

Recommendation 3. Educational institutions, credentialing bodies, accrediting boards, state regulatory agencies, and health care delivery organizations should establish the appropriate training, certification, and/or licensure requirements to strengthen the palliative care knowledge and skills of all clinicians who care for individuals with advanced serious illness who are nearing the end of life.

Specifically,

- all clinicians across disciplines and specialties who care for people with advanced serious illness should be competent in basic palliative care, including communication skills, interprofessional collaboration, and symptom management;
- educational institutions and professional societies should provide training in palliative care domains throughout the professional's career;
- accrediting organizations, such as the Accreditation Council for Graduate Medical Education, should require palliative care education and clinical experience in programs for all specialties responsible
- for managing advanced serious illness (including primary care clinicians);
- certifying bodies, such as the medical, nursing, and social work specialty boards, and health systems should require knowledge, skills, and competency in palliative care; state regulatory agencies should include education and training in palliative care in licensure requirements for physicians, nurses, chaplains, social workers, and others who provide health care to those nearing the end of life;
- entities that certify specialty-level health care providers should create pathways to certification that increase the number of health care professionals who pursue specialty-level palliative care training; and
- entities such as health care delivery organizations, academic medical centers, and teaching hospitals that sponsor specialty-level training positions should commit institutional resources to increasing the number of available training positions for specialty-level palliative care.

Recommendation 4. Federal, state, and private insurance and health care delivery programs should integrate the financing of medical and social services to support the provision of quality care consistent with the values, goals, and informed preferences of people with advanced serious illness nearing the end of life. To the extent that additional legislation is necessary to implement this recommendation, the administration should seek and Congress should enact such legislation. In addition, the federal government should require public reporting on quality measures, outcomes, and costs regarding care near the end of life (e.g., in the last year of life) for programs it funds or administers (e.g., Medicare, Medicaid, the U.S. Department of Veterans Affairs). The federal government should encourage all other payment and health care delivery systems to do the same.

Specifically, actions should

- provide financial incentives for
 - medical and social support services that decrease the need for emergency room and acute care services,

- coordination of care across settings and providers (from hospital to ambulatory settings as well as home and community), and
- improved shared decision making and advance care planning that reduces the utilization of unnecessary medical services and those not consistent with a patient's goals for care;
- require the use of interoperable electronic health records that incorporate advance care planning to improve communication of individuals' wishes across time, settings, and providers, documenting (1) the designation of a surrogate/decision maker, (2) patient values and beliefs and goals for care, (3) the presence of an advance directive, and (4) the presence of medical orders for life-sustaining treatment for appropriate populations; and
- encourage states to develop and implement a Physician Orders for Life-Sustaining Treatment (POLST) paradigm program in accordance with nationally standardized core requirements.

Medical and social services provided should accord with a person's values, goals, informed preferences, condition, circumstances, and needs, with the expectation that individual service needs and intensity will change over time. High-quality, comprehensive, person-centered, and family-oriented care will help reduce preventable crises that lead to repeated use of 911 calls, emergency department visits, and hospital admissions, and if implemented appropriately, should contribute to stabilizing aggregate societal expenditures for medical and related social services and potentially lowering them over time.

Recommendation 5. Civic leaders, public health and other governmental agencies, community-based organizations, faith-based organizations, consumer groups, health care delivery organizations, payers, employers, and professional societies should engage their constituents and provide fact-based information about care of people with advanced serious illness to encourage advance care planning and informed choice based on the needs and values of individuals.

Specifically, these organizations and groups should

- use appropriate media and other channels to reach their audiences, including underserved populations;
- provide evidence-based information about care options and informed decision making regarding treatment and care;
- encourage meaningful dialogue among individuals and their families and caregivers, clergy, and clinicians about values, care goals, and preferences related to advanced serious illness; and
- dispel misinformation that may impede informed decision making and public support for health system and policy reform regarding care near the end of life.

In addition,

- health care delivery organizations should provide information and materials about care near the end of life as part of their practices to facilitate clinicians' ongoing dialogue with patients, families, and caregivers;
- government agencies and payers should undertake, support, and share communication and behavioral research aimed at assessing public perceptions and actions with respect to end-of-life care, developing and testing effective messages and tailoring them to appropriate audience segments, and measuring progress and results; and
- health care professional societies should prepare educational materials and encourage their members to engage patients and their caregivers and families in advance care planning, including end-of-life discussions and decisions.

All of the above groups should work collaboratively, sharing successful strategies and promising practices across organizations.

APPENDIX B

AMA Policies Relating to End-of-Life and Palliative Care

Policy	Issued
<i>Advance Care Planning</i>	
<u>E-2.191</u> Advance Care Planning	2011
<u>E-2.225</u> Optimal Use of Orders-Not-to-Intervene and Advance Directives	1998
<u>D-140.968</u> Standardized Advanced Directives	2007 ¹
<u>H-85.957</u> Encouraging Standardized Advance Directive Forms within States	2011
<u>H-140.845</u> Encouraging the Use of Advance Directives and Health Care Powers of Attorney	2014 ²
<u>H-330.891</u> Payment and Coverage for Voluntary Discussions of End-of-Life Issues	2011
<i>Decisions Regarding Life-Sustaining Treatment</i>	
<u>E-2.20</u> Withholding or Withdrawing Life-Sustaining Medical Treatment	1984 ³
<u>E-2.201</u> Sedation to Unconsciousness in End-of-Life Care	2008
<u>E-2.22</u> Do-Not-Resuscitate Orders	1992 ⁴
<u>E-8.081</u> Surrogate Decision Making	2001
<u>E-10.016</u> Pediatric Decision Making	2008 ⁵
<u>H-140.966</u> Decisions Near the End of Life	1991 ⁶
<u>H-140.970</u> Decisions to Forgo Life-Sustaining Treatment for Incompetent Patients	1991 ⁷
<u>H-280.968</u> Do Not Hospitalize Orders	1993 ⁸
<i>Symptom Management, Palliative Care & Hospice</i>	
<u>H-55.999</u> Symptomatic and Supportive Care for Patients with Cancer	1978 ⁹
<u>H-70.915</u> Good Palliative Care	2014
<u>H-85.955</u> Hospice Care	2014
<u>H-85.966</u> Hospice Coverage and Underutilization	1994 ¹⁰
<u>H-165.834</u> National Pain Care	2010
<u>H-295.875</u> Palliative Care and End-of-Life Care	2006 ¹¹
<i>Physician Education</i>	
<u>D-295.969</u> Geriatric and Palliative Training for Physicians	2002 ¹²
<u>H-85.956</u> Educating Physicians About Advance Care Planning	2014
<u>H-295.981</u> Geriatric Medicine	1985 ¹³
<u>H-295.995</u> Recommendations for Future Directions for Medical Education	1982 ¹⁴
<i>Physician Licensure & Certification</i>	
<u>H-275.997</u> Licensure by Specialty	1980 ¹⁵
<u>H-275.917</u> An Updated on Maintenance of Licensure	2015
<u>H-275.924</u> Maintenance of Certification	2009 ¹⁶
<i>Health Information Technologies</i>	
<u>D-478.994</u> Health Information Technology	2005 ¹⁷
<u>D-478.995</u> National Health Information Technology	2004 ¹⁸
<u>D-478.996</u> Information Technology Standards and Costs	2004 ¹⁹
<u>H-480.953</u> Interoperability of Medical Devices	2009 ²⁰
<i>Quality Measures</i>	
<u>H-450.958</u> Support for Development of Measures of Quality	1997 ²¹
<u>H-450.966</u> Quality Management	1994 ²²

- ¹ Reaffirmed 2015
- ² Reaffirmed 2015
- ³ Updated 1996
- ⁴ Updated 2005
- ⁵ Updated 2010
- ⁶ Reaffirmed 2013
- ⁷ Reaffirmed 2009
- ⁸ Reaffirmed 2010
- ⁹ Updated 2010
- ¹⁰ Updated 2014
- ¹¹ Amended, Res 322 A-14
- ¹² Reaffirmed 2012
- ¹³ Amended, Res 301 A-10
- ¹⁴ Reaffirmed 2011
- ¹⁵ Reaffirmed 2010
- ¹⁶ Updated 2015
- ¹⁷ Reaffirmed 2014
- ¹⁸ Reaffirmed 2015
- ¹⁹ Reaffirmed 2014
- ²⁰ Reaffirmed 2015
- ²¹ Reaffirmed 2007
- ²² Reaffirmed 2015

REPORT OF THE BOARD OF TRUSTEES

B of T Report 6-I-16

Subject: Designation of Specialty Societies for Representation in the House of Delegates

Presented by: Patrice A. Harris, MD, MA, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

At the American Medical Association's (AMA) 2007 Annual Meeting, Policy G-600.135 (see Appendix A for policies cited in report) was adopted, establishing a mechanism by which specialty society representation in the House of Delegates (HOD) would be determined. The mechanism for specialty society delegate allocation is based on a formula that looks at a society's AMA membership and the number of ballots cast for representation in each specialty (Appendix B). The specialty ballot is available online at www.ama-assn.org/go/ballot. The goal was to determine appropriate allocation of specialty society delegates. However, this system does not work as it relies on members making an active selection of a specialty society to represent them, and despite efforts by both our AMA and the specialty societies, few members make a choice, likely because the value of doing so is not well understood by the average member.

Since 2007, there have been a number of reports put forth attempting to improve the specialty delegate allocation process (Policies included in Appendix A). Previous reports have all attempted to present solutions to the challenge of fair allocation of specialty society delegates. The most recent report was at the 2016 Annual Meeting and as with previous reports, was referred back for further development. From the debate at A-16 two critical issues have been identified; the HOD wants parity in representation; and there is a desire for a simple method of allocation that is applied to both the constituent associations and the specialty societies. (AMA Bylaws define constituent associations as recognized medical associations of states, commonwealths, districts, or territories of the United States.)

This report seeks to address these issues and offer a solution. The Board of Trustees (BOT), with input from the Specialty and Service Society (SSS), believes that the following is a reasonable and equitable solution.

In order to establish parity the number of constituent delegates and specialty delegates should be equal. Under the theory that every AMA member should be represented by both a constituent association and a specialty society in the HOD—the stated goal since 1996—the number of constituent and specialty delegates should be equal. The total AMA membership figure that determines the number of constituent delegates should also be used to determine the number of specialty delegates.

Constituent delegate allocation will continue to be based on the address for each AMA member, without respect to constituent society membership. Specialty delegate allocation is slightly more challenging because while one can only reside in one state, a member may belong to more than one specialty society.

1 Specialty society delegate allocation should be determined using data that is submitted by each
2 specialty society every five years to determine their eligibility to remain in the HOD. While the
3 membership numbers may fluctuate over five years, this will be the most reliable mark of AMA
4 membership for each specialty.

5
6 Under AMA bylaws delegates are apportioned for the coming year each January, after the prior
7 year's membership figures have been finalized. Current policy allows for one AMA delegate for
8 every 1,000 AMA members or fraction thereof an organization has. The same standard should
9 apply to both the constituent association and specialty society delegate allocation.

10
11 Once the total number of constituent society delegates allocated for any given year is determined
12 then specialty society delegates would be adjusted up or down so that the total number of specialty
13 society delegates equals the number of constituent society delegates. If the total number of
14 allocated specialty society delegates is fewer than the total number of delegates allocated to
15 constituent societies, additional delegates would be apportioned, one each, to those specialty
16 societies that are numerically closest to qualifying for an additional delegate, until the total number
17 of national specialty society delegates equals the number of constituent society delegates.
18 Conversely, should the total number of allocated specialty society delegates be greater than the
19 number of delegates allocated to constituent societies, then the excess delegates will be removed,
20 one each, from those societies numerically closest to losing a delegate, until the total number of
21 national specialty society delegates equals the number of constituent society delegates. With the
22 adjustment, a few specialty societies will not truly have a 1 to 1,000 or fraction thereof ratio, but no
23 specialty would gain or lose more than one delegate. This method would allow for the adjustment
24 of delegation sizes to achieve parity between constituent society and specialty society
25 representation while still using membership data as the guide.

26
27 Organizations with fewer than 1,000 AMA members would remain at one delegate as long as they
28 retain representation in the HOD. Delegate allocation would continue to be adjusted annually based
29 on AMA membership data, and specialty delegates would move annually in concert with the
30 number of state delegates. In addition, as new specialty societies enter or leave the HOD, the
31 delegate allocation of all specialties would be adjusted.

32
33 The attached chart (Appendix C) shows the impact implementation of this system would have had
34 in 2016; the membership numbers on the chart are the latest available membership numbers, some
35 of which were collected in preparing BOT Report 15-A-16.

36 37 RECOMMENDATION

38
39 The Board of Trustees recommends that the following recommendations be adopted and the
40 remainder of the report be filed:

- 41
42 1. That the current specialty society delegation allocation system (using a formula that
43 incorporates the ballot) be discontinued; and that specialty society delegate allocation in the
44 House of Delegates be determined so that the total number of national specialty society
45 delegates shall be equal to the total number of delegates apportioned to constituent societies
46 under section 2.1.1 (and subsections thereof) of AMA bylaws, and will be distributed based on
47 the latest available membership data for each society, which is generally from the society's
48 most recent five year review. (Directive to Take Action)
49
50 2. That specialty society delegate allocation be determined annually, based on the latest available
51 membership data, using a two-step process:

- 1 a) First, the number of delegates per specialty society will be calculated as one delegate per
2 1,000 AMA members in that society, or fraction thereof.
3
- 4 b) Second, the total number of specialty society delegates will be adjusted up or down to
5 equal the number of delegates allocated to constituent societies.
6
- 7 i) Should the calculated total number of specialty society delegates be fewer than the
8 total number of delegates allocated to constituent societies, additional delegates will be
9 apportioned, one each, to those societies that are numerically closest to qualifying for
10 an additional delegate, until the total number of national specialty society delegates
11 equals the number of constituent society delegates.
12
- 13 ii) Should the calculated total number of specialty society delegates be greater than the
14 number of delegates allocated to constituent societies, then the excess delegates will be
15 removed, one each, from those societies numerically closest to losing a delegate, until
16 the total number of national specialty society delegates equals the number of
17 constituent society delegates. (Directive to Take Action)
18
- 19 3. That the Council on Constitution and Bylaws investigate the need to change any policy or
20 bylaws needed to implement a new system to apportion national medical specialty society
21 delegates. (Directive to Take Action)
22
- 23 4. That this new specialty society delegate apportionment process be implemented at the first
24 Annual Meeting of the House of Delegates following the necessary bylaws revisions.
25 (Directive to Take Action)

Fiscal Note: Less than \$500 to implement.

Appendix A – Bylaws and Policy

Retention of Delegate, B-2.1.1.1.1

If the membership information as recorded by the AMA as of December 31 warrants a decrease in the number of delegates representing a constituent association, the constituent association shall be permitted to retain the same number of delegates, without decrease, for one additional year, if it promptly files with the AMA a written plan of intensified AMA membership development activities among its members. At the end of the one year grace period, any applicable decrease will be implemented.

G-600.021 Specialty Society Representation in our AMA House

The number of AMA delegate positions allocated to the specialty societies in our AMA/Federation House will be determined in the following manner: (1) The number of delegates and alternate delegates allocated to a specialty society will be on the basis of one delegate and one alternate delegate for each 1,000 AMA members, or portion of 1,000 AMA members, who select that a particular specialty society on the annual ballot and return the ballot to our AMA; and (2) Each specialty society that meets the eligibility criteria and is represented in our AMA/Federation House will be assured of at least one delegate and alternate delegate position regardless of the number of AMA members who select the society on the ballot and return the ballot to the AMA. (3) Our AMA will: (a) continue to include the ballot postcard in the Member Welcome Kit; (b) continue to promote the online ballot application to increase specialty society designations; (c) work with all willing specialty societies to solicit additional specialty society designations, using both printed ballots and electronic communications vehicles; and (d) continue to send email ballot solicitations to members who have not yet cast a ballot. (4) The current ballot system will remain in place while the Speakers, working with the Specialty and Service Society, examine other options for ensuring that each member of the American Medical Association is adequately represented by both a state medical association and national medical specialty society.

G-600.023 Designation of Specialty Societies for Representation in the House of Delegates

1. Specialty society delegate allocation in the House of Delegates shall be determined in the same manner as state medical society delegate allocation based on membership numbers allowing one delegate per 1,000 AMA members or fraction thereof. 2. Specialty society membership data shall be submitted annually by all societies with more than one delegate or societies seeking to obtain an additional delegate or delegates as part of a two-year pilot program with a report back at the 2016 Annual Meeting of our AMA House of Delegates. 3. The current specialty delegation allocation system (ballot and formula) will be continued until the pilot program is completed and the 2016 Annual Meeting report is acted upon by the House of Delegates. 4. This system shall be tested with all specialty societies with more than one delegate seated in the House of Delegates. 5. Organizations that would lose or gain one or more delegates through this pilot delegate allocation system shall assist our AMA with documenting the impact. However, no actual changes to delegation allocation other than those which occur through the five-year review and balloting system will be implemented until the data are collected and presented for acceptance to our AMA House of Delegates at the 2016 Annual Meeting. 6. In the future, any system of delegate allocation will continue to be monitored and evaluated for improvements.

G-600.135 Specialty Society Delegate Representation in the House of Delegates

1. Our AMA will continue efforts to expand awareness and use of the designation mechanism for specialty society representation, working wherever possible with relevant members of the Federation. 2. The system of apportioning delegates to specialty societies be enhanced by a systematic allocation of delegates to specialty societies by extrapolating from the current process in which members designate a specialty society for representation. The recommended model will: (a) establish annual targets for the overall proportion of AMA members from whom designations should have been received; (b) adjust actual designations by increasing them proportionately to achieve the overall target level of designations; (c) limit the number of delegates a society can acquire to the number that would be obtained if all the society's AMA members designated it for representation; (d) be initiated with delegate allocations for 2008, following the expiration of the freeze, which ends December 31, 2007; and (e) be implemented over five years because this will result in the least disruption to the House of Delegates and allow the process to unfold naturally. 3. The Board of Trustees will prepare annual reports to the House describing efforts undertaken to solicit designations from members, characterizing progress in collecting designations, and recommending changes in strategies that might be required to implement existing policy on representation of specialty societies. In addition, the Board should, in these or other reports: (a) develop a system for use among direct members to solicit their designations of specialty societies for representation, with an eye on how that system might be expanded or adapted for use among other members; and (b) engage in discussions with specialty societies that will lead to enhanced data sharing so that delegate allocations for both state and specialty societies can be handled in parallel fashion. 4. Our AMA will include in the specialty designation system an option to permit those members who wish to opt out of representation by a specialty society to do so when any automatic allocation system is used to provide representation for specialty societies that are represented in the House of Delegates. 5. If any specialty society loses delegates as a result of the apportionment process, the specialty society shall have a one-year grace period commencing January 1, 2008. At the expiration of this one-year grace period, a phase-in period shall be implemented such that the number of delegate seats lost will be limited to one seat per year for the succeeding three years. In the fourth year, any remaining reduction of seats will be implemented. 6. AMA Bylaw 2.11111 grants state societies a one-year grace period following the freeze expiring December 31, 2007 (per Bylaw 2.121). At the end of the grace period, a phase-in period will be implemented such that the number of delegate seats lost will be limited to one seat per year for the succeeding three years. In the fourth year, any remaining reduction of seats will be implemented.

Appendix B – 2016 Apportionment of Specialty Society Delegates

Board of Trustees Report 17-A-07 implemented the current mechanism for apportioning delegates to specialty societies in the House of Delegates.

The starting point for societies is the number of ballots submitted by AMA members designating a particular specialty society to represent their interests in the House of Delegates. That number is weighted, using the formula developed in BOT Report 17-A-07, and the resulting figure apportions delegates at the rate of one per 1,000 or fraction thereof, subject to a cap based on the number of AMA members in the society.

The weighting factor is directly related to the total AMA membership and inversely related to the proportion of AMA members who have actually designated a society for representation purposes. That is, as AMA membership increases, the weight increases, and as the proportion of members casting a ballot increases, the weight decreases. The weight is limited to 80% of its calculated value, and the same weight applies to every specialty society.

Elements of the formula are (with their 2016 values):

- a. Members eligible to ballot, 4th year student or beyond (198,408)
- b. Actual ballots (54,571, which includes 447 who chose NOT to designate a specialty society)
- c. a/b ($54,571/198,408 = 0.27504$)
- d. $1/c$ ($1 / 0.27504 = 3.635777$)
- e. $d * 0.8$ ($3.635777 * 0.8 = 2.908622$)
- f. $e * \text{ballots} / 1000$, with result rounded up to next whole number

The delegate apportionment is subject to the following constraints:

1. Every specialty society seated in the House of Delegates has at least one delegate;
2. The number of delegates cannot exceed the figure that would apply if ALL its AMA members selected that society for representation purposes.

The following example illustrates use of the formula. If at year end 2015 a society had 1,015 ballots and 7,913 AMA members:

$1015 * 2.909 / 1000 \rightarrow 2952.6 / 1000 \rightarrow 2.9 \rightarrow$ rounds up to 3; but if all 7913 AMA members had designated the society, the cap would be 8 delegates ($7913 / 1000 = 7.9 \rightarrow$ rounds up to 8). The society gets the lesser of the calculated number or the cap, or in this case 3 delegates.

Appendix C

The 2016 delegate allocation for the constituent medical societies was 265 delegates. Applying the system outlined in this report would have resulted in the delegate allocation shown in the column labeled adjusted delegate allocation for the specialties.

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
Academy of Physicians in Clinical Research	148	1	1			1
Aerospace Medical Association	173	1	1			1
AMDA - The Society for Post-Acute and Long Term Care Medicine	873	1	1			1
American Academy of Allergy, Asthma and Immunology	361	1	1			1
American Academy of Child and Adolescent Psychiatry	1,446	1	2	446		2
American Academy of Cosmetic Surgery	348	1	1			1
American Academy of Dermatology	2,955	4	3	955		3
American Academy of Facial Plastic and Reconstructive Surgery	365	1	1			1
American Academy of Family Physicians	17,323	18	18	323		18
American Academy of Hospice and Palliative Medicine	700	1	1			1
American Academy of Insurance Medicine	64	1	1			1
American Academy of Neurology	2,207	3	3	207		3
American Academy of Ophthalmology	3,380	4	4	380		4
American Academy of Orthopaedic Surgeons	6,755	5	7	755		7
American Academy of Otolaryngic Allergy Inc.	386	1	1			1
American Academy of Otolaryngology-Head and Neck Surgery	2,895	3	3	895		3
American Academy of Pain Medicine	471	1	1			1
American Academy of Pediatrics	8,160	7	9	160		9

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
American Academy of Physical Medicine and Rehabilitation	1,838	2	2	838		2
American Academy of Psychiatry and the Law	359	1	1			1
American Academy of Sleep Medicine	1,236	1	2	236		2
American Association for Geriatric Psychiatry	876	1	1			1
American Association for Hand Surgery	266	1	1			1
American Association for Thoracic Surgery	279	1	1			1
American Association of Clinical Endocrinologists	815	1	1			1
American Association of Clinical Urologists,	968	1	1			1
American Association of Gynecologic Laparoscopists	1,264	1	2	264		2
American Association of Hip and Knee Surgeons	381	1	1			1
American Association of Neurological Surgeons	902	2	1			1
American Association of Neuromuscular & Electrodiagnostic Medicine	809	1	1			1
American Association of Plastic Surgeons	175	1	1			1
American Association of Public Health Physicians	45	1	1			1
American Clinical Neurophysiology Society	197	1	1			1
American College of Allergy, Asthma and Immunology	555	1	1			1
American College of Cardiology	5,693	4	6	693		6
American College of Chest Physicians	2,552	1	3	552		3
American College of Emergency Physicians	6,705	5	7	705		7
American College of Gastroenterology	1,383	2	2	383		2
American College of Legal Medicine	133	1	1			1

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
American College of Medical Genetics and Genomics	356	1	1			1
American College of Medical Quality	134	1	1			1
American College of Mohs Surgery	219	1	1			1
American College of Nuclear Medicine	81	1	1			1
American College of Occupational and Environmental Medicine	547	1	1			1
American College of Phlebology	310	1	1			1
American College of Physicians	22,690	13	23	690		23
American College of Preventive Medicine	484	1	1			1
American College of Radiation Oncology	323	1	1			1
American College of Radiology	6,077	7	7	77	-1	6
American College of Rheumatology	1,095	2	2	95	-1	1
American College of Surgeons	12,445	6	13	445		13
American Congress of Obstetricians and Gynecologists	12,000	12	12			12
American Gastroenterological Association	1,709	1	2	709		2
American Geriatrics Society	927	1	1			1
American Institute of Ultrasound in Medicine	1,216	1	2	216		2
American Medical Group Association	2,928	1	3	928		3
American Orthopaedic Association	311	1	1			1
American Orthopaedic Foot and Ankle Society	262	1	1			1
American Psychiatric Association	7,478	8	8	478		8
American Roentgen Ray Society	2,377	1	3	377		3

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
American Society for Aesthetic Plastic Surgery, Inc.	348	1	1			1
American Society for Clinical Pathology	2,127	1	3	127		3
American Society for Dermatologic Surgery	1,016	1	2	16	-1	1
American Society for Gastrointestinal Endoscopy	1,662	1	2			2
American Society for Radiation Oncology	839	1	1			1
American Society for Reproductive Medicine	794	1	1			1
American Society for Surgery of the Hand	666	1	1			1
American Society of Addiction Medicine	623	1	1			1
American Society of Anesthesiologists	6,146	7	7	146		7
American Society of Breast Surgeons	568	1	1			1
American Society of Cataract and Refractive Surgery	1,133	1	2	133		2
American Society of Clinical Oncology	3,227	2	4	227		4
American Society of Colon and Rectal Surgeons	228	1	1			1
American Society of Cytopathology	214	1	1			1
American Society of Dermatopathology	344	0	1			1
American Society of Echocardiography	1,135	1	2	135		2
American Society of General Surgeons	341	1	1			1
American Society of Hematology	861	1	0			0
American Society of Interventional Pain Physicians	544	1	1			1
American Society of Maxillofacial Surgeons	82	1	1			1
American Society of Metabolic and Bariatric Surgery	313	1	1			1

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
American Society of Neuroimaging	90	1	1			1
American Society of Neuroradiology	478	1	1			1
American Society of Ophthalmic Plastic and Reconstructive Surgery	160	1	1			1
American Society of Plastic Surgeons	919	2	1			1
American Society of Retina Specialists	608	1	1			1
American Thoracic Society	1,307	1	2	307		2
American Urological Association	1,181	2	2	181		2
Association of Military Surgeons of the United States	687	1	1			1
Association of University Radiologists	181	1	1			1
College of American Pathologists	3,294	4	4	294		4
Congress of Neurological Surgeons	983	1	1			1
Contact Lens Association of Ophthalmologists, Inc.	37	1	1			1
The Endocrine Society	1,086	1	2	86	-1	1
Heart Rhythm Society	651	1	1			1
Infectious Diseases Society of America	1,147	1	2	147		2
International Academy of Independent Medical Evaluators	191	1	1			1
International College of Surgeons - US Section	313	1	1			1
International Society for the Advancement of Spine Surgery	134	1	1			1
International Society for Hair Restoration Surgery	91	1	0			0
National Association of Medical Examiners	169	1	1			1
North American Spine Society	1,345	1	2	345		2
Obesity Medical Association	259	1	1			1

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
Radiological Society of North America	2,446	1	3			3
Renal Physicians Association	586	1	1			1
Spine Intervention Society	542	1	1			1
Society for Cardiovascular Angiography and Interventions	434	1	1			1
Society for Investigative Dermatology, Inc.	207	1	1			1
Society for Vascular Surgery	762	1	1			1
Society of American Gastrointestinal Endoscopic Surgeons	1,131	1	2	131		2
Society of Critical Care Medicine	911	1	1			1
Society of Hospital Medicine	1,556	1	2	556		2
Society of Interventional Radiology	580	1	1			1
Society of Laproendoscopic Surgeons	982	1	1			1
Society of Nuclear Medicine and Molecular Imaging	505	1	1			1
Society of Thoracic Surgeons	1,192	2	2	192		2
The Triological Society	152	1	1			1
Undersea and Hyperbaric Medical Society	186	1	1			1
United States and Canadian Academy of Pathology, Inc.	1,281	1	2	281		2
Total delegates		220	269		-4	265

REPORT OF THE BOARD OF TRUSTEES

B of T Report 7-I-16

Subject: Supporting Autonomy for Patients with Differences of Sex Development (DSD)
(Resolution 3-A-16)

Presented by: Patrice A. Harris, MD, MA, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

At the 2016 Annual Meeting, the American Medical Association (AMA) House of Delegates referred to the Board of Trustees Resolution 3-A-16, “Supporting Autonomy for Patients with Differences of Sex Development (DSD),” introduced by the Medical Student Section. Resolution 3 asked:

That our AMA affirm that medically unnecessary surgeries in individuals born with differences of sex development are unethical and should be avoided until the patient can actively participate in decision-making.

Testimony was largely in favor of referral. Those offering testimony understood the key developmental issues surrounding individuals born with DSD. However, testimony revealed gaps in understanding about how to address appropriately surgical and medical options in providing care, necessitating a call for further study.

BACKGROUND

The term “differences of sex development” (DSD) refers to congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical [1]. The frequency of DSDs varies with etiology [2], but overall incidence of DSD is estimated to be one in 5,500 births; some 60 percent of affected children are now diagnosed prenatally [3]. Diagnosis of DSD is complex, encompassing family and prenatal history, physical examination (particularly of genital anatomy), and various laboratory tests, including determination of chromosomal sex. Diagnosis may also involve ultrasound or other imaging studies, hormonal stimulation tests (eg, human chorionic gonadotropin or adrenocorticotropin stimulation), and, in rare cases, laparotomy or laparoscopy [3]. Not all cases of DSD are diagnosed perinatally.

DSD include potentially life-threatening developmental anomalies that may require immediate intervention, for example, hypotension resulting from salt-wasting nephropathy, which occurs in 75 percent of infants born with congenital adrenal hyperplasia. DSD also includes “cosmetic” abnormalities for which elective interventions to normalize appearance can be undertaken at various stages in the child’s life [2,4].

Historically, assigning gender in a newborn with ambiguous genitalia has been viewed as a “medical emergency,” with immediate surgery recommended to match genitalia to the assigned gender, on the rationale that uncertain gender is distressing for the family, may adversely affect the child’s mental health, and can lead to stigmatization [3,5]. This view has been increasingly

challenged [2,4,6]. DSD communities and a growing number of health care professionals have condemned such genital “normalizing,” arguing that except in the rare cases in which DSD presents as life-threatening anomalies, genital modification should be postponed until the patient can meaningfully participate in decision making [4,7,8].

In 2006, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) observed the lack of sufficient data to guide decisions about gender assignment and absence of clear guidelines for clinical practice [9]. The NIDDK also noted that there are only limited long-term outcome data on early surgical reconstruction, despite concern about irreversibility and possible sensory damage to the genitalia. Finally, the NIDDK cited a lack of “systematic outcome data about sexual function in individuals with disorders of sexual differentiation [sic]” and of data “pertaining to the association of sexual function with genital appearance and types of genital surgery.” It therefore called for prospective studies of gender identity, reproductive function, and quality of life for patients with DSD “to guide clinicians and families in making decisions about gender assignment and surgical reconstruction.”

Also in 2006, the Intersex Society of North America (ISNA) released its “Clinical Guidelines for the Management of Disorders of Sex Development in Childhood,” gathering perspectives of treating physicians, past patients, and parents who have been involved in the management of DSD [1]. The guidelines address appropriate treatment options for common genital anomalies, focusing on patient- and family-centered care provided by a well-trained multidisciplinary team. The guidelines acknowledge that each patient requires unique attention and resources. Importantly, ISNA guidelines note that gender assignment “is a social and legal process *not requiring medical or surgical intervention*” (original emphasis) [1].

A small study carried out in 2011-2012 among medical students in Zurich found that how physicians discussed treatment for a child with DSD influenced the choice for or against surgery, despite respondents’ belief that their personal attitudes governed decision making [10]. Participants watched brief counseling videos that offered either a “medicalized” or “demedicalized” approach. That is, the video described DSD as a condition that is static, has an inherent psychosocial component, and requires treatment, and for which predetermined treatment regimens focus on biological function, or as a dynamic disorder characterized by context-dependent impairment for which coping strategies should be fostered, with treatment geared to the individual’s interests and capabilities. Sixty-six percent of participants who viewed the medicalized video said they would choose early surgery for their child, compared to 23 percent of those who viewed the demedicalized video.

CURRENT AMA POLICY

Current AMA policy does not address treatment for patients with DSD directly. Rather, a limited number of ethics and House policies speak to decisions for minors more broadly, as well as to issues pertaining to gender identity, sexual orientation, transgender health, and discrimination toward sexual minority communities:

- [Opinion 2.2.1](#), “Pediatric Decision Making,” encourages involving minor patients in decision making at a developmentally appropriate level, including decisions that involve life-sustaining interventions, and recommends that clinicians work with parents or guardians to simplify complex treatment regimens for children with chronic health conditions.
- [Opinion 2.2.4](#), “Treatment Decisions for Seriously Ill Newborns,” articulates the considerations that must be taken into account when addressing emotionally and ethically challenging cases involving newborns, including: the medical needs of the child; the interests, needs, and

resources of the family; available treatment options; and respect for the child’s right to an “open future.” It calls on physicians to inform parents about available therapeutic options and the nature of those options and to discuss the child’s expected prognosis with and without intervention.

- [Opinion 2.2.5](#), “Genetic Testing of Children,” identifies conditions under which physicians may ethically offer genetic testing for minor patients. It observes that testing implicates important concerns about the autonomy and best interests of the minor patient and holds that medical decisions made on behalf of a child should not abrogate the opportunity to choose to know his or her genetic status as an adult.
- [H-525.987](#), “Surgical Modification of Female Genitalia,” opposes medically unnecessary surgical modification of female genitalia and encourages the development of educational programs to address complications and corrective procedures.
- [H-475.992](#), “Definitions of ‘Cosmetic’ and ‘Reconstructive’ Surgery,” distinguishes cosmetic surgery, performed on normal bodily structures to improve patient appearance, from reconstructive surgery, performed on abnormal bodily structures to improve function or approximate normal appearance.

DECISIONS FOR PEDIATRIC PATIENTS

Parents (or guardians) are granted the authority to make health care decisions for their minor children when the child lacks the ability to act independently or does not have the capacity to make medical decisions [11]. Parents are deemed to be in a better position than others to understand their child’s unique needs and interests, as well as their families’, and thus to be able to make appropriate decisions regarding their child’s health care. Historically, the best interest standard has predominated as the appropriate decision-making standard for medical decisions for minors. Current consensus rests on a more nuanced view that encompasses not only the patient’s medical interests, but psychosocial and familial concerns as well [11].

The “harm principle” has been suggested as a further refinement on the decision-making standard, requiring not only that decision makers consider the patient’s best interests, broadly understood, but also that a threshold of harm be identified, below which decisions should not be tolerated [11]. Parents (or guardians) are also recognized to have a responsibility to foster their children’s autonomy and moral growth, a responsibility clinicians share. Providing information in a developmentally appropriate way that respects the minor patient’s cognitive ability, engaging the child in decision making to the extent possible, and seeking the child’s assent to proposed interventions helps to fulfill that responsibility [11].

With respect to DSD specifically, it has been suggested that decisions should seek to foster the well-being both of the current child and the adult he or she will become; respect the rights of patients to participate or make decisions that affect them; and foster family and parent-child relationships [4].

In cases of DSD, decisions about a child’s best interests and appropriate interventions involve sensitive issues of sex, gender, and sexuality, and interventions that may be irreversible. Parents are often concerned about the future well-being of their child with regard to self-identity, relationships, and reproductive capacity [7]. Because of these concerns, they may be quick to want to establish sex and gender identity for their child in order to promote “normalcy” and reduce stigmatization. Moreover, when physicians perceive early intervention to be urgently needed or wholly beneficial, they may not fully recognize that there is a decision to be made, or the complexity of that decision for the family and patient.

1 A 2013 lawsuit, though unsuccessful, raised constitutional issues with respect to early surgical
2 intervention and sex assignment. In 2013, the adoptive parents of a South Carolina child, MC, born
3 with “ovotesticular DSD” filed suit in the US District Court for the District of South Carolina
4 against physicians who had performed feminizing genitoplasty on the child at age 16 months. At
5 the time of surgery, MC was under the legal custody of the South Carolina Department of Social
6 Services, which authorized the intervention. Despite initially being raised as a girl by his adoptive
7 parents, consistent with his surgically assigned sex, MC identified as a boy and at the time the
8 lawsuit was filed was living as a boy. Because of the surgery, MC is now sterile. Although the
9 action was dismissed on appeal by the US Court of Appeals for the Fourth Circuit (in January
10 2015) [12], the lower court had denied the defendants’ request for dismissal on the grounds that the
11 defendants may have violated MC’s constitutional right to procreate [13].
12

13 RECOMMENDATION

14
15 The Board of Trustees recommends that the following be adopted in lieu of Resolution 3-A-16 and
16 the remainder of this report be filed:
17

18 That our American Medical Association support optimal management of DSD through
19 individualized, multidisciplinary care that: (1) seeks to foster the well-being of the child and
20 the adult he or she will become; (2) respects the rights of the patient to participate in decisions
21 and, except when life-threatening circumstances require emergency intervention, defers
22 medical or surgical intervention until the child is able to participate in decision making; and
23 (3) provides psychosocial support to promote patient and family well-being. (New HOD
24 Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE BOARD OF TRUSTEES

B of T Report 8-I-16

Subject: Medical Reporting for Safety-Sensitive Positions
(Resolution 14-A-16)

Presented by: Patrice A. Harris, MD, MA, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

At the 2016 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred to the Board of Trustees Resolution 14-A-16, “Medical Reporting for Safety Sensitive Positions,” which was introduced by the Aerospace Medical Association. Resolution 14-A-16 asked:

That our American Medical Association advocate for a uniform national policy on mandatory reporting of significant medical conditions for employees in Safety Sensitive positions to protect public safety, as well as to enhance protection of reporting physicians.

Testimony was supportive of the intent of the resolution, but was concerned about the ambiguity of language in light of the complexity of the issue. Testimony also offered an amendment to use the Department of Transportation’s definition of “Safety-Sensitive Position.” It was expressed that, while addressing this issue as timely and necessary, clarification must be provided before the resolution is recommended for adoption.

BACKGROUND

According to the Department of Transportation (DOT), a safety-sensitive position is a job or position where the employee holding this position has the responsibility for his or her own safety or other people’s safety. Under DOT regulations, this term is currently used to describe positions that are subject to drug and alcohol testing. These regulations cover transportation employees in various capacities, including aviation, trucking, rail, mass transit, pipeline, and maritime professions [1].

The DOT requires that employees in safety-sensitive positions be given approval to work by a certified physician. Qualifications for physician certification are regulated by the various agencies of the DOT. For example, the Federal Aviation Administration (FAA) has regulations for the certification of Aviation Medical Examiners [2]. The Federal Motor Carrier Safety Administration has a registry and certification process for physicians who perform medical exams for truck drivers [3]. Once certified, these physicians grant medical certificates to safety-sensitive employees, allowing them to work. The requirements for safety-sensitive positions depend on the job’s duties and are regulated by the various agencies of the DOT. Employees must be free of certain disqualifying conditions, such as poor vision or hearing, epilepsy, or diabetes [4]. Furthermore, there is no requirement that physicians report to the relevant agencies; rather, if an employee is not eligible for work, the physician is expected not to grant a certificate to work.

Mandatory reporting by physicians is required by states in other contexts in which there is concern for public health or safety, such as certain infectious diseases or neurological conditions (e.g., epilepsy) that may impair the driving ability of individuals who hold noncommercial motor vehicle licenses. Specific reporting requirements vary by state.

Professional organizations also have their own recommendations for reporting when a threat to public safety exists. For example, the Federation of State Physician Health Programs recommends immediate reporting to the licensing authority by the state physician health program (PHP) if a physician enrolled in the PHP has an impairing condition and refuses to cease practice or otherwise presents a threat to public safety. Similarly, the physician must be reported if he or she rejects recommendations for evaluation or treatment or has been directed by the licensing authority to undergo evaluation or treatment. Although the safety of individual patients and the public may be the primary consideration, protecting the confidentiality of the impaired physician is also an important consideration [5].

CURRENT AMA POLICY

AMA policy does not speak to safety-sensitive positions specifically. However, the following address issues of mandatory reporting in the context of public health and safety.

- Opinion 1.2.6, “Work-Related and Independent Medical Examinations,” addresses the unique relationships industry-employed physicians have with patients, often confined to the isolated examination required by the industry employer. Physicians are encouraged to disclose the limited nature of the patient-physician relationship, and to be forthright with the patient about the physician’s contractual role with the employer. The physician must maintain professional standards of confidentiality, and, when necessary, should assist the patient in connecting with a qualified physician or in pursuing follow-up care.
- Opinion 3.2.3, “Confidentiality: Industry-Employed Physicians and Independent Medical Examiners,” urges that, when a physician assesses an individual’s health or disability for work-related illness or injury, the information must remain confidential unless consent is given by the individual or is required by law. When authorized to release medical information, physicians should only release information that is reasonably relevant to the individual’s ability to perform work.
- Opinion 8.2, “Impaired Drivers and Their Physicians,” urges a physician to assess at-risk patients for conditions that may affect their driving ability. If such a risk exists, a physician should discuss driving risks with the patient and the patient’s family in order to minimize risk. The physician should notify the patient that continued driving against advice to stop will result in reporting to authorities, who will make the final determination on the status of the patient’s license. The physician should only disclose the minimum necessary information when reporting.
- Opinion 9.3.2, “Reporting Impaired Colleagues,” discusses the situation in which a physician or mental health condition interferes with a physician’s ability to engage safely in professional activities, potentially compromising patient care. In such situations, physicians have an ethical obligation to intervene in a timely manner, to report colleagues in keeping with ethical guidance and applicable law, and to work collectively to support impaired physicians through the promotion of physician health and wellness and the creation of mechanisms to assist impaired physicians in ceasing their practice.
- H-15.954, “Older Driver Safety,” urges physicians to adhere to their state’s reporting statutes for medically at-risk drivers.
- H-15.958, “Fatigue, Sleep Disorders, and Motor Vehicle Crashes,” recommends collaboration between DOT and other agencies to study fatigue among truck drivers and operator other

commercial vehicles. It recommends that physicians become knowledgeable about sleep-related disorders and inform patients of hazards of driving while fatigued, as well as becoming aware of the laws and regulations concerning drivers in their state.

TARGETING MENTAL FITNESS CONCERNS

DOT regulations directly address mental health issues, such as substance use disorders and depression, through the certification process, as well as through drug and alcohol testing. The DOT also requires screening for other physically impairing conditions such as epilepsy or seizure disorders through the medical certification process. Formal psychiatric examinations, however, are not required [6]. In response to the Germanwings crash of 2015, Resolution 14-A-16 seeks to address any gap in mental health screening among employees in safety-sensitive positions.

Following the Bureau d'Enquêtes et d'Analyse report, which confirmed the Germanwings crash of 2015 was caused by the suicide of a co-pilot known to have major depression with psychosis, agencies around the world are working to improve mental health evaluations and treatment, as well as encourage voluntary reporting of mental health issues. Several commercial airlines already have mechanisms in place that allow pilots in distress to report, seek treatment, and return to work once successfully evaluated [7].

In January of 2016, the Aviation Rulemaking Committee (ARC) of the FAA issued several recommendations to the FAA, airlines, and pilots' unions. Collectively, they agreed to develop programs to reduce mental health stigma and promote resources for treatment, including expanding the use of pilot assistance programs to cover mental health. ARC concluded that routine screening for depression is neither productive nor cost effective and therefore did not recommend it be adopted. They instead advocated for education, outreach, and training in order to encourage self-reporting to employers to enroll in treatment programs [7].

CONSIDERING A NATIONAL MANDATORY REPORTING POLICY

Transportation and safety-sensitive positions are primarily inter-state in nature at this time. Truck drivers, pilots, and railroad workers operate in a capacity that affects the safety of people from many different states. The intent of national mandatory reporting for safety-sensitive positions would be to overcome the variability in state requirements.

However, it is not clear as a practical matter that such a policy would achieve the intended goal. A study among primary care physicians in Canada found that they rarely report unsafe drivers to licensing authorities, even when the reporting laws require it. The study surveyed vehicle crashes and prior doctor visits to see how often doctors reported unsafe drivers before accidents occurred. The study found that reporting was very low even though many of the drivers had been to their physician before their crashes. The authors suggest that these findings are due to ambiguous language in the statute, as well as the difficulty in detecting impairing conditions, such as alcohol abuse, in a primary care context [8].

A national reporting mandate must be robustly structured to avoid unintended consequences, such as damage to the reputation or employability of an individual inappropriately identified as impaired. Among the minimum requirements needed for an effective reporting system would be clearly delineated criteria for identifying individuals who pose a plausible, significant risk to public safety and a clear mechanism for reporting such individuals to authorities in a position to take action to protect the public. Appropriate safeguards to protect the confidentiality of individuals

1 identified as impaired and clear means for referring them for appropriate treatment would also be
2 required.

3
4 Whether the possible, but as yet unknown, gain in public safety would offset the additional burdens
5 national mandatory reporting would pose administratively for oversight authorities and for primary
6 care or other physicians who do not routinely screen patients for these purposes is uncertain. A
7 more limited approach may be more effective; for example, focusing on training the physicians
8 who currently carry out evaluation of individuals for safety-sensitive positions, such as Aviation
9 Medical Examiners and other certified physicians to better identify mental health issues during
10 their periodic evaluations of safety-sensitive employees.

11
12 CONCLUSION

13
14 National standards already exist for employees in safety-sensitive positions for their physical and
15 mental health, which require employees to be cleared for work by DOT-certified physicians. The
16 likely gain in public safety that would be achieved by mandatory reporting is at present
17 undemonstrated, while the burden on physicians who are not DOT-certified and not otherwise
18 required to report impairing conditions could be substantial.

19
20 RECOMMENDATION

21
22 The Board of Trustees recommends that Resolution 14-A-16, "Medical Reporting for Safety-
23 Sensitive Positions," not be adopted and the remainder of the report be filed.

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REPORT OF THE COUNCIL ON CONSTITUTION AND BYLAWS

CCB Report 1-I-16

Subject: Membership and Representation in the Organized Medical Staff Section--Updated Bylaws

Presented by: Colette R. Willins, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

At the 2016 Annual Meeting, our AMA House of Delegates adopted Policy G-615.101, "Membership and Representation in the Organized Medical Staff Section," introduced by the Organized Medical Staff Section, which called for amendments to the AMA Bylaws to accomplish the following:

1. An expanded member base, whereby all active AMA members who are members of the medical staff of a hospital or a group of practicing physicians organized to provide health care are eligible for OMSS membership. Also, Section membership shall continue to include active resident and fellow members of the AMA who are selected by their medical staffs as representatives to the OMSS business meeting.
2. A modified OMSS representation structure such that the medical staff of each hospital or group of practicing physicians organized to provide health care may select up to two AMA member representatives to the OMSS business meeting, with the president or chief of staff of the medical staff also able to attend the meeting as a representative if he or she is an AMA member.
3. When a multi-hospital system and its component medical staffs have exercised the option under the Medicare Conditions of Participation to unify the medical staffs, the medical staff members who hold specific privileges to practice at each separately Medicare-certified hospital within the system may select up to two AMA member representatives to the OMSS business meeting, with the president or chief of staff of the unified medical staff also able to attend the meeting as a representative if he or she is an AMA member.
4. Certification of all representatives in accordance with procedures established by the OMSS Governing Council.
5. Clarification of the rights of OMSS representatives, non-OMSS representatives, non AMA members and guests.

The Council on Constitution and Bylaws presents the requested amendments to the AMA Bylaws.

RECOMMENDATIONS

The Council on Constitution and Bylaws recommends that the following amendments to the AMA Bylaws be adopted, that Policy G-615.101 be rescinded, and that the remainder of this report be filed. Adoption requires the affirmative vote of two-thirds of the members of the House of Delegates present and voting.

7.4 Organized Medical Staff Section. The Organized Medical Staff Section is a delineated Section.

7.4.1 Membership. Membership in the Section shall be ~~limited open to all active~~ physician members of the AMA who are members of a medical staff of a hospital or a medical staff of a group of practicing physicians organized to provide healthcare. ~~physicians, including residents and fellows, selected by physician members of the medical staffs of hospitals and other delivery systems. Selected physicians who are not AMA members may participate in the Section's Business Meeting as provisional members without the right to vote. Provisional members may attend a maximum of 2 Business Meetings. Active resident and fellow~~ members of the AMA who are selected by their medical staffs as representatives to the Business Meeting also shall be considered members of the Section.

7.4.32 Representatives to the Business Meeting. ~~The physician members of the Each medical staff of each a hospital and each medical staff of a group of practicing physicians organized to provide healthcare delivery system meeting the requirements established by the Governing Council may select one or more up to two active physician AMA member representatives to the Business Meeting. The president or chief of staff of a medical staff may also attend the Business Meeting as a representative if he or she is an active physician member of the AMA. The representatives must be physician members of the medical staff of a hospital or group of practicing physicians organized to provide healthcare or residents/fellows affiliated with the medical staff of a hospital or group of practicing physicians organized to provide healthcare delivery system. Selected physicians who are not AMA members may participate in the Business Meeting as provisional representatives without the right to vote. Provisional representatives may attend a maximum of 2 Business Meetings. Selected All representatives to the Business Meeting shall be properly certified by the President or Secretary of the medical staff in accordance with procedures established by the Governing Council and approved by the Board of Trustees.~~

7.4.32.1 When a multi-hospital system and its component medical staffs have unified the medical staffs, those medical staff members who hold specific privileges to practice at each separate entity within the unified system may select up to two representatives to the Business Meeting, so long as they are active physician members of the AMA. The president or chief of staff of a unified medical staff also may attend the Business Meeting as a representative if he or she is an active physician member of the AMA.

Members of the Governing Council who have completed their terms and the chairs of state association hospital medical staff sections or organized medical staff sections may be seated as ex-officio representatives to the Business Meeting, provided they are AMA members and are properly certified by the President or Secretary of the state association. Ex-officio representatives have the right to speak and debate in the meeting but do not have the right to introduce business, introduce an amendment, make a motion, or vote.

~~7.4.3.2 All past chairs of the AMA Organized Medical Staff Section may attend the Business Meeting as ex officio members. They shall have the right to speak and debate in the meeting, but do not have the right to introduce business, introduce an amendment, make a motion, or vote.~~

7.4.23 Cessation of Eligibility. If any officer or Governing Council member ceases to meet the membership requirements of Bylaw 7.4.1 or ceases to be credentialed as a representative consistent with Bylaw 7.4.2 prior to the expiration of the term for which elected, the term of such officer or member shall terminate and the position shall be declared vacant.

7.4.4 Member Rights and Privileges

7.4.4.1 An OMSS member who is certified as a representative in accordance with 7.4.2 has the right to speak and debate, and has the right to introduce business, make motions, vote, and run for office to the OMSS Governing Council.

7.4.4.2 An OMSS member who is not certified as a representative in accordance with 7.4.2 has the right to speak and debate, but does not have the right to introduce business, make motions, vote or run for office to the OMSS Governing Council.

7.4.4.3 A physician who is not an AMA member may attend one Business Meeting as a guest, without the right to speak or debate, introduce business, make motions, vote or run for office to the OMSS Governing Council.

7.4.4.4 At the discretion of the Governing Council, a nonphysician may attend the Business Meetings as a guest.

(Modify AMA Bylaws)

Fiscal note: Less than \$500

AMA Policy

G-615.101 – Our AMA Bylaws will be amended to reflect the following statements about membership and representation in the Organized Medical Staff Section (OMSS):

1. Membership. Membership in the OMSS shall be open to all active physician members of the AMA who are members of the medical staff of a hospital or members of the medical staff of a group of practicing physicians organized to provide health care. Membership in the Section also shall continue to include active resident and fellow members of the AMA who are selected by their medical staffs as representatives to the OMSS business meeting.
2. Representation. a. The medical staff of each hospital or group of practicing physicians organized to provide health care meeting the requirements established by the OMSS Governing Council may select up to two AMA member representatives to the OMSS business meeting; additionally, the president or chief of staff of the medical staff may attend the meeting as a representative if he or she is an AMA member. b. When a multi-hospital system and its component medical staffs have exercised their option under the Medicare Conditions of Participation to unify the medical staffs, the medical staff members who hold specific privileges to practice at each separately Medicare-certified hospital within the system may select up to two AMA member representatives to the OMSS business meeting. Additionally, the president or chief of staff of the unified medical staff may attend the meeting as a representative if he or she is an AMA member. c. All OMSS representatives shall be certified in accordance with procedures established by the OMSS Governing Council.
3. Rights of OMSS representatives. Only certified OMSS representatives shall have the right to introduce business, make motions, and vote at OMSS business meetings, and to serve as members of the OMSS Governing Council.
4. Rights of non-OMSS representatives. a. OMSS members who are not certified OMSS representatives, as well as all other AMA members, shall have the right to attend OMSS business meetings and to speak and debate but not to introduce business, make motions, or vote. b. A physician who is not an AMA member may attend one business meeting as a guest, without the right to speak or debate, introduce business, make motions, or vote at OMSS business meetings. c. At the discretion of the Governing Council, non-physicians may attend business meetings as guests, without the right to speak or debate, introduce business, make motions, or vote.

REPORT OF THE COUNCIL ON CONSTITUTION AND BYLAWS

CCB Report 2-I-16

Subject: Bylaw Amendments pertaining to Late Resolutions and Emergency Business

Presented by: Colette R. Willins, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

1 At the 2016 Annual Meeting of the AMA House of Delegates, the House adopted Policy
2 G-600.054, “Procedures of the House of Delegates,” which recommended changes in how the
3 House of Delegates handles late and emergency resolutions from delegates. Policy G-600.054(6),
4 derived from Speakers Report 2-A-16, defined late resolutions as those submitted less than 30 days
5 before the opening day of a House of Delegates meeting but before the opening session recesses
6 and not meeting the definition of regular business. Policy G-600.054(6) defined resolutions from
7 delegates that are submitted after the recess of the opening session as emergency resolutions,
8 subject to a three-fourths vote for acceptance as business. Emergency resolutions are not referred to
9 a reference committee but rather handled by the House as a whole. For adoption, emergency
10 resolutions, like late resolutions, would require only a simple majority.

11
12 The Council on Constitution and Bylaws was asked to prepare bylaws amendments to effect the
13 changes in definitions of late and emergency resolutions as well as handling of late resolutions and
14 emergency resolutions from delegates. As part of that undertaking, the Council also was directed to
15 consider whether some elements currently in the bylaws related to the handling of late and
16 emergency business would be more appropriately defined in policy.

17 18 DISCUSSION

19 20 *Bylaw Changes to Incorporate House Action on Late and Emergency Resolutions—* 21 *Recommendation 1*

22
23 Several subprovisions of Bylaw 2.11.3, “Introduction of Business,” deal exclusively with late
24 and/or emergency resolutions (Bylaws 2.11.3.1.3 and 2.11.3.1.4). In its Recommendation 1, the
25 Council has proposed bylaw amendments that are consistent with Policy G-600.054(6). For Bylaw
26 2.11.3.1.4, the Council has also proposed retitling the heading for accuracy to read “Emergency
27 Resolutions.” Similarly, the Council proposes to modify Bylaw 2.11.3.2, “Reports of Board” to
28 “Business of the Board of Trustees” for accuracy.

29
30 The Council notes that existing Bylaw 2.11.5.2, “New Business on the Final Day of the House of
31 Delegates Meeting,” is now obsolete due to Policy G-600.065(7), which changed how emergency
32 resolutions are handled. Emergency resolutions are no longer referred to a reference committee
33 and, once accepted as business by the House of Delegates by a three-fourths vote of delegates
34 present and voting, require only a majority vote for adoption. Thus, the Council proposes to
35 incorporate much of the language from 2.11.5.2 into an amended 2.11.3.1.4, “Emergency
36 Resolutions,” and proposes a new Bylaw 2.11.3.1.6, “Resolutions not Accepted” to incorporate the
37 language of 2.11.5.2.2, but also modify it for clarity to state that resolutions that the House voted to

not accept can be resubmitted for possible consideration at any future meeting of the House of Delegates rather than just at the next meeting.

Amended Bylaws 2.11.4 and 2.13.1.7.1 reiterate and clarify that items of business, with few exceptions such as informational reports, memorial resolutions, etc., that have been submitted prior to the recess of the opening session of the House of Delegates and accepted as business are referred to a reference committee.

The criteria for considering and adopting emergency resolutions were changed with adoption of Speakers Report 2-A-16. The timing regarding when these items are considered emergency resolutions was also changed. Per Speakers Report 2-A-16, late resolutions continue to be subject to a two-thirds vote for acceptance as business and upon acceptance, are referred to a reference committee. Emergency resolutions are not referred to a reference committee but rather handled by the House of Delegates as a whole. For adoption, late resolutions and emergency resolutions, like all other items of business with the exceptions of amendments to the AMA Constitution and Bylaws and changes to the Principles of Medical Ethics, require only a majority vote.

Because emergency resolutions must be processed without the benefit of a reference committee hearing, their acceptance should meet a higher hurdle. At the same time, a situation that is truly emergent and that requires action before the next meeting of the House of Delegates should generally be self-evident presumably rendering the three-fourths vote largely a formality.

Previously, resolutions presented on the final day of the meeting were not considered late, but rather emergency resolutions. The change in the definition of emergency resolutions eliminated using the “final day of the House” as the time at which resolutions are considered emergency, and instead set the time as after the close of the opening session of the House of Delegates. Speakers Report 2 noted that the “final day of the House” is not known with certainty, as in recent years the House has adjourned a day early multiple times.

According to Speakers Report 2, “The committee believes that establishing an unambiguous cut-off for defining late and emergency resolutions will be of obvious value. Reference committee hearings on a resolution are essential to the House of Delegates process and should only be bypassed for emergency resolutions. Therefore the defining point favored here for late resolutions is recess of the first session of the House of Delegates.”

*Elimination of References to “The Final Day” as a Defining Point for Other Business—
Recommendation 2*

During its comprehensive review of the AMA Bylaws and concurrent review of the House of Delegates Reference Manual: Procedures, Policies and Practices, the Council considered eliminating references to the final day when defining emergency resolutions but noted there are many other items of business that had different rules for consideration and/or adoption using “the final day of the House of Delegates meeting” as the defining point in our bylaws.

As noted above, Speakers Report 2 stated that the “final day of the House” is not known with certainty, as in recent years the House has adjourned a day early multiple times. The Council agrees that reference committee hearings are essential to the House of Delegates process and feels they should only be bypassed for extraordinary business, not just emergency resolutions. The Council also agrees that establishing an unambiguous cut-off for defining when an item is beyond “late” will be of obvious value. Therefore the defining point favored here for late resolutions, the

recess of the first session of the House of Delegates, should be applied to other items of business that currently use the defining point of “the final day.”

In proposing the bylaw amendments in Recommendation 2, the Council offers the following rationale for its recommendations, and notes that the House has the ability to adopt, adopt as amended, not adopt, refer, etc.

- 2.11.3.1.2, AMA Sections. The Council believes that it is appropriate to change the cut-off point for resolutions from sections from “the close of business on the day preceding the final day of the meeting” to “no later than the recess of the House of Delegates opening session.” The Council has also conferred with the Office of the House of Delegate Affairs and confirms that the Council’s proposed language is consistent with the sections’ current practice of submitting resolutions before the opening of the House of Delegates so that resolutions can be included in the Sunday tote, accepted as business and referred to a reference committee for discussion.
- 2.11.3.3, Reports of Councils. Currently, reports, opinions or recommendations from a council of the AMA or a special committee of the House of Delegates may be presented at any time before the close of business on the day preceding the final day of a meeting. The Council felt that the language referring to the final day must be eliminated since the “final day of the House” is not known with certainty. However, it is not as simple as substituting the new defining point. Unlike business from the Board presented on the final day which requires a three-fourths vote for adoption, business from the councils simply is not allowed on the final day under our current bylaws. It was felt that these groups should be able to present items of business after the recess of the House of Delegates opening session. To avoid this unintended consequence, the council eliminated the final day language which then allows these council and special committee items of business to be presented at any time during a meeting.
- 2.11.5 and 2.11.5.1, New Business presented after recess of the opening session of the House of Delegates meeting. The Council has deleted reference to “final day” and instead used the defining point of business presented after the recess of the opening session of the House of Delegates. At that point in time, the business will be presented too late for reference committees. The current higher bar of three-fourths vote for adoption still stands as it is currently in our Bylaws. While Speakers Report 2 gave an excellent explanation why the final day could no longer be used as a defining point, it made no recommendations regarding changing the higher bar for consideration currently set for business other than resolutions from delegates.

Other Considerations

As directed by Policy G-600.054, the Council has considered whether some bylaw provisions would better exist in policy. The Council discussed whether or not the voting threshold to accept late resolutions and/or emergency resolutions for consideration should continue to be embodied in the Bylaws or be solely in the HOD Reference Manual: Procedures, Practices and Policies, and agreed to retain them in the Bylaws for completeness as well as include them in the HOD Reference Manual. The Council, however, has elected not to specify in the Bylaws the vote required for adoption.

RECOMMENDATIONS

The Council on Constitution and Bylaws recommends the following:

1. That the following amendments to the AMA Bylaws be adopted consistent with Policy G-600.054(6):

2.11.3 Introduction of Business.

2.11.3.1 Resolutions. To be considered as regular business, each resolution must be introduced by a delegate or organization represented in the House of Delegates and must have been submitted to the AMA not later than 30 days prior to the commencement of the meeting at which it is to be considered, with the following exceptions.

2.11.3.1.1 Exempted Resolutions. If any member organization's house of delegates or primary policy making body, as defined by the organization, adjourns during the 5-week period preceding commencement of an AMA House of Delegates meeting, the organization is allowed 7 days after the close of its meeting to submit resolutions to the AMA. All such resolutions must be received by noon of the day before the commencement of the AMA House of Delegates meeting. The presiding officer of the organization shall certify that the resolution was adopted at its just concluded meeting and that the body directed that the resolution be submitted to the AMA House of Delegates.

2.11.3.1.3 Late Resolutions. Late resolutions may be presented by a delegate prior to the recess of the opening session of the House of Delegates ~~any time prior to the final day of a meeting, and~~ but will be accepted as business of the House of Delegates only upon two-thirds vote of delegates present and voting.

2.11.3.1.4 Emergency Nature Resolutions. ~~On the final day of a meeting, delegates may present resolutions of an emergency nature which shall be accepted pursuant to Bylaw 2.11.5.2. Resolutions of an emergency nature may be presented by a delegate any time after the opening session of the House of Delegates is recessed.~~ Emergency resolutions will be accepted as business only upon a three-fourths vote of delegates present and voting, and if accepted shall be presented to the House of Delegates without consideration by a reference committee.

2.11.3.1.5 Withdrawal of Resolutions. A resolution may be withdrawn by its sponsor at any time prior to its acceptance as business by the House of Delegates.

2.11.3.1.6 Resolutions not Accepted. Late resolutions and emergency resolutions not accepted as business by the House of Delegates

1 may be submitted for consideration at a future meeting in
2 accordance with the procedure in Bylaw 2.11.3.
3

4 **2.11.3.2 Reports Business of the Board of Trustees.** Reports, recommendations,
5 resolutions or other new business, may be presented by the Board of
6 Trustees at any time during a meeting.

7 ***

8
9 **2.11.4 Referral to Reference Committee.** Reports, recommendations, resolutions or other
10 new business presented prior to the recess of the opening session of the House of
11 Delegates before the close of business on the day preceding the final day of a
12 meeting shall be referred to an appropriate reference committee for hearings and
13 report, subject to acceptance as business of the House of Delegates. Items of business
14 presented after the recess of the opening session are not referred to reference
15 committee, but rather heard by the House of Delegates as a whole, subject to
16 acceptance as business of the House of Delegates. Informational items are not referred
17 to a reference committee.
18

19 ***

20 ~~**2.11.5.2 Emergency Resolutions.** Resolutions of an emergency nature presented by~~
21 ~~delegates on the final day of a meeting shall be referred by the Speaker to an~~
22 ~~appropriate reference committee, which shall then report to the House of~~
23 ~~Delegates as to whether the matter involved is or is not of an emergency~~
24 ~~nature.~~

25
26 ~~**2.11.5.2.1** If the reference committee reports that the matter is of an~~
27 ~~emergency nature, the resolution shall be presented to the House~~
28 ~~of Delegates without further consideration by a reference~~
29 ~~committee. Adoption of the recommendation(s) in the~~
30 ~~emergency resolution shall require a three-fourths vote of~~
31 ~~delegates present and voting.~~

32
33 ~~**2.11.5.2.2** If the reference committee reports that the matter is not of an~~
34 ~~emergency nature, the resolution may be submitted for~~
35 ~~consideration at the next meeting in accordance with the~~
36 ~~procedure in Bylaw 2.11.3.~~

37 ***

38
39 **2.13.1 Reference Committees of the House of Delegates.**

40 ***

41
42 **2.13.1.7 Procedure and Reports.**

43
44 **2.13.1.7.1 Method.** Resolutions, reports, extracted opinions and proposals
45 presented to the House of Delegates prior to the recess of the
46 opening session of the House of Delegates shall be referred to
47 appropriate reference committees, subject to acceptance as
48 business of the House of Delegates. The reports of reference
49 committees shall be presented to the House of Delegates before
50 final action may be taken on such resolutions, reports and

proposals, unless otherwise provided in these Bylaws, or unless otherwise unanimously decided by the House of Delegates.

(Modify AMA Bylaws)

2. That the following amendments to the AMA Bylaws be adopted:

2.11 Procedure.

2.11.3 Introduction of Business.

2.11.3.1 Resolutions. To be considered as regular business, each resolution must be introduced by a delegate or organization represented in the House of Delegates and must have been submitted to the AMA not later than 30 days prior to the commencement of the meeting at which it is to be considered, with the following exceptions.

2.11.3.1.1 Exempted Resolutions. If any member organization's house of delegates or primary policy making body, as defined by the organization, adjourns during the 5-week period preceding commencement of an AMA House of Delegates meeting, the organization is allowed 7 days after the close of its meeting to submit resolutions to the AMA. All such resolutions must be received by noon of the day before the commencement of the AMA House of Delegates meeting. The presiding officer of the organization shall certify that the resolution was adopted at its just concluded meeting and that the body directed that the resolution be submitted to the AMA House of Delegates.

2.11.3.1.2 AMA Sections. Resolutions presented from the business meetings of the AMA Sections may be presented for consideration by the House of Delegates no later than the recess of the House of Delegates opening session. ~~At any time before the close of business on the day preceding the final day of the meeting.~~

2.11.3.2 Reports of Board of Trustees. Reports, recommendations, resolutions or other new business, may be presented by the Board of Trustees at any time during a meeting.

2.11.3.3 Reports of Councils. Reports, opinions or recommendations from a council of the AMA or a special committee of the House of Delegates may be presented at any time ~~before the close of business on the day preceding the final day of~~ during a meeting.

2.11.3.4 Informational Reports of Sections. Informational reports may be presented by the AMA Sections on an annual basis.

1 **2.11.5 New Business ~~on Final Day of~~ Presented After Recess of the Opening**
2 **Session of the House of Delegates Meeting.**
3

4 **2.11.5.1 Requirements.** Reports, recommendations, resolutions or other new
5 business presented by the Board of Trustees after recess of the opening
6 session of the House of Delegates meeting on the final day of a
7 ~~meeting~~ shall be accepted as business before the House and shall not
8 be referred to a reference committee, but adoption of the
9 recommendation(s) in the report or other item(s) of business shall
10 require a three-fourths vote of delegates present and voting.
11

12 (Modify AMA Bylaws)

- 13
14 3. That Policy G-600.054(6) and (7) be rescinded; and
15
16 4. That the balance of this report be filed.

Fiscal Note: Less than \$500

RELEVANT AMA POLICY

G-600.054 - Procedures of the House of Delegates

1. Our AMA reaffirms The American Institute of Parliamentarians Standard Code of Parliamentary Procedure as our parliamentary authority, including the use of the motion to table and the motion to adopt in-lieu-of, and treat amendments by substitution as first-order amendments.
2. The rules and procedures of the House of Delegates will be amended as follows:
 - A. The motion to table a report or resolution that has not yet been referred to a reference committee is not permitted and will be ruled out of order.
 - B. A new motion is added to the House of Delegates Reference Manual, Object to Consideration. If a Delegate objects to consideration of an item of business by our HOD, the correct motion is to Object to Consideration. The motion cannot interrupt a speaker, requires a second, cannot be amended, takes precedence over all subsidiary motions and cannot be renewed. The motion requires a 3/4 vote for passage. Debate is restricted to why the item should not be considered.
3. The procedures of our House of Delegates distinguish between a motion to refer, which is equivalent to a motion to refer for report, and a motion to refer for decision and that the motion to refer for decision be one step higher in precedence.
4. The procedures of our House of Delegates specify that both sides must have been heard before a motion to close debate is in order and that absent an express reference to "all pending matters" the motion applies only to the matter under debate.
5. The procedures of our House of Delegates clarify that adjournment of any House of Delegates meeting finalizes all matters considered at that meeting, meaning that items from one meeting are not subject to a motion to recall from committee, a motion to reconsider or any other motion at a succeeding meeting.
6. Late resolutions are defined as those submitted less than 30 days before the opening day of a House of Delegates meeting but before the opening session recesses and not meeting the definition of regular business, and that business submitted after the recess of the opening session be regarded as emergency business, subject to a three-fourths vote for acceptance as business.
7. The Council on Constitution and Bylaws will prepare bylaws amendments to effect the changes in definitions as well as handling of late resolutions and emergency business and as part of that effort consider whether some related elements currently in the bylaws would better exist in policy.
8. The Council on Constitution and Bylaws, in consultation with the speakers, will review the House of Delegates Reference Manual and revise it accordingly.

REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (1-I-16)
Collaborative Care
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

Traditionally, the practice of medicine was conceived as a single physician providing care directly to an individual patient. But as health care focuses increasingly on quality, efficiency, and the experiences and outcomes of the patient, services are no longer necessarily provided by a single physician. Rather, a patient's care now often lies in the hands of many collaborating health care professionals.

Teams that collaborate effectively can enhance the quality of care for individual patients. By being prudent stewards and delivering care efficiently, teams also have the potential to expand access to care for populations of patients. Physicians are uniquely situated to serve as clinical leaders. By virtue of their thorough and diverse training, experience, and knowledge, physicians have a distinctive appreciation of the breadth of health issues and treatments that enables them to synthesize the diverse professional perspectives and recommendations of the team into an appropriate, coherent plan of care for the patient.

As leaders within health care teams physicians have a responsibility to model ethical leadership, promote core team values, support transparent decision making, encourage open discussion and shared accountability, and respect the patient's and family's unique relationship as team members. As leaders within health care institutions, physicians should advocate for the resources and support health care teams need to function effectively, encourage institutions to identify and address barriers to collaboration, and promote policies and procedures to constructively address conflicts that adversely affect patient care.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-I-16

Subject: Collaborative Care

Presented by: Ronald A. Clearfield, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

Traditionally, the practice of medicine was conceived as a single physician providing care directly to an individual patient. But as health care focuses increasingly on quality, efficiency, and the experiences and outcomes of the patient, services are no longer necessarily provided by a single physician. Rather, a patient's care now often lies in the hands of many collaborating health care professionals. Teams may be formal structured units or ad hoc groups of physicians, nurses, social workers and other health professionals, at one or several sites of care, all of whom play various clinical and administrative roles in the care of a single patient.

Systemic changes in the nation's health care system are also driving the movement toward collaborative care as a tool for pursuing coordinated, patient-centered care [1]. Collaborative care has been tested and measured in clinical settings around the country and its importance has been translated into law and policy [2, 3]. A growing body of research indicates that collaborative care can enhance health care quality and outcomes for individual patients, may enhance access to care, and may help lower—or slow the rate of increase of—health care costs [4, 5, 6, 7]. Further, well-functioning teams that provide safe, efficient, high-quality care can reduce burnout and improve morale among health care personnel [8].

This report examines key ethical considerations for health care teams engaged in providing care collaboratively and develops guidance for physicians as leader-members of care teams.

ETHICAL PRINCIPLES FOR COLLABORATIVE CARE

A well-functioning team capable of optimizing patient outcomes is defined by dedication to providing patient-centered care, protecting the integrity of the patient-physician relationship, sharing mutual respect and trust, communicating effectively, sharing accountability and responsibility, and upholding common ethical values as team members.

Patient-Centered Care

Collaborative care is first and foremost patient-centered care. The physician's duty to hold the patient's interests paramount (Principle VIII) does not diminish when care is provided by professionals working as a team. Like individual health care professionals, teams must ensure that the care they deliver aligns with the values and needs of the patient [9]. Teams must support

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 patients as decision makers (and families where appropriate) and afford them opportunities to
2 participate actively in treatment as members of the team. Patients and their families should feel
3 they are understood and respected by the health professionals who provide care. They must be able
4 to ask questions and must be confident that all health care personnel will address any issues openly
5 and honestly.

6 7 *Protecting the Patient-Physician Relationship*

8
9 The patient-physician relationship remains central in collaborative care environments, just as in any
10 other health care setting [9]. Physicians remain advocates for their patients and are responsible for
11 putting the patient's welfare above obligations to others [10]. The relationship that the team as a
12 whole has with the patient should be supportive of the interaction between the patient and
13 physician.

14 15 *Mutual Respect and Trust*

16
17 To provide efficient, effective care, all members of a health care team must contribute actively,
18 which requires that members mutually respect and trust one another. Health care professionals
19 must be confident that their colleagues are performing at their highest standard of practice, and that
20 the team, overall, is providing optimal care. When members do not respect and trust one another,
21 individual contributions can be misinterpreted or ignored, leading to tension or lapses in
22 communication that can in turn compromise a patient's health and safety. Members of a well-
23 functioning team will acknowledge and appreciate the contributions made by each and every team
24 member [9]. Mutual respect and trust strengthen the clinical team and give all members an
25 opportunity to serve as positive role models for one another and to inspire and motivate their
26 colleagues [9]. Honoring the work of one's colleagues not only underscores the importance of
27 individual contributions, but also emphasizes the contribution of the team as a cohesive unit [9].

28 29 *Effective Communication*

30
31 Effective communication is fundamental to providing safe, optimal care to patients [9]. Every
32 member of the team shares the responsibility to communicate effectively, clearly, and consistently.
33 Physicians can play a leading role by modeling effective communication strategies. When
34 physicians provide clear, concise information or instructions to colleagues they demonstrate
35 behaviors that others on the team can utilize to communicate efficiently and effectively themselves
36 [9].

37 38 *Accountability*

39
40 Accountability is likewise a core ethical principle for collaborative care. Given the fiduciary nature
41 of the patient-physician relationship as well as the expectations society places on physicians
42 because of their knowledge and training, physicians are accountable for patient care and outcomes
43 [9]. Nonetheless, all members of the team are accountable for their individual practice and each
44 shares responsibility for the functioning of the team as a whole, while protecting patient well-being
45 and ensuring that the team focuses on patient care as the common goal.

46
47 Beyond accountability to individual patients, physicians and health care teams also have a
48 responsibility to the communities in which they work to be prudent stewards of community
49 resources [11]. Physicians and teams have a responsibility to ensure that providing care
50 collaboratively not only benefits individual patients, but also helps to achieve efficiency and value
51 for the health care system to benefit the whole community.

KEY ATTRIBUTES OF EFFECTIVE TEAM MEMBERS

The attributes that individual members bring to a team are also important for effective team functioning. The Institute of Medicine, for example, suggests the following five key attributes: honesty, discipline, creativity, humility, and curiosity [1].

Within a successful team, members are honest and transparent about goals, decisions, mistakes, and fears [1], and engage in open dialogue that creates mutual trust [12].

A functional team also has disciplined members, with each performing assigned duties and sharing new information with other members to improve individual and team operations [1]. They fulfill responsibilities even when doing so is inconvenient or uncomfortable [1]. Such disciplined performance allows members not only to comply with established protocols, but to develop mutual respect and pursue improvement while doing so [1, 12].

Creativity is another important attribute that allows the team to work together effectively on complicated health issues. Creativity involves team members enthusiastically engaging new problems to find innovative solutions [1]. Further, creative teams do not view failed attempts and negative outcomes as the destruction of team goals, but as opportunities to learn [1].

With humility, team members recognize differences in training among the group, but do not view one form of training as wholly superior to all others [1]. Also, members understand that they are all humans susceptible to making mistakes [12]. These attitudes enable members to rely on one another, regardless of hierarchy [1], and to share constructive criticism to overcome professional and ethical obstacles.

Lastly, effective members of collaborative care teams exhibit curiosity and actively use knowledge gained from their daily lives toward the continuous improvement of individual and team efforts [1].

The composition of the team that delivers care—more or fewer physicians relative to other clinicians, mix of expertise, etc.—may vary in different contexts, such as chronic versus acute care or in-patient versus outpatient settings. For example, chronic illness is often managed most effectively by a team whose membership is stable. In contrast, acute care, especially in-patient care, is frequently provided by specialists who may work with different teams from day to day. Yet in every context, an identified individual needs to play a leadership role and take responsibility for collecting and synthesizing the diverse professional perspectives and recommendations of the team into an appropriate, coherent plan for the patient [9]. In most contexts, a physician is best able to serve as team leader.

LEADERSHIP BEHAVIOR AND CONCEPTS

An effective team requires a clinical leader who takes responsibility “for maximizing the expertise and input of the entire team in order to provide the patient with comprehensive and definitive care” [9]. Clinical leaders ensure that the team as a whole functions well and facilitates decision-making [9], and is ultimately accountable to patients. Clinical leaders must use their training and experience to interpret and synthesize the information provided by team members to make a differential diagnosis and develop a plan of care. Effective clinical leaders foster common understanding about responsibilities and encourage open communication among patients, families, and the entire health care team.

Physicians are uniquely suited to serve as clinical leaders by virtue of their thorough and diverse training, experience, and knowledge [9]. Their distinctive appreciation of the breadth of health issues and treatment options in their field of practice also enables them to synthesize the diverse professional perspectives and recommendations of the team into an appropriate, coherent plan of care for the patient. This expertise, as well as patient expectations—which hold as much in a setting of collaborative care as in a one-on-one office visit—make it most appropriate that a physician serve as a team’s clinical leader although this does not necessarily mean that physicians will take the helm for every aspect of decision-making or coordinate every detail of treatment. Other health care personnel bring expertise and knowledge to the team and in many instances will be in charge when their expertise is most needed [9].

Although traditional notions of liability map poorly against the changes taking place in how, where, and by whom health care is delivered, physicians still can be held legally accountable for the actions of medical personnel working under their supervision [13]. To this extent, it currently makes sense from a legal perspective to have the physician serve as clinical leader. However, as health care continues to evolve and roles become increasingly fluid there is need for a more nuanced understanding of how teams and their members are mutually accountable to patients and to one another over the course of a patient’s care, legally as well as ethically.

The role of clinical leader should be distinguished from that of clinical coordinator. While a physician should be the clinical leader of the health care team, the clinical coordinator of the team need not be. The clinical coordinator is the team member who, “based on his or her training, competencies and experience, is best able to coordinate the services provided by the team so that they are integrated to provide the best care for the patient” [9].

Transactional versus transformational leadership

The concepts of “transactional” versus “transformational” leadership offer a powerful framework for thinking about physician leadership in the context of collaborative care. Briefly, transactional leaders largely intervene in a “corrective” mode episodically when members deviate from a defined standard [14]. Transformational leaders, in contrast, are continuously engaged in relationships that inspire followers through charisma, clearly articulated visions, and ongoing personalized guidance [14, 15]. In a clinical context, for example, a transformational physician leader might hold informal five- to ten-minute “huddles,” in addition to weekly team meetings, to keep the team on the same page [16].

Some evidence suggests that transformational leadership has positive effects on followers’ task performance and perceptions of job characteristics and their leaders, and that such leadership behaviors can be taught [14, 15, 17, 18]. Leadership behavior influences how well a team functions. Clearly communicating a shared vision, connecting well to emotional needs, seeking consensus and collaboration, role-modeling, or coaching can each enhance the effectiveness of a team [19].

Responsibilities as Individuals, Team Members & Institutional Leaders

As clinical leaders in collaborative care, physicians have ethical responsibilities as individuals, as members of the team, and as leaders in their institutions [12].

As individuals, physicians have a responsibility to respect other team members, understand their own and other team members’ range of skill and expertise and role in the patient’s care, and master broad teamwork skills [12]. Like all team members, physicians should be open to adopting insights

1 from other members. They should communicate respectfully with other team members, even in the
2 face of controversy, and should be welcoming to new members. Physicians can model ethical
3 conduct for fellow team members—e.g., by avoiding intimidating body language or speaking
4 disrespectfully about patients—and should encourage other team members to behave accordingly
5 [20].

6
7 As clinical leaders in health care teams, physicians are in a position to foster the key attributes of
8 effective team members and to promote respect among team members. They can and should help
9 clarify expectations so that the team can establish systematic and transparent decision making. As
10 leaders, physicians can likewise encourage open discussion of clinical and ethical concerns and
11 help ensure that every member's opinion is heard and considered [21], and that team members
12 share responsibility and accountability for decisions and outcomes [12].

13
14 Teams need support and resources to optimize patient-centered care [12]. Such resources might
15 include additional training in teamwork skills, clerical support, flexibility in staff scheduling to
16 promote continuity of team membership, or additional staff to provide skills not already
17 represented among team members. Teams also need the organizations in which they provide care to
18 recognize and respect the unique relationship between team and patient. Further, explicit
19 recognition of effective teams by organizational leadership conveys the message that teamwork is
20 valued and important to the organization. Finally, teams need their organizations to provide fair
21 mechanisms for assessing the team's performance [12]. As leaders within their institutions,
22 physicians should help ensure that teams are well supported and that their contributions to the
23 quality and patients' experience of care are appropriately recognized.

24 25 CHALLENGES TO COLLABORATION

26
27 Teams can face a variety of challenges to effective collaboration, many of which are tied to the
28 culture and structure of the health care institution within which they work. Of particular concern,
29 teams may fall short of the goal of optimizing patient-centered care and outcomes when they lack
30 resources, when institutional barriers inhibit effective team functioning, and when there is ongoing
31 conflict within the team.

32 33 *Inadequate Resources*

34
35 While some individuals may naturally possess the necessary traits to work successfully in a team,
36 many others do not. Physicians have ultimate responsibility and expect accountability within a
37 team; development of team leadership skills will foster effective teamwork. Changes in how
38 physicians and other health care personnel are taught to view teamwork, such as the use of RACI
39 charts (which delineate who is Responsible, Accountable, Consulted, or Informed in the given
40 context)[22], as well as specific training in teamwork skills can reduce conflict and improve team
41 performance [23]. Ideally, interdisciplinary training begins early in medical education, a concept
42 that has been embraced by the medical community [24]; the Accreditation Council for Graduate
43 Medical Education identifies interpersonal and communication skills as a core competency. The
44 ACGME notes that these skills "result in effective information exchange and teaming with ...
45 professional associates" [23]. Organizations may also find it useful to implement their own training
46 for teamwork tailored to the culture of the institution. Such training can provide common
47 structures, processes and expectations for health care professionals who work together on a regular
48 basis.

49
50 Institutions also need to provide adequate administrative support for teams, promote scheduling
51 practices that help ensure workload and duty hours are distributed fairly across personnel, and

1 sustain stable team membership to the extent possible. Teams function best when they have input
2 into the structure and function of the institutions in which they practice.

3 4 *Institutional Culture*

5
6 The culture of an institution can also pose challenges for effective teamwork. In order to create a
7 practice environment that encourages collaborative care, an organization's leaders must actively
8 foster this new environment. Leaders must commit fully to change over the long term; adhering to
9 new methods of communication and teamwork requires diligence and oversight, lest old patterns
10 reemerge [25]. Organizations have the opportunity and responsibility to nurture supportive
11 environments by helping teams develop shared goals and establish and maintain clear roles within
12 the team. Leaders foster collaborative environments by being seen to value other health care
13 professionals in addition to physicians; fostering mutual trust within teams; supporting effective
14 communication and fair, objective measurement of processes focused on improving team function
15 and outcomes [1].

16
17 Health care institutions share accountability both to individual patients and to their communities for
18 ensuring high quality care, although other influences, including, prominently, the decisions and
19 policies of third-party payers, also may be involved. Physicians can play an important role in
20 holding institutions to this responsibility by advocating for the resources teams need to function
21 effectively and by identifying aspects of institutional culture that create barriers to effective
22 teamwork.

23 24 *Fluctuating Team Membership*

25
26 The complex nature of health care delivery means that a team's composition is not always constant
27 [26]. For example, in emergency care scenarios, teams often are abruptly created to address a
28 patient's imminent needs only to disband when the patient is transferred or discharged. An
29 institution's rotation of health care personnel can also lead to new teams continuously being
30 created, with each individual joining a new team during his or her next shift. Since trust and mutual
31 respect between team members is often built over time, a constant fluctuation of membership can
32 pose significant obstacles for effective team performance. Educating individual staff members on
33 the principles of effective teamwork enables them to bring their understandings to each newly
34 founded collaboration [1].

35 36 *Conflict within Teams*

37
38 Constructive debate is necessary for a group of individuals to come to a consensus on a
39 complicated health decision [12]. Because each team member adds a distinct perspective to the
40 team, conflict may arise when the team's decision is at odds with a member's training, experience,
41 or personal beliefs and values, or when a member's behavior hampers team performance [9, 12]. A
42 conflict resolution mechanism is needed when the degree of conflict interferes with team
43 performance [12].

44
45 Without institutional means to address conflicts, teams risk demise when members are unable to
46 voice their concerns and frustrations without fear of reprisal [12]. Conflicts that are not addressed
47 or resolved, or not handled fairly, undermine the team and degrade any trust and mutual respect
48 that has been built [25]. Because collaborative care has become essential to contemporary health
49 care, conflict must be minimized to prevent the reduction of team functionality [1]. Institutions
50 must establish standards for determining when conflict interferes with achieving the team's goals
51 and must be addressed and what procedures should be used to resolve the situation [9, 12].

RECOMMENDATION

In light of the foregoing analysis, the Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

In health care, teams that collaborate effectively can enhance the quality of care for individual patients. By being prudent stewards and delivering care efficiently, teams also have the potential to expand access to care for populations of patients. Such teams are defined by their dedication to providing patient-centered care, protecting the integrity of the patient-physician relationship, sharing mutual respect and trust, communicating effectively, sharing accountability and responsibility, and upholding common ethical values as team members.

An effective team requires the vision and direction of an effective leader. In medicine, this means having a clinical leader who will ensure that the team as a whole functions effectively and facilitates decision-making. Physicians are uniquely situated to serve as clinical leaders. By virtue of their thorough and diverse training, experience, and knowledge, physicians have a distinctive appreciation of the breadth of health issues and treatments that enables them to synthesize the diverse professional perspectives and recommendations of the team into an appropriate, coherent plan of care for the patient.

As leaders within health care teams, physicians individually should:

(a) Model ethical leadership by:

- (i) understanding the range of their own and other team members' skills and expertise and roles in the patient's care;
- (ii) clearly articulating individual responsibilities and accountability;
- (iii) encouraging insights from other members and being open to adopting them; and
- (iv) mastering broad teamwork skills.

(b) Promote core team values of honesty, discipline, creativity, humility, and curiosity and commitment to continuous improvement.

(c) Help clarify expectations to support systematic, transparent decision making.

(d) Encourage open discussion of ethical and clinical concerns and foster a team culture in which each member's opinion is heard and considered and team members share accountability for decisions and outcomes.

(e) Communicate appropriately with the patient and family and respect their unique relationship as members of the team.

As leaders within health care institutions, physicians individually and collectively should:

(f) Advocate for the resources and support health care teams need to collaborate effectively in providing high-quality care for the patients they serve, including education about the principles of effective teamwork and training to build teamwork skills.

- 1 (g) Encourage their institutions to identify and constructively address barriers to effective
- 2 collaboration.
- 3
- 4 (h) Promote the development and use of institutional policies and procedures, such as an
- 5 institutional ethics committee or similar resource, to address constructively conflicts within
- 6 teams that adversely affect patient care.
- 7
- 8 (New HOD policy)

Fiscal note: less than \$500

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REPORT 2 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (2-I-16)
Competence, Self-Assessment and Self-Awareness
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society.

The ethical responsibility of competence encompasses more than knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient's well-being.

To fulfill their ethical responsibility of competence, physicians at all stages in their professional lives should cultivate and exercise skills of self-awareness and active self-observation; take advantage of tools for self-assessment that are appropriate to their practice settings and patient populations; and be attentive to environmental and other factors that may compromise their ability to bring their best skills to the care of individual patients. As a profession, medicine should provide meaningful opportunity for physicians to hone their ability to be self-reflective.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-16

Subject: Competence, Self-Assessment and Self-Awareness

Presented by: Ronald A. Clearfield, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

The expectation that physicians will provide competent care is central to medicine. This expectation shaped the founding mission of the American Medical Association (AMA) and runs throughout the AMA *Code of Medical Ethics* [1-4]. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society [5]. The profession promises that practitioners will have the knowledge, skills, and characteristics to practice safely and that the profession as a whole and its individual members will hold themselves accountable to identify and address lapses [6-9].

Yet despite the centrality of competence to professionalism, the *Code* has not hitherto examined what the commitment to competence means as an ethical responsibility for individual physicians in day-to-day practice. This report by the Council on Ethical and Judicial Affairs explores this topic to develop ethics guidance for physicians.

DEFINING COMPETENCE

A caveat is in order. Various bodies in medicine undertake point-in-time, cross-sectional assessments of physicians' technical knowledge and skills. However, this report is not concerned with matters of technical proficiency assessed by medical schools and residency programs, specialty societies (for purposes of board certification), or hospital and other health care institutions (e.g., for privileging and credentialing). Such matters lie outside the council's purview.

The ethical responsibility of competence encompasses more than knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole. For purposes of this analysis, competence is understood as "the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and the community being served" and as "developmental, impermanent, and context dependent" [10].

Moreover, the council is keenly aware that technical proficiency evolves over time—what is expected of physicians just entering practice is not exactly the same as what is expected of mid-

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 career physicians or physicians who are changing or re-entering practice or transitioning out of
2 active practice to other roles. Each phase of a medical career, from medical school through
3 retirement, carries its own implications for what a physician should know and be able to do to
4 practice safely and to maintain effective relationships with patients and with colleagues.

5
6 The concept that informs this report differs as well from the narrower legal definition of
7 competence as the knowledge and skills an individual has to do a job. Rather, this report explores a
8 broader notion of competence that encompasses deeper aspects of wisdom, judgment and practice
9 that enable physicians to assure patients, the public, and the profession that they provide safe, high
10 quality care moment to moment over the course of a professional lifetime.

11 12 SELF-ASSESSMENT & ITS LIMITATIONS

13
14 Health care institutions and the medical profession as a whole take responsibility to regulate
15 physicians through credentialing and privileging, routinely testing knowledge (maintenance of
16 certification, requirements for continuing education, etc.) and, when needed, taking disciplinary
17 action against physicians who fail to meet expectations for competent, professional practice.
18 However, the better part of the responsibility to maintain competence rests with physicians’
19 “individual capacity, as clinicians, to self-assess [their] strengths, deficiencies, and learning needs
20 to maintain a level of competence commensurate with [their] clinical roles” [11].

21
22 Self-assessment has thus become “integral to many appraisal systems and has been espoused as an
23 important aspect of personal professional behavior by several regulatory bodies and those
24 developing learning outcomes for students” [12]. Undergraduate and graduate medical education
25 programs regularly use self-assessment along with third-party evaluations to ensure that trainees
26 are acquiring the knowledge and skills necessary for competent practice [5, 10, 13-16].

27
28 Yet how accurately physicians assess their own performance is open to question. Research to date
29 suggests that there is poor correlation between how physicians rate themselves and how others rate
30 them [5, 12, 13]. Various studies among health professionals have concluded that clinicians and
31 trainees tend to assess their peers’ performance more accurately than they do their own; several
32 have found that poor performers (e.g., those in the bottom quartile) tend to over-estimate their
33 abilities while high performers (e.g., those in the top quartile), tend to under-estimate themselves
34 [5, 12, 17].

35
36 The available findings suggest that self-assessment involves an interplay of factors that can be
37 complicated by lack of insight or of metacognitive skill, that is, ability to be self-observant in the
38 moment. Similarly, personal characteristics (e.g., gender, ethnicity, or cultural background) and the
39 impact of external factors (e.g., the purpose of self-assessment or whether it is designed to assess
40 practical skills or theoretical knowledge) can all affect self-assessment [12, 18]. The published
41 literature also indicates that interventions intended to enhance self-assessment may seek different
42 goals—improving the accuracy of self-assessors’ perception of their learning needs, promoting
43 appropriate change in learning activities, or improving clinical practice or patient outcomes [12].

44
45 Self-assessment alone is not a reliable enough tool to ensure that physicians acquire and maintain
46 the competence they need to provide safe, high quality care. Feedback from third parties is
47 essential—or as one researcher has observed, “The road to self-knowledge may run through other
48 people” [19]. However, physicians are often wary of assessment. They have indicated that while
49 they want feedback, they are not sure how to use information that is not congruent with their self-
50 appraisals [20]. Physicians can be hesitant to seek feedback for fear of looking incompetent or
51 exposing possible deficiencies or out of concern that soliciting feedback could adversely affect

1 their relationships with those whom they approach [20]. They may also question the accuracy and
2 credibility of the assessment process and the data it generates [21].
3

4 To be effective, feedback must be valued by both those being assessed and those offering
5 assessment [14]. When there is tension between the stated goals of assessment and the implicit
6 culture of the health care organization or institution, assessment programs can too readily devolve
7 into an activity undertaken primarily to satisfy administrators that rarely improves patient care [20].
8 Feedback mechanisms should be appropriate to the skills being assessed—multi-source reviews
9 (“360° reviews”), for example, are generally better suited to providing feedback on communication
10 and interpersonal skills than on technical knowledge or skills—and easy for evaluators to
11 understand and use [14]. High quality feedback will come from multiple sources; be specific and
12 focus on key elements of the ability being assessed; address behaviors rather than personality or
13 personal characteristics; and “provide both positive comments to reinforce good behavior and
14 constructive comments with action items to address deficiencies” [22].
15

16 EXPERTISE & EXPERT JUDGMENT

17

18 On this broad understanding of competence, physicians’ thought processes are as important as their
19 knowledge base or technical skills. Thus, understanding competence requires understanding
20 something of the nature of expertise and processes of expert reasoning, themselves topics of
21 ongoing exploration [23, 24, 25, 26]. Prevailing theory distinguishes “fast” from “slow” thinking;
22 that is, reflexive, intuitive processes that require minimal cognitive resources versus deliberate,
23 analytical processes that require more conscious effort [25]. Some scholars take expertise to
24 involve “fast” processes, and specifically decision making that involves automatic, nonanalytic
25 resources acquired through experience [23]. Others argue that expertise consists in using “slow,”
26 effortful, analytic processes to address problems [23]. A more integrative view argues that
27 expertise resides in being able to transition between intuitive and analytical processes as
28 circumstances require. On this account, experts use automatic resources to free up cognitive
29 capacity so that they maintain awareness of the environment (“situational awareness”) and can
30 determine when to shift to effortful processes [23].
31

32 Expert judgment is the ability “to respond effectively in the moment to the limits of [one’s]
33 automatic resources and to transition appropriately to a greater reliance on effortful processes when
34 needed” [23], a practice described as “slowing down.” Knowing when to slow down and be
35 reflective has been demonstrated to improve diagnostic accuracy and other outcomes [25]. To
36 respond to the unexpected events that often arise in a clinical situation, the physician must
37 “vigilantly monitor relevant environmental cues” and use these as signals to slow down, to
38 transition into a more effortful state [24]. This can happen, for example, when a surgeon confronts
39 an unexpected tumor or anatomical anomaly during a procedure. “Slowing down when you should”
40 serves as a critical marker for intraoperative surgical judgment [23].
41

42 INFLUENCES ON CLINICAL REASONING

43

44 Clinical reasoning is a complex endeavor. Physicians’ capabilities develop through education,
45 training, and experiences that provide tools with which to shape their clinical reasoning. Every
46 physician arrives at a diagnosis and treatment plan for an individual in ways that may align with or
47 differ from the analytical and investigative processes of their colleagues in innumerable ways.
48 When something goes wrong in the clinic, it can be difficult to discern why. Nonetheless, all
49 physicians are open to certain common pitfalls in reasoning, including relying unduly on heuristics
50 and habits of perception, and succumbing to overconfidence.

Heuristics

Physicians often use various heuristics—i.e., cognitive short cuts—to aid decision making. While heuristics can be useful tools to help physicians identify and categorize relevant information, these time-saving devices can also derail decision making. For example, a physician may mistakenly assume that “something that seems similar to other things in a certain category is itself a member of that category” (the representative heuristic) [27], and fail to diagnose a serious health problem. Imagine a case in which a patient presents with symptoms of a possible heart attack or a stroke that the physician proceeds to discount as stress or intoxication once the physician learns that the patient is going through a divorce or smells alcohol on the patient’s breath. Or a physician may miscalculate the likelihood of a disease or injury occurring by placing too much weight “on examples of things that come to mind easily, ... because they are easily remembered or recently encountered” (the availability heuristic) [27]. For example, amidst heavy media coverage of an outbreak of highly infectious disease thousands of miles away in a remote part of the world, a physician seeing a patient with symptoms of what is actually a more commonplace illness may misdiagnose (or over diagnose) the exotic condition because that is what is top of mind.

Clinical reasoning can be derailed by other common cognitive missteps as well. These can include misperceiving a coincidental relationship as a causal relationship (illusory bias), or the tendency to remember information transferred at the beginning (or end) of an exchange but not information transferred in the middle (primary or recency bias) [25, 27, 29].

Habits of Perception

Like every other person, physicians can also find themselves prone to explicit (conscious) or implicit (unconscious) habits of perception or biases. Physicians may allow unquestioned assumptions based on a patient’s race or ethnicity, gender, socioeconomic status, or health behavior, among other features, to shape how they perceive the patient and how they engage with, evaluate and treat the individual. Basing one’s interactions with a patient on pre-existing expectations or stereotypes demeans the patient, undermines the patient’s relationship with the physician and the health care system, and can result in significant health disparities across entire communities [30]. This is of particular concern for patients who are members of minority and historically disadvantaged populations [30]. Physicians may fall victim to the tendency to seek out information that confirms established expectations or dismiss contradicting information that does not fit into predetermined beliefs (confirmatory bias) [27]. These often inadvertent thought processes can result in a physician pursuing an incorrect line of questioning or testing that then leads to a misdiagnosis or the wrong treatment.

No matter how well a patient may seem to fit a stereotype, it is imperative that the physician look beyond categories and assumptions to investigate openly the health issues experienced by the patient. Although all human beings exhibit both conscious and unconscious habits of perception, physicians must remain vigilant in not allowing preconceived or unexamined assumptions to influence their medical practice.

Overconfidence

Finally, another obstacle to strong clinical reasoning that physicians may encounter is overconfidence. Despite their extensive training, physicians, like all people, are poor at identifying the gaps in their knowledge [27, 29]. Physicians may consider their skills to be excellent, when, in fact, their peers have identified areas for improvement [29]. Overconfidence in one’s abilities can

lead to suboptimal care for a patient, be it through mismanaging resources, failing to consider the advice of others, or not acknowledging one's limits [27, 29].

To avoid falling into such traps, physicians must recognize that many factors can and will influence their clinical decisions [27]. They need to be aware of the information they do and do not have and they need to acknowledge that many factors can and will influence their judgment. They should keep in mind the likelihood of diseases and conditions and take the time to distinguish information that is truly essential to sound clinical judgment from the wealth of possibly relevant information available about a patient. They should consider reasons their decisions may be wrong and seek alternatives, as well as seek to disprove rather than confirm their hypotheses [27]. And they should be sensitive to the ways in which assumptions may color their reasoning and not allow expectations to govern their interactions with patients.

Shortcomings can be an opportunity for growth in medicine, as in any other field. By becoming aware of areas in which their skills are not at their strongest and seeking additional education or consulting with colleagues, physicians can enhance their practice and best serve their patients.

FROM SELF-ASSESSMENT TO SELF-AWARENESS

Recognizing that many factors affect clinical reasoning and that self-assessment as traditionally conceived has significant shortcomings, several scholars have argued that a different understanding of self-assessment is needed, along with a different conceptualization of its role in a self-regulating profession [31]. Self-assessment, it is suggested, is a mechanism for identifying both one's weaknesses and one's strengths. One should be aware of one's weaknesses in order to self-limit practice in areas in which one has limited competence, to help set appropriate learning goals, and to identify areas that "should be accepted as forever outside one's scope of competent practice" [31]. Knowing one's strengths, meanwhile, allows a physician both to "act with appropriate confidence" and to "set appropriately challenging learning goals" that push the boundaries of the physician's knowledge [31].

If self-assessment is to fulfill these functions, physicians need to reflect on past performance to evaluate not only their general abilities but also specific completed performances. At the same time, they must use self-assessment predictively to assess how likely they are to be able to manage new challenges and new situations. More important, physicians should understand self-assessment as an ongoing process of monitoring tasks during performance [32]. The ability to monitor oneself in the moment is critical to physicians' ethical responsibility to practice safely, at the top of their expertise but not beyond it.

Expert practitioners rely on pattern recognition and other automatic resources to be able to think and act intuitively. As noted above, an important component of expert judgment is transitioning effectively from automatic modes of thinking to more effortful modes as the situation requires. Self-awareness, in the form of attentive self-observation (metacognitive monitoring), alerts physicians when they need to direct additional cognitive resources to the immediate task. For example, among surgeons, knowing when to "slow down" during a procedure is critical to competent professional performance, whether that means actually stopping the procedure, withdrawing attention from the surrounding environment to focus more intently on the task at hand, or removing distractions from the operating environment [24].

Physicians should also be sensitive to the ways that interruptions and distractions, which are common in health care settings, can affect competence in the moment [33, 34], by disrupting memory processes, particularly the "prospective memory" —i.e., "a memory performance in which

a person must recall an intention or plan in the future without an agent telling them to do so”—important for resuming interrupted tasks [34, 35]. Systems-level interventions have been shown to help reduce the number or type of interruptions and distractions and mitigate their impact on medical errors [36].

A key aspect of competence is demonstrating situation-specific awareness in the moment of being at the boundaries of one’s knowledge and responding accordingly [32]. Slowing down, looking things up, consulting a colleague, or deferring from taking on a case can all be appropriate responses when physicians’ self-awareness tells them they are at the limits of their abilities. The capacity for ongoing, attentive self-observation, for “mindful” practice, is an essential marker of competence broadly understood:

Safe practice in a health professional’s day-to-day performance requires an awareness of when one lacks the specific knowledge or skill to make a good decision regarding a particular patient ... This decision making in context is importantly different from being able to accurately rate one’s own strengths and weaknesses in an acontextual manner.... Safe practice requires that self-assessment be conceptualized as repeatedly enacted, situationally relevant assessments of self-efficacy and ongoing ‘reflection-in-practice,’ addressing emergent problems and continuously monitoring one’s ability to effectively solve the current problem [31].

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills [31]. Self-aware physicians are also alert to how external stressors—the death of a loved one or other family crisis, or the reorganization of their practice, for example—may be affecting their ability to provide care appropriately at a given time. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient’s well-being.

MAINTAINING COMPETENCE ACROSS A PRACTICE LIFETIME

For physicians, the ideal is not simply to be “good” practitioners, but to excel throughout their professional careers. This ideal holds not just over the course of a sustained clinical practice, but equally when physicians re-enter practice after a hiatus, transition from active patient care to roles as educators or administrators, or take on other functions in health care. Self-assessment and self-awareness are central to achieving that goal.

A variety of strategies are available to physicians to support effective self-assessment and help physicians cultivate the kind of self-awareness that enables them to “know when to slow down” in day-to-day practice. One such strategy might be to create a portfolio of materials for reflection in the form of written descriptions, audio or video recording, or photos of encounters with patients that can provide evidence of learning, achievement and accomplishment [16] or of opportunities to improve practice. A strength of portfolios as a tool for assessing one’s practice is that, unlike standardized examinations, they are drawn from one’s actual work and require self-reflection [15].

As noted above, to be effective, self-assessment must be joined with input from others. Well-designed multi-source feedback can be useful in this regard, particularly for providing information about interpersonal behaviors [14]. Research has shown that a four-domain tool with a simple response that elicits feedback about how well one maintains trust and professional relationships with patients, one’s communication and teamwork skills, and accessibility offers a valid, reliable tool that can have practical value in helping to correct poor behavior and, just as important,

consolidate good behavior [14]. Informal arrangements among colleagues to provide thoughtful feedback will not have the rigor of a validated tool but can accomplish similar ends.

Reflective practice, that is, the habit of using critical reflection to learn from experience, is essential to developing and maintaining competence across a physician's practice lifetime [37]. It enables physicians to "integrate personal beliefs, attitudes, and values in the context of professional culture," and to bridge new and existing knowledge. Studies suggest that reflective thinking can be assessed, and that it can be developed, but also that the habit can be lost over time with increasing years in practice [37].

"Mindful practice," that is, being fully present in everyday experience and aware of one's own mental processes (including those that cloud decision making) [38], sustains the attitudes and skills that are central to self-awareness. Medical training, with its fatigue, dogmatism, and emphasis on behavior over consciousness, erects barriers to mindful practice, while an individual's unexamined negative emotions, failure of imagination, and literal-mindedness can do likewise. Mindfulness can be self-taught, but for most it is most effectively learned in relationship with a mentor or guide. Nonetheless, despite challenges, there are myriad ways physicians can cultivate mindfulness. Meditation, which may come first to mind, is one, but so is keeping a journal, reviewing videos of encounters with patients, or seeking insight from critical incident reports [38].

"Exemplary physicians," one scholar notes, "seem to have a capacity for self-critical reflection that pervades all aspects of practice, including being present with the patient, solving problems, eliciting and transmitting information, making evidence-based decisions, performing technical skills, and defining their own values" [38].

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

The profession of medicine promises that throughout their careers practitioners will have the knowledge, skills, and characteristics to practice safely and that the profession as a whole and its individual members will hold themselves accountable to identify and address lapses. Medical schools, residency and fellowship programs, specialty societies, and other health care institutions regularly assess physicians' technical knowledge and skills.

However, the ethical responsibility of competence encompasses more than medical knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

To fulfill the ethical responsibility of competence, individual physicians and physicians in training should:

- (a) Routinely exercise skills of self-awareness and active self-observation;
- (b) Recognize that different points of transition in professional life can make different demands on competence;

- 1 (c) Take advantage of tools for self-assessment appropriate to their practice settings and
- 2 patient populations;
- 3
- 4 (d) Regularly seek feedback from peers and others;
- 5
- 6 (e) Be attentive to environmental and other factors that may compromise their ability to bring
- 7 their best skills to the care of individual patients, immediately or over the longer term.
- 8
- 9 Medicine as a profession should continue to refine mechanisms to meaningfully assess
- 10 physician competence, including:
- 11
- 12 (f) Developing appropriate ways to assess knowledge and skills across the professional
- 13 lifecycle;
- 14
- 15 (g) Providing meaningful opportunity for physicians and physicians in training to hone their
- 16 ability to be self-reflective and attentive in the moment;
- 17
- 18 (h) Supporting efforts to develop more and better techniques to address gaps in knowledge,
- 19 skills, and self-awareness.
- 20

21 (New HOD Policy)

Fiscal Note: Less than \$500.

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 001
(I-16)

Introduced by: Medical Student Section

Subject: Support for the Decriminalization and Treatment of Suicide Attempts
Amongst Military Personnel

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

Whereas, The Department of Defense Suicide Event Report states that in 2014, 269 active duty service members took their own lives, and there were 1,126 suicide attempts;¹ and

Whereas, Article 134.103a of the Uniform Code of Military Justice (UCMJ) states that active duty service members can be criminally charged for attempting suicide, regardless of supposed intention to avoid duty;² and

Whereas, Punitive measures upon conviction after a suicide attempt include dishonorable discharge, forfeiture of all pay and allowances, and confinement for up to 5 years;¹ and

Whereas, The policy for criminally charging “self injury without intent to avoid service” was established in the Manuals of Court Martials of the U.S. Army in 1949 and added to the UCMJ during its initiation in 1951, at a time when mental illness was not well understood;¹ and

Whereas, Punishing suicide attempt survivors goes against current recommendations and Department of Defense progress to destigmatize mental illness and improve self-reported care;^{3,4} and

Whereas, Existing AMA policy calls for awareness of suicide as a mental health issue (D-345.994, H-60.937), and states that the AMA will use its influence to expedite quality medical care, including mental health care, for all military personnel (D-510.996); therefore be it

RESOLVED, That our American Medical Association support efforts to decriminalize suicide attempts in the military (New HOD Policy); and be it further

RESOLVED, That our AMA support efforts to provide treatment for survivors of suicide attempt in lieu of punishment in the military. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 08/29/16

¹ Pruitt LD, Smolenski DJ, Reger MA, Bush NE, Skopp NA, Campise RL. Department of Defense Suicide Event Report (DoDSER): Calendar Year 2014 Annual Report: iv-v.

² UCMJ – United States Code of Military Justice. UCMJ United States Code of Military Justice RSS. Available at: https://www.loc.gov/rr/frd/Military_Law/pdf/MCM-2012.pdf. Accessed March 28, 2016.

³ Acosta, Joie, *et al.* Assessing the Department of Defense's Approach to Reducing Mental Health Stigma. Santa Monica, CA: RAND Corporation, 2016. Available at: http://www.rand.org/pubs/research_briefs/RB9881.html. Last Accessed: August 15, 2016.

⁴ Ramchand, Rajeev, *et al.* Suicide Postvention in the Department of Defense: Evidence, Policies and Procedures, and Perspectives of Loss Survivors. Santa Monica, CA: RAND Corporation, 2015. Available at: http://www.rand.org/pubs/research_reports/RR586.html. Last Accessed: August 15, 2016.

RELEVANT AMA POLICY

Increasing Detection of Mental Illness and Encouraging Education D-345.994

1. Our AMA will work with: (A) mental health organizations, state, specialty, and local medical societies and public health groups to encourage patients to discuss mental health concerns with their physicians; and (B) the Department of Education and state education boards and encourage them to adopt basic mental health education designed specifically for preschool through high school students, as well as for their parents, caregivers and teachers.

2. Our AMA will encourage the National Institute of Mental Health and local health departments to examine national and regional variations in psychiatric illnesses among immigrant, minority, and refugee populations in order to increase access to care and appropriate treatment.

Citation: (Res. 412, A-06; Appended: Res. 907, I-12)

Teen and Young Adult Suicide in the United States H-60.937

Our AMA recognizes teen and young-adult suicide as a serious health concern in the US.

Citation: (Res. 424, A-05; Reaffirmed: CSAPH Rep. 1, A-15)

Military Care in the Public and Private Sector D-510.996

Our AMA will use its influence to expedite quality medical care, including mental health care, for all military personnel and their families by developing a national initiative and strategies to utilize civilian health care resources to complement the federal health care systems.

Citation: (Res. 444, A-07)

Support of Human Rights and Freedom H-65.965

Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States.

Citation: (CCB/CLRPD Rep. 3, A-14)

Teen and Young Adult Suicide in the United States H-60.937

Our AMA recognizes teen and young-adult suicide as a serious health concern in the US.

Citation: (Res. 424, A-05; Reaffirmed: CSAPH Rep. 1, A-15)

Supporting Awareness of Stress Disorders in Military Members and Their Families H-510.988

Our AMA supports efforts to educate physicians and supports treatment and diagnosis of stress disorders in military members, veterans and affected families and continue to focus attention and raise awareness of this condition in partnership with the Department of Defense and the Department of Veterans Affairs.

Citation: (Sub. Res. 401, A-10)

Health Care for Veterans and Their Families D-510.994

Our AMA will: (1) work with all appropriate medical societies, the AMA National Advisory Council on Violence and Abuse, and government entities to assist with the implementation of all recommendations put forth by the President's Commission on Care for America's Wounded Warriors; and (2) advocate for improved access to medical care in the civilian sector for returning military personnel when their needs are not being met by resources locally available through the Department of Defense or the Veterans Administration.

Citation: (BOT Rep. 6, A-08; Reaffirmed: Sub. Res. 709, A-15)

Military Care in the Public and Private Sector D-510.996

Our AMA will use its influence to expedite quality medical care, including mental health care, for all military personnel and their families by developing a national initiative and strategies to utilize civilian health care resources to complement the federal health care systems.

Citation: (Res. 444, A-07)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 002
(I-16)

Introduced by: Medical Student Section

Subject: Living Organ Donation at the Time of Imminent Death

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

Whereas, Patients who receive organs procured from living donors have better outcomes than those who receive organs from deceased donors;^{1,2,3} and

Whereas, The kidney is the most commonly transplanted organ from a living donor; in rare cases, a segment of organs such as lung, intestine, or pancreas can be transplanted from a living donor;⁴ and

Whereas, The ethics of organ transplantation have been premised on “the dead donor rule” (DDR), which states that vital organs should be taken only from persons who are dead;⁵ and

Whereas, It is unclear why certain living patients, such as those who are near death but on life support, should not be allowed to donate their organs, if doing so would benefit others and be consistent with their own interests;⁵ and

Whereas, AMA Ethical Opinion 6.1.1 states, “Donation of nonvital organs and tissue from living donors can increase the supply of organs available for transplantation, to the benefit of patients with end-stage organ failure and enabling individuals to donate nonvital organs is in keeping with the goals of treating illness and relieving suffering so long as the benefits to both donor and recipient outweigh the risks to both;” therefore be it

RESOLVED, That our American Medical Association study the implications of the removal of barriers to living organ donation at the time of imminent death. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

¹ Mezrich J, Scalea J. As They Lay Dying. The Atlantic, 2015.

² Meier-Kriesche HU, Kaplan B. Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: a paired donor kidney analysis. Transplantation. 2002;74: 1377-1381.

³ Davis CL, Delmonico FL. Living-donor kidney transplantation: a review of the current practices for the live donor. J Am Soc Nephrol. 2005;16: 2098-2110.

⁴ The United Network for Organ Sharing, Types of Living Donor Transplants. Available at: <https://www.unos.org/donation/living-donation/>. Last Accessed: August 11, 2016.

⁵ Robert D. Truog, M.D., Franklin G. Miller, Ph.D., and Scott D. Halpern, M.D., Ph.D., The Dead Donor Rule and the Future of Organ Donation, N Engl J Med 2013; 369:1287-1289. Available at: <http://www.nejm.org/doi/full/10.1056/NEJMp1307220#t=article>. Last Accessed: August 11, 2016.

RELEVANT AMA POLICY

Methods to Increase the US Organ Donor Pool H-370.959 - In order to encourage increased levels of organ donation in the United States, our American Medical Association: (1) supports studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation; (2) urges development of effective methods for meaningful exchange of information to educate the public and support well-informed consent about donating organs; and (3) encourages continued study of ways to enhance the allocation of donated organs and tissues. BOT Rep. 13, A-15

UNOS Kidney Paired Donation Program H-370.960 - Our AMA: (1) encourages the continued expansion of the United Network for Organ Sharing's (UNOS) Kidney Paired Donation program which provides a national registry of living donors, carries out ongoing data collection on key issues of concern in transplantation from living donors, and through its operational guidelines provides consistent, national standards for the transplant community; and (2) encourages voluntary coordination among private donor registries and UNOS to enhance the availability of organs for transplantation. BOT Action in response to referred for decision Res. 2, A-13

Removing Financial Barriers to Living Organ Donation H-370.965 - Our AMA supports federal and state laws that remove financial barriers to living organ donation, such as: (1) provisions for expenses involved in the donation incurred by the organ donor, (2) providing access to health care coverage for any medical expense related to the donation, (3) prohibiting employment discrimination on the basis of living donor status, and (4) prohibiting the use of living donor status as the sole basis for denying health and life insurance coverage. BOT Rep. 15, A-12

Organ Donation D-370.985 - Our AMA will study potential models for increasing the United States organ donor pool. Res. 1, A-14 Reaffirmed in lieu of Res. 5, I-14

Surrogate Consent for Living Organ Donation H-370.964 - Our AMA opposes the practice of surrogate consent for living organ donation from patients in a persistent vegetative state. Res. 7, A-12

Ethical Procurement of Organs for Transplantation H-370.967 - Our AMA will continue to monitor ethical issues related to organ transplantation and develop additional policy as necessary. BOT Rep. 13, A-08

Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients H-370.982 - Our AMA has adopted the following guidelines as policy: (1) Decisions regarding the allocation of scarce medical resources among patients should consider only ethically appropriate criteria relating to medical need. (a) These criteria include likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in some cases, the amount of resources required for successful treatment. In general, only very substantial differences among patients are ethically relevant; the greater the disparities, the more justified the use of these criteria becomes. In making quality of life judgments, patients should first be prioritized so that death or extremely poor outcomes are avoided; then, patients should be prioritized according to change in quality of life, but only when there are very substantial differences among patients. (b) Research should be pursued to increase knowledge of outcomes and thereby improve the accuracy of these criteria. (c) Non-medical criteria, such as ability to pay, social worth, perceived obstacles to treatment, patient contribution to illness, or past use of resources should not be considered. (2) Allocation decisions should respect the individuality of patients and the particulars of individual cases as much as possible. (a) All

candidates for treatment must be fully considered according to ethically appropriate criteria relating to medical need, as defined in Guideline 1. (b) When very substantial differences do not exist among potential recipients of treatment on the basis of these criteria, a "first-come-first-served" approach or some other equal opportunity mechanism should be employed to make final allocation decisions. (c) Though there are several ethically acceptable strategies for implementing these criteria, no single strategy is ethically mandated. Acceptable approaches include a three-tiered system, a minimal threshold approach, and a weighted formula. (3) Decisionmaking mechanisms should be objective, flexible, and consistent to ensure that all patients are treated equally. The nature of the physician-patient relationship entails that physicians of patients competing for a scarce resource must remain advocates for their patients, and therefore should not make the actual allocation decisions. (4) Patients must be informed by their physicians of allocation criteria and procedures, as well as their chances of receiving access to scarce resources. This information should be in addition to all the customary information regarding the risks, benefits, and alternatives to any medical procedure. Patients denied access to resources have the right to be informed of the reasoning behind the decision. (5) The allocation procedures of institutions controlling scarce resources should be disclosed to the public as well as subject to regular peer review from the medical profession. (6) Physicians should continue to look for innovative ways to increase the availability of and access to scarce medical resources so that, as much as possible, beneficial treatments can be provided to all who need them. (7) Physicians should accept their responsibility to promote awareness of the importance of an increase in the organ donor pool using all available means. CEJA Rep. K, A-93 Reaffirmed: CSA Rep. 12, I-99 Reaffirmed: CSA Rep. 6, A-00 Appended: Res. 512, A-02 Reaffirmed: CEJA Rep. 3, A-12

Ethical Issues in the Procurement of Organs Following Cardiac Death H-370.975 - The Pittsburgh Protocol: The following guidelines have been adopted: The Pittsburgh protocol, in which organs are removed for transplantation from patients who have had life-sustaining treatment withdrawn, may be ethically acceptable and should be pursued as a pilot project. The pilot project should (1) determine the protocol's acceptability to the public, and (2) identify the number and usability of organs that may be procured through this approach. The protocol currently has provisions for limiting conflicts of interest and ensuring voluntary consent. It is critical that the health care team's conflict of interest in caring for potential donors at the end of life be minimized, as the protocol currently provides, through maintaining the separation of providers caring for the patient at the end of life and providers responsible for organ transplantation. In addition to the provisions currently contained in the protocol, the following additional safeguards are recommended: (a) To protect against undue conflicts of interest, the protocol should explicitly warn members of the health care team to be sensitive to the possibility that organ donation decisions may influence life-sustaining treatment decisions when the decisions are made by surrogates. Further, if there is some reason to suspect undue influence, then the health care team members should be required, not merely encouraged, to obtain a full ethics consultation. (b) The recipients of organs procured under the Pittsburgh protocol should be informed of the source of the organs as well as any potential defects in the quality of the organs, so that they may decide with their physicians whether to accept the organs or wait for more suitable ones. (c) Clear clinical criteria should be developed to ensure that only appropriate candidates, whose organs are reasonably likely to be suitable for transplantation, are considered eligible to donate organs under the Pittsburgh protocol. CEJA Rep. 4 - I-94 Reaffirmed: CSA Rep. 4, I-02 Reaffirmed: CEJA Rep. 3, A-12

Transplantable Organs as a National Resource H-370.990 - Our AMA: (1) supports the United Network of Organ Sharing (UNOS) policy calling for regional allocation of livers to status 1 (most urgent medical need) patients as an effort to more equitably distribute a scarce resource; (2) opposes any legislation, regulations, protocols, or policies directing or allowing

governmental agencies to favor residents of a particular geo-political jurisdiction as recipients of transplantable organs or tissues; (3) reaffirms its position that organs and tissues retrieved for transplantation should be treated as a national, rather than a regional, resource; and (4) supports the findings and recommendations of the Institute of Medicine Committee on Organ Procurement and Transplantation Policy. Res. 94, I-87 Reaffirmed: Sunset Report, I-97 Appended and Reaffirmed CSA Rep. 12, I-99 Reaffirmed: CSA Rep. 4, I-02 Reaffirmed: CSAPH Rep. 1, A-12

Organ Donor Recruitment H-370.995 - Our AMA supports development of "state of the art" educational materials for the medical community and the public at large, demonstrating at least the following: (1) the need for organ donors;(2) the success rate for organ transplantation;(3) the medico-legal aspects of organ transplantation; (4) the integration of organ recruitment, preservation and transplantation; (5) cost/reimbursement mechanisms for organ transplantation; and(6) the ethical considerations of organ donor recruitment. Res. 32, A-82 Reaffirmed: CLRPD Rep. A, I-92 Reaffirmed: CSA Rep. 6, A-00 Reaffirmed: CSA Rep. 4, I-02 Reaffirmed: CSAPH Rep. 1, A-12

Organ Donor Recruitment H-370.996 - Our AMA (1) continues to urge Americans to sign donor cards; (2) supports continued efforts to teach physicians through continuing medical education courses, and the lay public through health education programs, about transplantation issues in general and the importance of organ donation in particular; (3) encourages state governments to attempt pilot studies on promotional efforts that stimulate each adult to respond "yes" or "no" to the option of signing a donor card.; and (4) in collaboration with all other interested parties, support the exploration of methods to greatly increase organ donation, such as the "presumed consent" modality of organ donation. CSA Rep. D, A-81 Reaffirmed: CLRPD Rep. F, I-91 Appended: Res. 509, I-98 Reaffirmed: CSA Rep. 6, A-00 Reaffirmed: CSA Rep. 4, I-02 Reaffirmed: CSAPH Rep. 1, A-12

Equal Access to Organ Transplantation for Medicaid Beneficiaries H-370.962 - Our AMA supports federal funding of organ transplants for Medicaid patients. BOT Rep. 15, A-13

Tissue and Organ Donation H-370.983 - Our AMA will assist the United Network for Organ Sharing in the implementation of their recommendations through broad-based physician and patient education. Res. 533, A-92 Reaffirmed: CSA Rep. 12, I-99 Reaffirmed: CSA Rep. 6, A-00 Reaffirmed: CSA Rep. 4, I-02 Reaffirmed: CSAPH Rep. 1, A-12

Donor Tissues and Organs for Transplantation H-370.986 - The AMA strongly urges physicians or their designees to routinely contact their hospital's designated tissue or organ procurement agency (as appropriate), at or near the time of each patient's death, to determine the feasibility of tissue and/or organ donation. Res. 103, I-90 Reaffirmed: CSA Rep. 6, A-00 Reaffirmed: CSA Rep. 4, I-02 Reaffirmed: CSAPH Rep. 1, A-12

The Physician's Role in Organ Donation D-370.997 - Our AMA will continue to promote organ donation awareness. CSA Rep. 6, A-00 Modified: CSAPH Rep. 1, A-10

Removing Disincentives and Studying the Use of Incentives to Increase the National Organ Donor Pool H-370.958 - 1. Our AMA supports the efforts of the National Living Donor Assistance Center, Health Resources Services Administration, American Society of Transplantation, American Society of Transplant Surgeons, and other relevant organizations in their efforts to eliminate disincentives serving as barriers to living and deceased organ donation. 2. Our AMA supports well-designed studies investigating the use of incentives, including valuable considerations, to increase living and deceased organ donation rates.

3. Our AMA will seek legislation necessary to remove legal barriers to research investigating the use of incentives, including valuable considerations, to increase rates of living and deceased organ donation. Res. 7, I-15

6.1.1 Transplantation of Organs from Living Donors

Donation of nonvital organs and tissue from living donors can increase the supply of organs available for transplantation, to the benefit of patients with end-stage organ failure. Enabling individuals to donate nonvital organs is in keeping with the goals of treating illness and relieving suffering so long as the benefits to both donor and recipient outweigh the risks to both.

Living donors expose themselves to harm to benefit others; novel variants of living organ donation call for special safeguards for both donors and recipients.

Physicians who participate in donation of nonvital organs and tissues by a living individual should:

- (a) Ensure that the prospective donor is assigned an advocacy team, including a physician, dedicated to protecting the donor's well-being.
- (b) Avoid conflicts of interest by ensuring that the health care team treating the prospective donor is as independent as possible from the health care team treating the prospective transplant recipient.
- (c) Carefully evaluate prospective donors to identify serious risks to the individual's life or health, including psychosocial factors that would disqualify the individual from donating; address the individual's specific needs; and explore the individual's motivations to donate.
- (d) Secure agreement from all parties to the prospective donation in advance so that, should the donor withdraw, his or her reasons for doing so will be kept confidential.
- (e) Determine that the prospective living donor has decision-making capacity and adequately understands the implications of donating a nonvital organ, and that the decision to donate is voluntary.
- (f) In general, decline proposed living organ donations from unemancipated minors or legally incompetent adults, who are not able to understand the implications of a living donation or give voluntary consent to donation.
- (g) In exceptional circumstances, enable donation of a nonvital organ or tissue from a minor who has substantial decision-making capacity when:
 - (i) the minor agrees to the donation;
 - (ii) the minor's legal guardians consent to the donation;
 - (iii) the intended recipient is someone to whom the minor has an emotional connection.
- (h) Seek advice from another adult trusted by the prospective minor donor when circumstances warrant, or from an independent body such as an ethics committee, pastoral service, or other institutional resource.
- (i) Inform the prospective donor:
 - (i) about the donation procedure and possible risks and complications for the donor;
 - (ii) about the possible risks and complications for the transplant recipient;
 - (iii) about the nature of the commitment the donor is making and the implications for other parties;
 - (iv) that the prospective donor may withdraw at any time before undergoing the intervention to remove the organ or collect tissue, whether the context is paired, domino, or chain donation; and
 - (v) that if the donor withdraws, the health care team will report simply that the individual was not a suitable candidate for donation.
- (j) Obtain the prospective donor's separate consent for donation and for the specific intervention(s) to remove the organ or collect tissue.

- (k) Ensure that living donors do not receive payment of any kind for any of their solid organs. Donors should be compensated fairly for the expenses of travel, lodging, meals, lost wages, and medical care associated with the donation only.
- (l) Permit living donors to designate a recipient, whether related to the donor or not.
- (m) Decline to facilitate a living donation to a known recipient if the transplantation cannot reasonably be expected to yield the intended clinical benefit or achieve agreed on goals for the intended recipient.
- (n) Permit living donors to designate a stranger as the intended recipient if doing so produces a net gain in the organ pool without unreasonably disadvantaging others on the waiting list. Variations on donation to a stranger include:
 - (i) prospective donors who respond to public solicitations for organs or who wish to participate in a paired donation ("organ swap," as when donor-recipient pairs Y and Z with incompatible blood types are recombined to make compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y);
 - (ii) domino paired donation;
 - (iii) nonsimultaneous extended altruistic donation ("chain donation").
- (o) When the living donor does not designate a recipient, allocate organs according to the algorithm that governs the distribution of deceased donor organs.
- (p) Protect the privacy and confidentiality of donors and recipients, which may be difficult in novel donation arrangements that involve many patients and in which donation-transplant cycles may be extended over time (as in domino or chain donation).
- (q) Monitor prospective donors and recipients in proposed nontraditional donation arrangements for signs of psychological distress during screening and after the transplant is complete.
- (r) Support the development and maintenance of a national database of living donor outcomes to support better understanding of associated harms and benefits and enhance the safety of living donation.

AMA Principles of Medical Ethics: I, V, VII, VIII

6.1.3 Studying Financial Incentives for Cadaveric Organ Donation

Physicians' ethical obligations to contribute to the health of the public and to support access to medical care extend to participating in efforts to increase the supply of organs for transplantation. However, offering financial incentives for donation raises ethical concerns about potential coercion, the voluntariness of decisions to donate, and possible adverse consequences, including reducing the rate of altruistic organ donation and unduly encouraging perception of the human body as a source of profit.

These concerns merit further study to determine whether, overall, the benefits of financial incentives for organ donation outweigh their potential harms. It would be appropriate to carry out pilot studies among limited populations to investigate the effects of such financial incentives for the purpose of examining and possibly revising current policies in the light of scientific evidence. Physicians who develop or participate in pilot studies of financial incentives to increase donation of cadaveric organs should ensure that the study:

- (a) Is strictly limited to circumstances of voluntary cadaveric donation with an explicit prohibition of the selling of organs.
- (b) Is scientifically well designed and clearly defines measurable outcomes and time frames in a written protocol.
- (c) Has been developed in consultation with the population among whom it is to be carried out.

- (d) Has been reviewed and approved by an appropriate oversight body, such as an institutional review board, and is carried out in keeping with guidelines for ethical research.
- (e) Offers incentives of only modest value and at the lowest level that can reasonably be expected to increase organ donation.

AMA Principles of Medical Ethics: I, III, V, VII, VIII, IX

6.1.4 Presumed Consent & Mandated Choice for Organs from Deceased Donors

Organ transplantation offers hope for patients suffering end-stage organ failure. However, the supply of organs for transplantation is inadequate to meet the clinical need. Proposals to increase donation have included studying possible financial incentives for donation and changing the approach to consent for cadaveric donation through “presumed consent” and “mandated choice.”

Both presumed consent and mandated choice models contrast with the prevailing traditional model of voluntary consent to donation, in which prospective donors indicate their preferences, but the models raise distinct ethical concerns. Under presumed consent, deceased individuals are presumed to be organ donors unless they have indicated their refusal to donate. Donations under presumed consent would be ethically appropriate only if it could be determined that individuals were aware of the presumption that they were willing to donate organs and if effective and easily accessible mechanisms for documenting and honoring refusals to donate had been established. Physicians could proceed with organ procurement based on presumed consent only after verifying that there was no documented prior refusal and that the family was not aware of any objection to donation by the deceased.

Under mandated choice, individuals are required to express their preferences regarding donation at the time they execute a state-regulated task. Donations under mandated choice would be ethically appropriate only if an individual’s choice was made on the basis of a meaningful exchange of information about organ donation in keeping with the principles of informed consent. Physicians could proceed with organ procurement based on mandated choice only after verifying that the individual’s consent to donate was documented.

These models merit further study to determine whether either or both can be implemented in a way that meets fundamental ethical criteria for informed consent and provides clear evidence that their benefits outweigh ethical concerns.

Physicians who propose to develop or participate in pilot studies of presumed consent or mandated choice should ensure that the study adheres to the following guidelines:

- (a) Is scientifically well designed and defines clear, measurable outcomes in a written protocol.
- (b) Has been developed in consultation with the population among whom it is to be carried out.
- (c) Has been reviewed and approved by an appropriate oversight body and is carried out in keeping with guidelines for ethical research.

Unless there are data that suggest a positive effect on donation, neither presumed consent nor mandated choice for cadaveric organ donation should be widely implemented.

AMA Principles of Medical Ethics: I, III, V

6.2.1 Guidelines for Organ Transplantation from Deceased Donors

Transplantation offers hope to patients with organ failure. As in all patient-physician relationships, the physician’s primary concern must be the well-being of the patient. However, organ transplantation is also unique in that it involves two patients, donor and recipient, both of whose interests must be protected. Concern for the patient should always take precedence over advancing scientific knowledge.

Physicians who participate in transplantation of organs from deceased donors should:

- (a) Avoid actual or perceived conflicts of interest by ensuring that:
 - (i) to the greatest extent possible that the health care professionals who provide care at the end of life are not directly involved in retrieving or transplanting organs from the deceased donor. Physicians should encourage health care institutions to distinguish the roles of health care professionals who solicit or coordinate organ transplantation from those who provide care at the time of death;
 - (ii) no member of the transplant team has any role in the decision to withdraw treatment or the pronouncement of death.
- (b) Ensure that death is determined by a physician not associated with the transplant team and in accordance with accepted clinical and ethical standards.
- (c) Ensure that transplant procedures are undertaken only by physicians who have the requisite medical knowledge and expertise and are carried out in adequately equipped medical facilities.
- (d) Ensure that the prospective recipient (or the recipient's authorized surrogate if the individual lacks decision-making capacity) is fully informed about the procedure and has given voluntary consent in keeping with ethical guidelines.
- (e) Except in situations of directed donation, ensure that organs for transplantation are allocated to recipients on the basis of ethically sound criteria, including but not limited to likelihood of benefit, urgency of need, change in quality of life, duration of benefit, and, in certain cases, amount of resources required for successful treatment.
- (f) Ensure that organs for transplantation are treated as a national, rather than a local or regional, resource.
- (g) Refrain from placing transplant candidates on the waiting lists of multiple local transplant centers, but rather place candidates on a single waiting list for each type of organ.

AMA Principles of Medical Ethics: I,III,V

6.2.2 Directed Donation of Organs for Transplantation

Efforts to increase the supply of organs available for transplant can serve the interests of individual patients and the public and are in keeping with physicians' obligations to promote the welfare of their patients and to support access to care. Although public solicitations for directed donation—that is, for donation to a specific patient—may benefit individual patients, such solicitations have the potential to adversely affect the equitable distribution of organs among patients in need, the efficacy of the transplant system, and trust in the overall system.

Donation of needed organs to specified recipients has long been permitted in organ transplantation. However, solicitation of organs from potential donors who have no pre-existing relationship with the intended recipient remains controversial. Directed donation policies that produce a net gain of organs for transplantation and do not unreasonably disadvantage other transplant candidates are ethically acceptable.

Physicians who participate in soliciting directed donation of organs for transplantation on behalf of their patients should:

- (a) Support ongoing collection of empirical data to monitor the effects of solicitation of directed donations on the availability of organs for transplantation.
- (b) Support the development of evidence-based policies for solicitation of directed donation.
- (c) Ensure that solicitations do not include potentially coercive inducements. Donors should receive no payment beyond reimbursement for travel, lodging, lost wages, and the medical care associated with donation.

(d) Ensure that prospective donors are fully evaluated for medical and psychosocial suitability by health care professionals who are not part of the transplant team, regardless of any relationship, or lack of relationship, between prospective donor and transplant candidate.

(e) Refuse to participate in any transplant that he or she believes to be ethically improper and respect the decisions of other health care professionals should they choose not to participate on ethical or moral grounds.

AMA Principles of Medical Ethics: VII, VIII, IX

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 003
(I-16)

Introduced by: Medical Student Section

Subject: Study of the Current Uses and Ethical Implications of Expanded Access Programs

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

Whereas, Expanded access refers to the use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient rather than to obtain the kind of information about the drug that is generally derived from clinical trials;¹ and

Whereas, The FDA's Expanded Access program requires that "the patient's physician determine that there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the person's disease or condition, and that the probable risk to the person from the investigational product is not greater than the probable risk from the disease or condition";¹ and

Whereas, Recent state legislation colloquially known as "Right-to-Try" laws, allows terminally ill patients access to investigational drugs that have passed phase 1 safety testing without FDA authorization;^{2,3,4} and

Whereas, "Right-to-Try" laws vary state to state, but basic requirements include that the patient with a terminal illness has considered alternative treatments that are currently available, received a prescription from their physician for an experimental, unapproved medical product, and provided written informed consent to undertake the risks inherent in utilizing the experimental treatment;⁷ and

Whereas, The FDA Expanded Access program and Right-to-Try laws have significant potential for misuse or unintended consequences including but not limited to offering patients false hope, adverse reactions to the drug, financial burdens, setbacks to clinical drug development, and unfair or biased decisions of approval for drug use;^{3,5,6} and

Whereas, A recurring argument in support of "Right-to-Try" laws is increased patient autonomy, namely that patients with serious conditions ought to be able to make their own decisions regarding their experimental treatment;⁶ therefore be it

¹ DHHS, FDA, CDER, CBER, Expanded Access to Investigational Drugs for Treatment Use – Questions and Answers, Guidance for Industry. June 2016. Available at:

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm351261.pdf>

² 'Right to try' law gives terminal patients access to drugs not approved by FDA. PBS. 2014. <http://www.pbs.org/newshour/bb/right-try-law-gives-terminal-patients-access-non-fda-approved-drugs/>. Accessed April 8, 2016.

³ Leonard K. Seeking the Right to Try. US News & World Report. 2014. <http://www.usnews.com/news/articles/2014/11/18/right-to-try-laws-allowing-patients-to-try-experimental-drugs-bypass-fda>.

⁴ Jacob JA. Questions of Safety and Fairness Raised as Right-to-Try Movement Gains Steam. JAMA. 2015;314(8):758–760. doi:10.1001/jama.2015.7691.

⁵ Right-to-Try Laws. Health Affairs. 2015. http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=135. Accessed April 10, 2016.

⁶ Hamel MB, Darrow JJ, Sarpatwari A, Avorn J, Kesselheim AS. Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs. New England Journal of Medicine. 2015;372(3):279–286. doi:10.1056/nejmhle1409465.

1 RESOLVED, That our American Medical Association study the implementation of expanded
 2 access programs, accelerated approval mechanisms, and payment reform models meant to
 3 increase access of experimental therapies (Directive to Take Action); and be it further
 4

5 RESOLVED, That our AMA study the ethics of expanded access programs, accelerated
 6 approval mechanisms, and payment reform models meant to increase access of experimental
 7 therapies. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

RELEVANT AMA POLICY

Cannabis for Medicinal Use H-95.952 - (1) Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease. (2) Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product. (3) Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support. (4) Our AMA believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions. CSA Rep. 10, I-97 Modified: CSA Rep. 6, A-01 Modified: CSAPH Rep. 3, I-09 Modified in lieu of Res. 902, I-10 Reaffirmed in lieu of Res. 523, A-11 Reaffirmed in lieu of Res. 202, I-12 Reaffirmed: CSAPH Rep. 2, I-13

Uniform Definition of Experimental Procedures and Therapies H-185.991 - The AMA supports working with the Health Insurance Association of America, the Blue Cross and Blue Shield Association, and other appropriate parties and federal agencies to develop uniform definitions for investigational or experimental therapies and procedures, so that methodologies can be established so that all who inquire may learn the status of a therapy or procedure. Res. 143, A-88 Reaffirmed: Sunset Report, I-98 Reaffirmed: CMS Rep. 4, A-08

Inclusion of Women in Clinical Trials H-525.991 - Our AMA: (1) encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; (2) supports the National

Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and (3) encourages translation of important research results into practice. Res. 183, I-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10 Modified: CSAPH Rep. 05, A-16

7.1.3 Study Design & Sampling

To be ethically justifiable, biomedical and health research that involves human subjects must uphold fundamental principles of respect for persons, beneficence, and justice. These principles apply not only to the conduct of research, but equally to the selection of research topics and study design.

Well-designed, ethically sound research aligns with the goals of medicine, addresses questions relevant to the population among whom the study will be carried out, balances the potential for benefit against the potential for harm, employs study designs that will yield scientifically valid and significant data, and generates useful knowledge. For example, research to develop biological or chemical weapons is antithetical to the goals of the medical profession, whereas research to develop defenses against such weapons can be ethically justifiable.

Physicians who engage in biomedical or health research with human participants thus have an ethical obligation to ensure that any study with which they are involved:

- (a) Is consistent with the goals and fundamental values of the medical profession.
- (b) Addresses research question(s) that will contribute meaningfully to medical knowledge and practice.
- (c) Is scientifically well designed to yield valid data to answer the research question(s), including using appropriate population and sampling controls, clear and appropriate inclusion/exclusion criteria, a statistically sound plan for data collection and analysis, appropriate controls, and when applicable, criteria for discontinuing the study (stopping rules).
- (d) Minimizes risks to participants, including risks associated with recruitment and data collection activities, without compromising scientific integrity.
- (e) Provides mechanisms to safeguard confidentiality.
- (f) Does not disproportionately recruit participants from historically disadvantaged populations or populations whose ability to provide fully voluntary consent is compromised. Participants who otherwise meet inclusion/exclusion criteria should be recruited without regard to race, ethnicity, gender, or economic status.
- (g) Recruits participants who lack the capacity to give informed consent only when the study stands to benefit that class of participants and participants with capacity would not yield valid results. In this event, assent should be sought from the participant and consent should be obtained from the prospective participant's legally authorized representative, in keeping with ethical guidelines.
- (h) Has been reviewed and approved by appropriate oversight bodies.

AMA Principles of Medical Ethics: I, II, III, V, VII

7.1.1 Physician Involvement in Research

Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients, rather than to the specific benefit of the individuals who participate as research subjects.

However, research involving human participants should be conducted in a manner that minimizes risks and avoids unnecessary suffering. Because research depends on the willingness of participants to accept risk, they must be able to make informed decisions about whether to participate or continue in a given protocol.

Physician researchers share their responsibility for the ethical conduct of research with the institution that carries out research. Institutions have an obligation to oversee the design, conduct, and dissemination of research to ensure that scientific, ethical, and legal standards are upheld. Institutional review boards (IRBs) as well as individual investigators should ensure that each participant has been appropriately informed and has given voluntary consent.

Physicians who are involved in any role in research with human participants have an ethical obligation to ensure that participants' interests are protected and to safeguard participants' welfare, safety, and comfort.

To fulfill these obligations, individually, physicians who are involved in research should:

- (a) Participate only in those studies for which they have relevant expertise.
- (b) Ensure that voluntary consent has been obtained from each participant or from the participant's legally authorized representative if the participant lacks the capacity to consent, in keeping with ethical guidelines. This requires that:
 - (i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;
 - (ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;
 - (iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.
- (c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.
- (d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.
- (e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.
- (f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research.

AMA Principles of Medical Ethics: I,II,III,V

7.3.1 Ethical Use of Placebo Controls in Research

A fundamental requirement of biomedical and health research is that it must provide scientifically valid data. In some research, this can best be achieved by comparing an intervention against a control to identify the effects of the intervention. Used appropriately, a placebo control can provide valuable data, particularly when there is no accepted therapy for the condition under study.

The existence of an accepted therapy does not necessarily preclude use of placebo controls, but because use of a placebo deprives participants in the control arm of access to accepted therapy for some period of time, it requires thoughtful ethical justification. In general, the use of a placebo control will more easily be justified as the severity and number of negative side effects of standard therapy increase.

To ensure that the interests of human participants are protected, physician-researchers and those who serve on oversight bodies should give careful attention to issues of methodological rigor, informed consent, characteristics of the medical condition under study, and safety and monitoring, in keeping with the following guidelines:

- (a) Evaluate each study protocol to determine whether a placebo control is scientifically necessary or an alternative study design using a different type of control would be sufficient for the purposes of the research. Placebo controls are ethically justifiable when no other research design will yield the requisite data.
- (b) Assess the use of placebo controls in relation to the characteristics of the condition under study in keeping with the following considerations:
 - (i) Studies that involve conditions likely to cause death or irreversible damage cannot ethically employ placebo controls if an alternative therapy would prevent or slow the progression of illness;
 - (ii) Studies that involve illnesses characterized by severe or painful symptoms require a thorough exploration of alternatives to the use of a placebo control;
 - (iii) In general, the more severe the consequences or symptoms of the illness under study, the more difficult it will be to justify the use of a placebo control when alternative therapy exists. Consequently, there will almost certainly be conditions for which placebo controls cannot ethically be justified.
- (c) Design studies to minimize the amount of time participants are on placebo without compromising the scientific integrity of the study or the value of study data.
- (d) Pay particular attention to the informed consent process when enrolling participants in research that uses a placebo control. In addition to general guidelines for informed consent in research, physician-researchers (or other health care professionals) who obtain informed consent from prospective subjects should:
 - (i) describe the differences among the research arms, emphasizing the essential intervention(s) that will or will not be performed in each;
 - (ii) be sensitive to the possible need for additional safeguards in the consent process, such as having a neutral third party obtain consent or using a consent monitor to oversee the consent process.
- (e) Ensure that interim data analysis and monitoring are in place to allow researchers to terminate a study because of either positive or negative results, thus protecting participants from remaining on placebo longer than needed to ensure the scientific integrity of the study.
- (f) Avoid using surgical placebo controls—i.e., a control arm in which participants undergo surgical procedures that have the appearance of therapeutic interventions but during which the essential therapeutic maneuver is not performed—when there is a standard treatment that is efficacious and acceptable to the patient and forgoing standard treatment would result in significant injury. In these situations, physician-researchers must offer standard treatment as part of the study design. Use of surgical placebo controls may be justified when:
 - (i) an existing, accepted surgical procedure is being tested for efficacy. Use of a placebo control is not justified to test the effectiveness of an innovative surgical technique that represents only a minor modification of an existing, accepted surgical procedure;
 - (ii) a new surgical procedure is developed with the prospect of treating a condition for which there is no known surgical therapy. In such cases, the use of placebo must be evaluated in light of whether the current standard of care includes a nonsurgical treatment and the risks, benefits, and side effects of that treatment;
 - (iii) the standard (nonsurgical) treatment is not efficacious or not acceptable to the patient;
 - (iv) Additional safeguards are in place in the informed consent process.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 004
(I-16)

Introduced by: Medical Student Section

Subject: Addressing Patient Spirituality in Medicine

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

Whereas, In 2010, The Joint Commission decreed that health care providers should "ask patients and families about staff responsiveness to their cultural, religious, and spiritual needs during care planning and treatment";¹ and

Whereas, In a study of 3,141 patients, 41% of patients desired a discussion of religious and spiritual concerns while hospitalized, but only half of those reported having such a discussion;² and

Whereas, According to the same study, "patients who had discussions of their religious and spiritual concerns were more likely to rate their care at the highest level on four different measures of patient satisfaction, regardless of whether or not they had desired such a discussion";² and

Whereas, Another prospective study of 339 patients with advanced cancer concluded that end-of-life costs were higher when the spiritual needs of patients were not supported by the healthcare team, especially among minorities and patients with higher religious coping;³ and

Whereas, A focal issue with practicing spirituality in medicine was that "the clinical environment did not support the inclusion of a spiritual dimension in an assessment and treatment of spiritual issues... and spiritual care was neglected in favor of physical care" in addition to perceived degree of "antagonism towards assessing spirituality during their placement in clinical settings";⁴ and

Whereas, According to a national study by Duke University, 90% of medical school deans indicated that patients stress spirituality in their healthcare and 90% reported that their school had courses or content on spirituality and health;⁵ therefore be it

RESOLVED, That our American Medical Association support inquiry into, as well as discussion and consideration of, individual patient spirituality as an important component of health (New HOD Policy); and be it further

¹ The Joint Commission. Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care: A Roadmap for Hospitals. Oakbrook Terrace, Ill.: The Joint Commission; 2011.

² Williams, J. A., Meltzer, D., Arora, V., et al. Attention to inpatients' religious and spiritual concerns: predictors and association with patient satisfaction. J Gen Intern Med. 2011; 26(11): 1265-1271.

³ Balboni T, Balboni M, Paulk ME, et al. Support of cancer patients' spiritual needs and associations with medical care costs at end of life. Cancer. 2011;117:5383-91.

⁴ Paal P, Helo Y, Frick E. Spiritual care training provided to healthcare professionals: A systematic review. J Pastoral Care Counsel. 2015. 69(1):19-30.

⁵ Koenig, H., Hooten, E., Lindsay-Calkins, E., et al. Spirituality in Medical School Curricula: Findings from a National Survey. Int J Psychiat Med. 2010; 391-398.

- 1 RESOLVED, That our AMA encourage expanded patient access to spiritual care services and
- 2 resources beyond trained healthcare professionals. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/29/16

RELEVANT AMA POLICY

Good Palliative Care H-70.915 - Our AMA: (1) encourages all physicians to become skilled in palliative medicine; (2) recognizes the importance of providing interdisciplinary palliative care for patients with disabling chronic or life-limiting illness to prevent and relieve suffering and to support the best possible quality of life for these patients and their families; (3) encourages education programs for all appropriate health care professionals, and the public as well, in care of the dying patient; and the care of patients with disabling chronic or life-limiting illness; (4) supports improved reimbursement for health care practices that are important in good care of the dying patient, such as the coordination and continuity of care, "maintenance" level services, counseling for patient and family, use of multidisciplinary teams, and effective palliation of symptoms; (5) encourages physicians to become familiar with the use of current coding methods for reimbursement of hospice and palliative care services; (6) advocates for reimbursement of Evaluation and Management (E/M) codes reflecting prolonged time spent on patients' care outside of the face-to-face encounter.
CCB/CLRPD Rep. 3, A-14

Support of Human Rights and Freedom H-65.965 - Our AMA: (1) continues to support the dignity of the individual, human rights and the sanctity of human life, (2) reaffirms its long-standing policy that there is no basis for the denial to any human being of equal rights, privileges, and responsibilities commensurate with his or her individual capabilities and ethical character because of an individual's sex, sexual orientation, gender, gender identity, or transgender status, race, religion, disability, ethnic origin, national origin, or age; (3) opposes any discrimination based on an individual's sex, sexual orientation, gender identity, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies; (4) recognizes that hate crimes pose a significant threat to the public health and social welfare of the citizens of the United States, urges expedient passage of appropriate hate crimes prevention legislation in accordance with our AMA's policy through letters to members of Congress; and registers support for hate crimes prevention legislation, via letter, to the President of the United States.
CCB/CLRPD Rep. 3, A-14

Symptomatic and Supportive Care for Patients with Cancer H-55.999 - Our AMA recognizes the need to ensure the highest standards of symptomatic, rehabilitative, and supportive care for patients with both cured and advanced cancer. The Association supports clinical research in evaluation of rehabilitative and palliative care procedures for the cancer patient, this to include such areas as pain control, relief of nausea and vomiting, management of complications of surgery, radiation and chemotherapy, appropriate hemotherapy, nutritional support, emotional support, rehabilitation, and the hospice concept. Our AMA actively encourages the implementation of continuing education of the practicing American physician regarding the most effective methodology for meeting the symptomatic, rehabilitative, supportive, and other human needs of the cancer patient.
CSA Rep. H, I-78 Reaffirmed: CLRPD Rep. C, A-89 Reaffirmed: Sunset Report, A-00
Reaffirmed: Sub. Res. 514, I-00 Modified: CSAPH Rep. 1, A-10

Model Pain Management Program For Medical School Curricula D-295.982 - Our AMA will collect, synthesize, and disseminate information about effective educational programs in pain management and palliative care in medical schools and residency programs.

Res. 308, A-01 Reaffirmed: CME Rep. 2, A-11 Reaffirmed: CME Rep. 6, A-13

Decisions Near the End of Life H-140.966 - Our AMA believes that: (1) The principle of patient autonomy requires that physicians must respect the decision to forgo life-sustaining treatment of a patient who possesses decision-making capacity. Life-sustaining treatment is any medical treatment that serves to prolong life without reversing the underlying medical condition. Life-sustaining treatment includes, but is not limited to, mechanical ventilation, renal dialysis, chemotherapy, antibiotics, and artificial nutrition and hydration. (2) There is no ethical distinction between withdrawing and withholding life-sustaining treatment. (3) Physicians have an obligation to relieve pain and suffering and to promote the dignity and autonomy of dying patients in their care. This includes providing effective palliative treatment even though it may foreseeably hasten death. More research must be pursued, examining the degree to which palliative care reduces the requests for euthanasia or assisted suicide. (4) Physicians must not perform euthanasia or participate in assisted suicide. A more careful examination of the issue is necessary. Support, comfort, respect for patient autonomy, good communication, and adequate pain control may decrease dramatically the public demand for euthanasia and assisted suicide. In certain carefully defined circumstances, it would be humane to recognize that death is certain and suffering is great. However, the societal risks of involving physicians in medical interventions to cause patients' deaths is too great to condone euthanasia or physician-assisted suicide at this time. (5) Our AMA supports continued research into and education concerning pain management.

CEJA Rep. B, A-91 Reaffirmed by BOT Rep. 59, A-96 Reaffirmation A-97 Appended: Sub. Res. 514, I-00 Reaffirmed: CEJA Rep. 6, A-10 Reaffirmed in lieu of Res. 211, I-13

Hospice Care H-85.955 - Our AMA: (1) approves of the physician-directed hospice concept to enable the terminally ill to die in a more homelike environment than the usual hospital; and urges that this position be widely publicized in order to encourage extension and third party coverage of this provision for terminal care; (2) encourages physicians to be knowledgeable of patient eligibility criteria for hospice benefits and, realizing that prognostication is inexact, to make referrals based on their best clinical judgment; (3) supports modification of hospice regulations so that it will be reasonable for organizations to qualify as hospice programs under Medicare; (4) believes that each patient admitted to a hospice program should have his or her designated attending physician who, in order to provide continuity and quality patient care, is allowed and encouraged to continue to guide the care of the patient in the hospice program; (5) supports changes in Medicaid regulation and reimbursement of palliative care and hospice services to broaden eligibility criteria concerning the length of expected survival for pediatric patients and others, to allow provision of concurrent life-prolonging and palliative care, and to provide respite care for family care givers; and (6) seeks amendment of the Medicare law to eliminate the six-month prognosis under the Medicare Hospice benefit and support identification of alternative criteria, meanwhile supporting extension of the prognosis requirement from 6 to 12 months as an interim measure.

CCB/CLRPD Rep. 3, A-14

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 005
(I-16)

Introduced by: M. Zuhdi Jasser, MD, Delegate

Subject: No Compromise on Anti-Female Genital Mutilation Policy

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

1 Whereas, Female genital mutilation (FGM) is the forcible mutilation of the clitoris and external
2 genitalia of women and girls for non-medical reasons affecting not only women in Southern
3 Asia, the Middle East and Africa, but also remains within the immigrant communities in the U.S.
4 and Europe; and

5
6 Whereas, FGM practiced on girls typically between 4 and 12 years of age (but can range from
7 birth to prior to marriage) is responsible for the torture, maiming, and mutilation of millions upon
8 millions of women and girls worldwide; and

9
10 Whereas, FGM in any form is a violation of basic human rights and bodily autonomy. It denies
11 the victim physical integrity, a normal sexual life, freedom from violence and subjugation, and
12 most extreme cases, causes death; and

13
14 Whereas, The forcible mutilation of a girl's genitalia in any way sets the stage for male-dominant
15 psychological torture, control, and dehumanization of that girl and woman will suffer in her family
16 forever and can lead to a lifetime of depression, anxiety and trauma; and

17
18 Whereas, Existing AMA Policy H-525.980 explicitly condemns the practice of female genital
19 mutilation (FGM); and

20
21 Whereas, In the U.S. an estimated 513,000 women and girls are at risk of undergoing the
22 procedure back in their home country or the country of their parents and annual International
23 Day of Zero Tolerance to FGM found that 70 million more women and girls have undergone the
24 procedure than previously thought; and

25
26 Whereas, There has recently been significant media coverage in 2016 about recent attempts by
27 some academics and physicians in the American medical community to redefine FGM and
28 promote a type of FGM in the form of a genital 'nick' or 'alteration' as a "compromise" position; and

29
30 Whereas, Our AMA must remain clear in its stance on FGM and reject any type of patriarchal
31 'nicking' procedure as an unethical surrender to the barbaric underpinnings of the FGM culture; and

32
33 Whereas, Any compromise procedure is still FGM and entirely violates existing AMA policy
34 H-525.980 last modified A-12; and

35
36 Whereas, Survivors and advocates against FGM like Khadija Gbla, Leyla Hussein (also a
37 psychotherapist) as well as organizations like No FGM Australia and Amref Health Africa (led by
38 Dr. Githinji Gitahi, a gynecologist) wholly rejected the compromise on FGM; and

Whereas, Our AMA, in the spirit of our existing Policy H-525.980, should listen to the victims, advocate on their behalf in the ethical practice of medicine, and update our policy to make it clear in 2016 that our AMA rejects any compromise procedures and that we uncompromisingly stand with individuals and organizations who have experienced FGM and who are surrounded by the horrors of FGM in all its incarnations; and

Whereas, AMA Policy H-525.980 needs to be updated to reflect not only its condemnation of FGM but its condemnation of any compromise procedures; therefore be it

RESOLVED, That our American Medical Association reaffirm its policy against female genital mutilation (FGM) (Reaffirm HOD Policy); and be it further

RESOLVED, That, due to the public debate in 2016 over whether the medical community sanctions a proposed 'nicking procedure,' our AMA must further clarify its current position on FGM to explicitly state that our AMA condemns any and all ritual procedures including, but not limited to, 'nicking' or 'genital alteration' procedures done to the genitals of women and girls (New HOD Policy); and be it further

RESOLVED, That our AMA, on behalf of the medical community, actively advocate against the practice of FGM in all its forms (including the recently proposed 'nicking' and 'alteration' procedures) and effectively add the voice of America's physicians to the voices of many anti-FGM human rights activists and their organizations which advocate for the survivors and victims of FGM (Directive to Take Action); and be it further

RESOLVED, That our AMA partner in this public advocacy with reputable anti-FGM activists and survivors including, but not limited to, Jaha Dukureh of the Tahirih Justice Center, Waris Dirie of Desert Flower Foundation, Layla Hussein of the Maya Center and the Dahlia Project, and Nimco Ali of the Daughters of Eve or Safe Hands for Girls to name a few (Directive to Take Action); and be it further

RESOLVED, That our AMA educate its membership and the American public about the harm of FGM prominently through its website and provide resources about the ethics and medical harm of any and all forms of FGM. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/11/16

RELEVANT AMA POLICY

Expansion of AMA Policy on Female Genital Mutilation H-525.980

Our AMA: (1) condemns the practice of female genital mutilation (FGM); (2) considers FGM a form of child abuse; (3) supports legislation to eliminate the performance of female genital mutilation in the United States and to protect young girls and women at risk of undergoing the procedure; (4) supports that physicians who are requested to perform genital mutilation on a patient provide culturally sensitive counseling to educate the patient and her family members about the negative health consequences of the procedure, and discourage them from having the procedure performed. Where possible, physicians should refer the patient to social support groups that can help them cope with societal mores; (5) will work to ensure that medical students, residents, and practicing physicians are made aware of the continued practice and existence of FGM in the United States, its physical effects on patients, and any requirements for reporting FGM; and (6) is in opposition to the practice of female genital mutilation by any physician or licensed practitioner in the United States. CSA Rep. 5, I-94 Res. 513, A-96 Reaffirmed: CSAPH Rep. 3, A-06 Modified: Res. 9, A-12

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 006
(I-16)

Introduced by: Washington

Subject: Effective Peer Review

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

1 Whereas, The Health Care Quality Improvement Act of 1986 (HCQIA) intended to protect the
2 public from incompetent physicians by allowing those physicians on peer review committees to
3 communicate in an open and honest environment and thus weed out incompetent physicians,
4 without the specter of a retaliatory lawsuit by the reviewed physician; and

5
6 Whereas, Most states have passed statutes that broaden the protections afforded by the HCQIA
7 in order to further promote peer review while severely limiting whistleblower protections to very
8 limited specific situations; and

9
10 Whereas, A number of states have specific whistleblower protections; however, California's
11 Health and Safety Code 1278.5(b)(1)(A) states that no health care facility shall discriminate or
12 retaliate against any person who has "presented a grievance, complaint or report to the facility";
13 and

14
15 Whereas; Common law protections are usually limited to situations where the offensive action
16 violates a clearly articulated public policy; and

17
18 Whereas; Many, if not most, physicians are now either employed or controlled by hospital
19 conglomerates; therefore, the threat of a retaliatory lawsuit is far less threatening than
20 termination of employment or elimination of hospital privileges; and

21
22 Whereas; Our AMA policy does not seem to reflect the dramatic recent change in workplace
23 arrangements nor protect employed physicians from retaliation as a result of effective peer
24 review; therefore be it

25
26 RESOLVED, That our American Medical Association study the current environment for effective
27 peer review, on both a federal and state basis, in order to update its current policy to include
28 strategies for promoting effective peer review by employed physicians as well as consider a
29 national strategy for protecting all physicians from retaliation as a result from participating in
30 effective peer review. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/13/16

RELEVANT AMA POLICY

Principles for Incident-Based Peer Review and Disciplining at Health Care Organizations

H-375.965

AMA policy is that:

(1) Summary suspension of clinical privileges is an extraordinary remedy which should be used only when the physician's continued practice presents an "imminent danger to the health of any individual." The decision to summarily suspend a member's medical staff membership or clinical privileges should be made by the chief of staff, chair or vice-chair of the member's clinical department, or medical executive committee. The medical executive committee (MEC) must meet as soon as possible, but in no event more than 14 days after the summary suspension is imposed, or before the time in which a report would be required to the state licensing agency if applicable, whichever is shorter, to review and consider the summary suspension. The MEC shall then promptly modify, continue or terminate the summary suspension. The suspended physician must be invited to attend and make a statement concerning the issues under investigation, but the meeting with the MEC shall not constitute the physician's fair hearing. If the MEC sustains the suspension, said action will trigger the fair hearing procedures contained in these policies.

(2) At the request of a medical staff department or of a member under review, or at its own initiative if needed for adequate and unbiased review, the medical executive committee may arrange, through the state or local medical society, the relevant specialty society or other appropriate source, for an external hearing panel to hear the case in order to assure professional and impartial clinical assessment.

(3) Prior to any disciplinary hearing, the physician should be provided with a clear, and if applicable, clinically supported basis for the proposed professional review action. A hearing panel of a health care organization should be guided by generally accepted clinical guidelines and established standards in its review actions.

(4) Physician health and impairment issues should be identified and managed by a medical staff committee, which should operate separately from the disciplinary process.

(5) Summary suspension reports that do not adhere to these principles should not be circulated or posted without confirmation by a state medical board or other appropriate authority allowing due process.

(6) Summary suspension reports should be immediately retracted or removed from posting if reversed or where a physician is exonerated.

(7) Physicians who are the subject of a summary suspension report should be afforded the right to add a statement or notice of dispute to the report that is of reasonable length.

BOT Action in response to referred for decision BOT Rep. 23, A-05; BOT Action in response to referred for decision Res. 220, I-08

<http://www.ama-assn.org/meetings/public/annual05/bot23a05.doc>

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 007
(I-16)

Introduced by: Washington

Subject: Fair Process for Employed Physicians

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(John P. Abenstein, MD, Chair)

1 Whereas, Employed physicians face unique challenges in that they are held accountable but
2 sometimes not given enough resources or authority; and
3

4 Whereas, Employed physicians sometimes face moral dilemmas within the workplace regarding
5 processes beyond their control, creating increased stress and even depression; often
6 contributing to physician burnout; and
7

8 Whereas, Fear of retaliation and the stigma associated with being a “troublemaker” or not being
9 a team player contributes to underreporting of problems in health care; and
10

11 Whereas, The more responsibility the physician has, the greater the exposure to serious events;
12 and
13

14 Whereas, Physicians find themselves facing a dilemma if their employer will not correct the
15 problem/situation; therefore be it
16

17 RESOLVED, That our American Medical Association support whistleblower protections for
18 health care providers and parties who raise questions of quality, safety, and efficacy of health
19 care and are adversely treated by any health care organization or entity (New HOD Policy); and
20 be it further
21

22 RESOLVED, That our AMA advocate for protection in medical staff bylaws to minimize negative
23 repercussions for physicians who report problems within their workplace. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 10/13/16

Reference Committee B

BOT Report(s)

- 02 AMA Support for State Medical Societies' Efforts to Implement MICRA-Type Legislation
- 03 Model State Legislation Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid Prescribing

Resolution(s)

- 201 Removing Restrictions on Federal Funding for Firearm Violence Research
- 202 Inclusion of Sexual Orientation and Gender Identity Information in Electronic Health Records
- 203 Universal Prescriber Access to Prescription Drug Monitoring Programs
- 204 Seamless Conversion of Medicare Advantage Programs
- 205 AMA Study of the Affordable Care Act
- 206 Advocacy and Studies on Affordable Care Act Section 1332 (State Innovation Waivers)
- 207 Limitation on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care
- 208 MIPS and MACRA Exemption
- 209 Affordable Care Act Revisit
- 210 Automatic Enrollment into Medicare Advantage
- 211 Electronic Health Records
- 212 Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation
- 213 SOAP Notes and Chief Complaint
- 214 Firearm Related Injury and Death: Adopt a Call to Action
- 215 Parental Leave
- 216* Ending Medicare Advantage Auto-Enrollment
- 217* The Rights of Patients, Providers and Facilities to Contract for Non-Covered Services
- 218* Support for Prescription Drug Monitoring Programs
- 219* Protect Individualized Compounding in Physicians' Offices as Practice of Medicine

* contained in Handbook Addendum

REPORT 2 OF THE BOARD OF TRUSTEES (I-16)
AMA Support for State Medical Societies' Efforts to Implement MICRA-type Legislation
(Resolution 214-I-15)
(Reference Committee B)

EXECUTIVE SUMMARY

Resolution 214-I-15, which was introduced by the Tennessee Delegation and referred to the Board of Trustees, asks "that our AMA engage its leadership and staff, those of the national medical specialty societies, and other stakeholder organizations to provide resources and technical assistance to efforts throughout the Federation to defeat no fault medical liability legislation."

No-fault liability or Patient Compensation Systems (PCS) propose compensating patients for any suboptimal medical outcome, regardless of whether negligence has occurred. Essentially, PCS proposals would replace the current medical liability system in a state with a system modeled on workers' compensation programs.

While individual proposals differ from state to state, generally, a PCS would operate as follows. Patients dissatisfied with their medical care would file a claim to a panel including individuals such as physicians, patient advocates, hospital administrators, and attorneys. Based on interviews and a medical record review, the panel would make a prima facie determination of whether a medical injury occurred. The panel would not be required to make a determination of whether medical negligence occurred. If the panel finds that a medical injury occurred, the claim will go to a compensation department for the determination of compensation based on a fee schedule for each type of injury and the severity of the injury. Appeals could be made based only on the process itself and not the size of the award.

This report summarizes no-fault medical liability legislation, analyzes available analyses pertaining to such legislation, recommends reaffirmation of longstanding AMA policy in support of MICRA-style reforms, and recommends that the AMA support the efforts of interested state medical associations to defeat efforts to replace state medical liability systems with no-fault liability or Patient Compensation Systems.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 2-I-16

Subject: AMA Support for State Medical Societies' Efforts to Implement MICRA-type
Legislation
(Resolution 214-I-15)

Presented by: Patrice A. Harris, MD, MA, Chair

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 INTRODUCTION

2
3 Resolution 214-I-15, which was introduced by the Tennessee Delegation and referred to the Board
4 of Trustees, asked "that our American Medical Association continue to support state medical
5 societies' efforts to implement MICRA-type legislation," and "that our AMA engage its leadership
6 and staff, those of the national medical specialty societies, and other stakeholder organizations to
7 provide resources and technical assistance to efforts throughout the Federation to defeat no fault
8 medical liability legislation." This report summarizes no-fault medical liability legislation and
9 analyzes available evidence pertaining to such legislation, and recommends new policy and
10 reaffirmation of existing policy.

11 12 BACKGROUND

13
14 No-fault liability or Patient Compensation Systems (PCS) propose compensating patients for any
15 suboptimal medical outcome, regardless of whether negligence has occurred. Essentially, PCS
16 proposals would replace the current medical liability system in a state with a system modeled on
17 workers' compensation programs or more limited systems like neurologic birth injury funds.

18
19 While individual proposals differ from state to state, generally, a PCS would operate as follows.
20 Patients dissatisfied with their medical care would file a claim to a panel including individuals such
21 as physicians, patient advocates, hospital administrators, and attorneys. Based on interviews and a
22 medical record review, the panel would make a prima facie determination of whether a medical
23 injury occurred. The panel would not be required to make a determination of whether medical
24 negligence occurred. If the panel finds that a medical injury occurred, the claim will go to a
25 compensation department for the determination of compensation based on a fee schedule for each
26 type of injury and the severity of the injury. Appeals could be made based only on the process itself
27 and not the size of the award.

28
29 PCS proponents claim that the system will "dramatically reduce the practice of defensive medicine,
30 thereby reducing health care costs, increasing the number of physicians practicing in a state,
31 improving patient safety, and providing patients fair and timely compensation without the expense
32 and delay of the court system."¹

33
34 PCS opponents question these claims, including the assumptions made about the impact on
35 defensive medicine, and counter that the PCS system will compensate patients where no negligence

has occurred, increase the number of claims filed, increase reporting to the National Practitioner Data Bank (NPDB), increase costs for physicians and other clinicians, and otherwise undermine medical liability reforms at the state and federal levels.

PATIENT COMPENSATION SYSTEM LEGISLATION

To date, PCS bills have been filed in about half a dozen states. To date, none of these bills has passed the respective state legislature. This report will focus on legislation filed in one state – Georgia – as representative of other state experiences.

Georgia Senate Bill 141 (2013) and subsequent bills

During the 2013 – 2014 legislative session, the Georgia General Assembly considered Senate Bill (S.B.) 141 and its companion bill, House Bill (H.B.) 662, both called the “Patient Injury Act.” Neither bill passed out of committee. The following is a summary of the PCS structure the bills proposed.

PCS administration and governance

The PCS would have been governed by an 11-member board representing the medical, legal, patient, and business communities, and would be appointed by the governor, the lieutenant governor, and the speaker of the House of Representatives. The Board would employ staff including an executive director, advocacy director, chief compensation officer, chief financial officer, chief medical officer, and chief quality officer. The chief medical officer’s office would manage medical review, with the authority to administer oaths, take depositions, issue subpoenas, compel the attendance of witnesses and the production of evidence, and obtain patient records pursuant to the patient’s release of protected health information.

The board would also establish committees, including a medical review committee composed of two physicians and one other board member, with the authority to convene an independent medical review panel to evaluate whether an application constitutes a medical injury. The panel would be composed of an odd number of at least three panelists chosen from a list of panelists recommended by the medical review committee and approved by the board.

The board would also establish a compensation committee responsible for recommending a compensation schedule for damage payments to the board.

Health care professionals included in a PCS

The following health care professionals and entities would have been included in a PCS pursuant to S.B. 141:

- Hospitals and health care facilities, including nursing homes and skilled nursing facilities
- Pharmacists and pharmacies
- Chiropractors
- Professional counselors, social workers, and marriage and family therapists
- Dentists, dental hygienists, and dental assistants
- Dieticians
- Nurses, including advanced practice nurses
- Nursing home administrators
- Occupational therapists

- Optometrists
- Physical Therapists
- Physicians
- Acupuncturists
- Physician assistants
- Cancer and glaucoma treatment practitioners, respiratory care, clinical perfusionists, and orthotics and prosthetic practitioners
- Podiatrists
- Psychologists
- Speech language pathologists and audiologists

Other versions of PCS bills have applied to:

- Physicians, hospitals, health systems or persons licensed or otherwise authorized to provide health care services²
- Only physicians³
- Only primary care physicians⁴

Notably, after facing opposition from many of the categories of health care professionals included, more recent versions of Georgia's PCS legislation – now coined the “Patient Compensation Act” – were pared down to apply only to physicians.

Provider taxes

According to S.B. 141, the PCS would be administered by the Department of Community Health, with an independent budget not controlled by the Department. The PCS' administrative costs would be supported by a tax on health professionals. The following are a sample of the taxes proposed.

- Dentists, dental hygienists, dental assistants, and nurses (except nurse anesthetists): \$100 per licensee
- Hospitals and ambulatory surgery centers: \$200 per bed
- Physician assistants and nurse anesthetists: \$250 per licensee
- Physicians and chiropractors: \$500 per licensee
- Other providers: \$2,500 per registration or license

A report by Aon Risk Solutions, prepared for Patients for Fair Compensation, the main proponent of the PCS system, estimated that the total contribution for a PCS more expansive than that proposed by S.B. 141 could be \$43.9 million annually from hospitals, nursing homes and assisted care facilities, medical and osteopathic practice, nurses, dentistry/dental hygiene/dental labs and other providers.⁵ Physician contributions from PCS taxes would account for approximately \$8.7 million of this total estimate.⁵

Notably, this estimate was taken from a longer list of health care professionals⁶ than was included in S.B. 141. The estimated tax on physicians from S.B. 141 is not known. Further, while subsequent PCS legislation significantly narrowed the list of health professionals potentially subject to the system, as is noted above, the Board is not aware of an estimate of what the tax on physicians would be with these more limited bills.

1 What is a medical injury?

2
3 S.B. 141 defines a medical injury as “a personal injury or wrongful death due to medical treatment,
4 including a missed diagnosis, which reasonably could have been avoided: (i) with care provided by
5 an individual practitioner, under the care of an experienced specialist or by an experienced general
6 practitioner practicing under the same or similar circumstances, or (ii) with care provided in a
7 system of care, if rendered within an optimal system of care under the same or similar
8 circumstances.”

9
10 Consideration of whether a medical injury could have been avoided shall only, per S.B. 141,
11 include “consideration of an alternate course of treatment if the injury could have been avoided
12 through a different but equally effective manner with respect to the treatment of the underlying
13 condition.” This consideration shall also only include “consideration of information that would
14 have been known to an experienced specialist or readily available to an optimal system of care at
15 the time of treatment.”

16
17 A medical injury, as defined by S.B. 141, does not include “an injury or wrongful death caused by
18 a product defect in a drug or device.”

19
20 More recent versions of PCS legislation⁷ in Georgia have defined medical injury as follows: A
21 personal injury or wrongful death due to medical treatment, including a missed diagnosis, where all
22 the following criteria exist:

- 23
24 • The provider performed a medical treatment on the applicant;
25 • The applicant suffered a medical injury with damages;
26 • The medical treatment was the proximate cause of the damages; and
27 • Based on the facts at the time of medical treatment, one or more of the following:
28 ○ An accepted method of medical services was not used for treatment; or
29 ○ An accepted method of medical services was used for treatment, but executed in a
30 substandard fashion.

31
32 The definition still excludes an injury or wrongful death caused by a product defect in a drug or
33 device.⁷

34
35 Process

36
37 To obtain compensation for a medical injury, a patient or his or her legal representative would file
38 an application with the PCS, including a brief statement of the facts and circumstances surrounding
39 the medical injury that gave rise to the application, as well as an authorization for the release of
40 protected health information potentially relevant to the application. Within 10 days of receipt of the
41 application, the office of medical review would determine whether the application on its face
42 constitutes a medical injury.

43
44 If the office determines that the application *does not*, on its face, constitute a medical injury, the
45 office must send a rejection to the applicant that informs the applicant of a right of appeal.

46
47 If the office determines that the application *does*, on its face, constitute a medical injury, the office
48 must notify each provider named in the application and his or her insurer. The provider then has 15
49 days to “support the application” or elect not to support the application. It is unclear from the plain
50 language of S.B. 141 what “supporting the application” would entail.

1 If the provider does support the application, and the office of medical review finds that the
2 application is valid, then the office of compensation shall determine a compensation award in
3 accordance with a compensation schedule, and offset by any past and future collateral source
4 payments. Periodic payment would be allowed.

5
6 If the provider does not support the application, the office then undertakes a 60-day investigation
7 conducted by a “multidisciplinary team with relevant clinical experience.” This investigation can
8 include document review and interviews. If the review panel determines that a medical injury has
9 occurred, the office of compensation must determine a compensation award in accordance with the
10 compensation schedule and the panel’s findings.

11
12 Both provider and patient have the opportunity to appeal the office’s determinations to an
13 administrative law judge, though the judge’s determinations are limited to whether the
14 requirements and rules of the PCS system were followed.

15 16 RESEARCH ON NO-FAULT MEDICAL LIABILITY PROPOSALS

17
18 A 2012 analysis by Aon Risk Solutions,⁸ prepared for Patients for Fair Compensation, estimates the
19 claims cost impact of a change from the fault-based liability system in Georgia to a PCS. Based on
20 the Aon work, claims cost (measured by indemnity payments and adjusted loss expenses) would
21 increase by 13 percent.

22
23 A subsequent independent actuarial analysis⁹ by TowersWatson of the Aon estimates suggests that
24 the cost increase could be much larger than 13 percent. TowersWatson finds that small changes in
25 Aon’s assumptions have a large impact on cost.

26
27 These two analyses being the primary evidence of the potential impact of PCS proposals on the
28 medical liability system, they are worth reviewing in more detail.

29 30 *Aon calculations*

31
32 In order to better understand Aon’s estimate it is important to look at the steps involved in their
33 analysis and the assumptions that they made.

- 34
35
- 36 • As a first step in estimating the additional claims cost of a PCS, Aon needed to know how
37 many claims are indemnified (paid) under the current system. Aon estimates that 864
38 claims are paid annually in Georgia. Because state-level claims data are not publically
39 available in the state, Aon bases this estimate (864 claims annually) on an internal
40 database.
 - 41 • Also important is the total number of patients in Georgia who seek indemnification (file
42 claims) in the current system. This metric is important because it forms the basis for the
43 number of claims that would be brought under a PCS. Again, because of a lack of data,
44 Aon had to estimate that number. Using the previous estimate of 864 paid claims, and an
45 assumption that 30 percent of patients who seek indemnification receive payment, Aon
46 estimates that 2,880 (864 / 0.30) patients per year file claims in Georgia under the current
47 system.
 - 48 • A key point of consideration in changing from a fault-based system to a PCS is the effect
49 on the number of patients who seek indemnification. Aon assumes the number who seek
50 indemnification would increase by 67 percent, with almost all of that increase occurring for
51 lower-cost claims: for example, Aon assumes there would be a 1,000 percent increase in
the number of patients seeking indemnity for insignificant injury under a PCS, from 133

patients annually to 1,468 patients annually. Taken together, Aon estimates that the number of patient claims will increase from 2,880 to roughly 4,800 ($2,800 \times 1.67$) annually under a PCS.

- Aon also had to make an assumption about how many of those patients would be indemnified under the PCS. Aon assumes that 40 percent of the 4,880 (about 1,920) would receive payment under a Georgia PCS.
- Finally, Aon assumes that average indemnity payments in Georgia within each of the nine injury severity categories would be 6.3 percent lower under the PCS than under the current system.

Aon combines those estimates and assumptions with data on claim costs from an internal database and data from PIAA. Aon's work suggests that in Georgia, claims cost would increase from \$423 million to \$478 million – a 13 percent increase. Further, the number of paid claims would more than double, and for some categories of injury, increase even more dramatically – up to 1,730 percent for insignificant injury.

Further, an individual analysis by TowersWatson demonstrates that the Aon estimates are subject to a greater deal of uncertainty than is present in usual actuarial calculations. As demonstrated below, small changes in each of the assumptions have a large impact on the estimated cost impact.

TowersWatson analysis

Changing the assumption about the indemnification ratio in the current system

As discussed, one concern with moving to a PCS is that the number of patients filing claims would greatly increase. Complicating the estimation process is that in many states there is not a good measure of how many patients file claims in the current system, including in Georgia. Aon estimates that 2,880 patients per year seek payment under the current system. They arrive at this estimate using the 864 paid claims and an assumption that 30 percent of patients seeking indemnity under the current system receive payment ($864 / 0.30 = 2,880$).

TowersWatson explored the cost impact if a 25 percent indemnification ratio were used instead of 30 percent. With 864 paid claims and an indemnification ratio of 25 percent, the number of patients seeking indemnification would be higher ($864 / 0.25 = 3455$). Keeping the other assumptions that Aon made the same, this modification would yield a claims cost increase of 35 percent rather than 13 percent.

Changing the assumption about the increase in the number of patients seeking indemnification

TowersWatson also analyzed the effect of the cost increase if more patients were to seek indemnification under the PCS than Aon estimates. Aon assumes the number of patients filing claims would increase by 67 percent, with almost all of that increase occurring in the lower-cost injury categories. TowersWatson modifies that assumption to an increase of 105 percent of patients filing claims, and allows more of that increase to occur within the higher-cost categories. With that modification – and using the 25 percent rather than the 30 percent indemnification ratio in the current system – the cost increase is 68 percent rather than the 13 percent given by the Aon analysis.

Changing the assumption about the indemnification ratio in the PCS

TowersWatson also calculated the effect on costs, were the PCS to indemnify far more patients than Aon assumed. Aon assumes that the indemnification ratio would be 40 percent under a PCS. When TowersWatson modifies this to 50 percent (resulting in more claims paid) on top of the changes to the other assumptions, the cost increase is 108 percent.

With these assumptions, the cost of a PCS would be more than twice that of the current system.

RELEVANT AMA POLICY

The AMA remains fully committed to the enactment of proven MLR laws, such as those modeled after the California Medical Injury Compensation Reform Act of 1975 (MICRA) (Policy H-435.967, “Report of the Special Task Force and the Advisory Panel on Professional Liability”). Caps on non-economic damages, such as those enacted in California and Texas, have proven to be successful at maintaining a stable state liability climate. A large and growing body of research shows that caps on non-economic damages lead to improved access to care for patients, lower medical liability premiums and lower health care costs. In addition to the cap on non-economic damages, the other reforms contained in MICRA (attorney contingency fee limits, collateral source reform and periodic payment of future damages), have helped to stabilize premiums in California and to stabilize California’s medical liability climate as whole. As such, the AMA continues to press for relief from the current medical liability system for physicians at both the federal and state levels through the enactment of these traditional reforms.

At the same time, the AMA generally calls for the implementation and evaluation of innovative reforms to see if they are able to improve the nation’s medical liability climate. These reforms could either complement traditional MLR provisions, such as caps, or they may be able to improve the liability climate in a state that is not able to enact traditional MLR provisions for political or judicial reasons.

The AMA has called for federal funding for pilot projects to test such concepts as health courts, liability safe harbors for the practice of evidence-based medicine, early disclosure and compensation models, expert witness guidelines and affidavits of merit, to name some of the more promising options.

The AMA Principles for Health Courts, which the AMA House of Delegates adopted in 2007, are particularly relevant here (Policy H-435.951, “Health Court Principles”). These principles are particularly relevant because the AMA believes that administrative liability systems such as those established by hospitals or insurers – or in this case, the state – should include many of the same requirements that the AMA supports for a health court established within a jurisdiction’s standard judicial system (Policy H-435.951, “Health Court Principles”). Reasoning dictates that the PCS should similarly include many of these requirements. However, a close examination of the PCS demonstrates that many key facets are not aligned with AMA policy and principles.

Standard of proof

The PCS would lower the standard of proof required for a judgment against a physician. To prove medical liability based on negligence, a plaintiff must establish four elements: (1) a duty by the physician to act according to the applicable standard of care; (2) a breach of that standard of care; (3) injury or harm to the plaintiff; and (4) a causal connection between the breach of the standard of care and the injury or harm. The PCS would skip step (2) and find judgment against a physician by

focusing only on step (3) – injury or harm to the patient – and not requiring a determination of whether the physician breached the standard of care, and whether that breach of the standard of care caused the injury or harm. Recent PCS proposals focus on “whether an accepted method of medical treatment” was used, while earlier proposals focus simply on whether the injury could have been avoided.

In other alternative medical liability reform systems such as health courts, the AMA has insisted that negligence must be proven for a patient to recover (Policy H-435.951, “Health Court Principles”). A PCS system would lower this standard of proof, and thus, is contrary to AMA policy.

Expert witnesses and judges

AMA principles recommend that health court judges have specialized training in the delivery of medical care that qualifies them for serving on a health court. In addition, qualified experts should be utilized to assist a health court in reaching a judgment (Policy H-435.951, “Health Court Principles”). AMA policy provides guidance on what the standards for those experts should be. At minimum, statutory requirement for qualification as an expert witness in medical liability cases should provide that the witness have:

- Comparable education, training, and occupational experience in the same field as the defendant or specialty expertise in the disease process or procedure performed in the case;
- Occupational experience that includes active medical practice or teaching experience in the same field as the defendant;
- Active medical practice or teaching experience within five years of the date of the occurrence giving rise to the claim; and
- Certification by a board recognized by the American Board of Medical Specialties or the American Osteopathic Association or by a board with equivalent standards (Policy H-265.994, “Expert Witness Testimony”).

In cases brought before health courts, AMA policy further recommends that:

- The health court task force maintain a list of qualified medical experts who meet the same qualifications as the medical experts who testify on behalf of the party in the lawsuit, from which a judge may select to help clarify or interpret medical testimony; and
- Party expert witnesses be a doctor of medicine or osteopathy who meets the same requirements outlined in AMA policy on expert witnesses (Policy H-435.951, “Health Court Principles”).

PCS cases would be decided by a panel of “individuals with relevant clinical expertise,” though what that expertise consists of is not specified. There is no requirement that the medical experts have the same or similar expertise, training, qualifications, or specialty certification as the defendant. Moreover, there is no standard at which to hold those experts who testify to the appropriateness of care provided. For these reasons, the PCS lowers – or at minimum, does not specify – standards for expert witnesses and decision makers, and goes against the high standards AMA policy expects for expert witnesses in medical liability cases.

Damages

AMA policy supports a fee structure system for damage awards based on type or severity of injury, or to have non-economic damages linked to the amount of economic damages included in the

judgment. The underlying principle is that consistent injuries should result in consistent non-economic damage awards based on the schedule. At the same time, economic damages should not be limited; injured parties should be fully compensated for their economic losses. Punitive damages, if allowed, should not be awarded unless the party alleging such damages meets the burden of producing clear and convincing evidence of oppression, fraud, malice, or the opposing party's intent to do harm (Policy H-435.951, "Health Court Principles"). With these considerations in mind, the fee structure system the PCS proposes is aligned with AMA policy.

National Practitioner Data Bank

PCS legislation commonly includes a provision stating that a physician who is the subject of an application shall not be found to have committed medical negligence and shall not be automatically reported to the state medical board. The PCS will only share with the medical board for disciplinary action information from those applications in which the department has determined that the provider represents an imminent risk of harm to the public. However, the plain language of PCS bills does not specify what standard the department should use to make this determination of risk of harm to the public.

Further, while PCS proponents commonly claim that PCS systems will not trigger reporting to the National Practitioner Data Bank (NPDB), the Board believes this assertion is debatable.

According to the NPDB Guidebook, "[e]ach entity that makes a payment for the benefit of a health care practitioner in settlement of or, in satisfaction in whole or in part of, a written claim or judgment for medical malpractice against that practitioner must report the payment information to the NPDB.... Medical malpractice payments are limited to exchanges of money and must be the result of a written complaint or claim demanding monetary payment for damages. The written complaint or claim must be based on a practitioner's provision of or failure to provide health care services. A written complaint or claim can include, but is not limited to, the filing of a cause of action based on the law of tort in any State or Federal court or other adjudicative body, such as a claims arbitration board."¹⁰

The NPDB interprets the written claim requirement "to include any form of writing, including pre-litigation communications."¹⁰ The NPDB, not any other entity, determines whether a written claim has occurred for purposes of filing a report. Unless the PCS system is to be entirely verbal, it seems possible that the NPDB would consider payments made as a result of a PCS system judgment to be reportable events. The issue whether a "medical malpractice" payment, for the purposes of the NPDB, requires wrongful conduct by the physician.

Given the findings of the Aon and TowersWatson estimates that claims made to the PCS system would dramatically increase in comparison to the current liability system, it is possible that reports to the NPDB would increase dramatically as well.

AMA policy opposes legislative or administrative efforts to expand the NPDB reporting requirements for physicians, such as the reporting of a physician who is dismissed from a medical liability lawsuit without any payment made on his or her behalf, or to expand the entities permitted to query the NPDB such as public and private third party payers for purposes of credentialing or reimbursement (Policy H-355.975, "Opposition to the National Practitioner Data Bank").

Because of the potential for the PCS to dramatically increase claims to the NPDB – including claims in which there has been no finding of negligence – the PCS system goes against longstanding AMA policy regarding reporting to the NPDB.

1 DISTINGUISHING PCS PROPOSALS FROM NEUROLOGIC INJURY FUNDS

2
3 Several states, including Florida and Virginia, have funds established to pay for the care of infants
4 born with certain neurological injuries. While these systems share the no-fault nature of PCS
5 proposals, they differ in that utilization of neurologic injury programs is an exclusive remedy,
6 providing absolute immunity from medical liability for participating health care professionals.
7 Because injury claims adjudicated by neurologic injury tribunals do not depend upon medical
8 liability, decisions do not need to be reported to the NPDB. Similarly, standard of care and expert
9 witness considerations are not present with neurologic injury funds as they are with PCS proposals.
10 Even so, neurologic injury programs continue to be a subject of debate.

11
12 CONCLUSION

13
14 Medical liability remains a continuing concern for physicians. It affects both how and where they
15 practice. The ramifications of the current liability system are wide-ranging, from patients who now
16 have limited access to health care to the financial implications on the health care system as a
17 whole. The AMA remains at the forefront on this issue by advocating at both the federal and state
18 levels and conducting research to improve the liability system. The AMA remains committed to
19 advocating for proven reforms – such as caps on non-economic damages – to fix the problem. At
20 the same time, the AMA will continue advocating for innovative reforms, such as health courts,
21 safe harbors for the practice of evidence-based medicine and early disclosure and compensation
22 models, as a way to complement traditional reforms and to solve this issue for both physicians and
23 patients.

24
25 Though some aspects of PCS proposals are consistent with AMA policy, significant aspects of the
26 proposals to date are inconsistent with AMA Health Court Principles and AMA medical liability
27 reform policy, including policies on the standard of care for medical liability cases, expert witness
28 requirements, and reporting to the NPDB. Moreover, analyses of PCS proposals – even those
29 prepared on behalf of PCS advocates – demonstrate the potential for a PCS to vastly increase the
30 cost of a state’s medical liability system. These shortcomings are deeply concerning to the Board of
31 Trustees.

32
33 Given the AMA’s in-house expertise and the ongoing MLR-related advocacy, the Board of
34 Trustees believes that support for a Patient Compensation System is not warranted.

35
36 RECOMMENDATION

37
38 The Board of Trustees recommends that the following be adopted in lieu of Resolution 214-I-15
39 and that the remainder of the report be filed.

- 40
41 1. That our American Medical Association (AMA) reaffirm Policy H-435.967, “Report of the
42 Special Task Force and the Advisory Panel on Professional Liability.” (Reaffirm HOD Policy)
43
44 2. That our AMA support the efforts of interested state medical associations to defeat efforts to
45 replace a state medical liability system with a no-fault liability or Patient Compensation
46 System. (Directive to Take Action)

Fiscal Note: Less than \$2500.

REFERENCES

- ¹ Georgia Senate Bill 141 (2013-2014 Regular Session).
- ² Maine L.D. 1311 (127th Legis. 2015).
- ³ Florida Senate Bill 1308 (2016 Session).
- ⁴ Vermont House 35 (2013-2014 Regular Session).
- ⁵ Aon Risk Solutions. Georgia Rating Model for the Implementation of a Patients Compensation System. Prepared for Patients for Fair Compensation. June 21, 2012.
- ⁶ Abortion clinics, acupuncture, assisted care facilities, athletic trainers, chiropractic medicine, clinical laboratories, clinical laboratory personnel, dentistry, dental hygiene, dental laboratories, dietetics, nutritional practice, electrolysis, HMOs, hospitals, maternal and child health, medical practice, medical transportation service – EMT, midwifery, multiphasic health testing, naturopathic, nursing, nursing home administration, nursing homes and related health care, occupational therapy, optometry, orthotics, prosthetics, pedorthics, osteopathic medicine, pharmacy, physical therapy, podiatric medicine, radiological, respiratory therapy, speech language pathology, and audiology.
- ⁷ Georgia Senate Bill 86 (2015-2016 Regular Session)
- ⁸ Aon Risk Solutions. An Evaluation of the Impact to Direct Medical Malpractice Costs in the State of Georgia Related to the Implementation of a Patients Compensation System. Prepared for Patients for Fair Compensation. October 10, 2012.
- ⁹ TowersWatson analysis of 2012 Aon Risk Solutions reports for Patients for Fair Compensation. August 9, 2013.
- ¹⁰ U.S. Department of Health and Human Resources, Health Resources and Services Administration. NPDB Guidebook. Rockville, Maryland. U.S. Department of Health and Human Services, 2015. A payment made as a result of a suit or claim solely against an entity (for example, a hospital, clinic, or group practice) that does not identify an individual practitioner should not be reported to the NPDB. See also, Wakefield memo to Sebelius regarding Appropriate Medical Malpractice Payment Reporting to the National Practitioner Data Bank (NPDB) in Light of Recent Medical Malpractice Reforms in Massachusetts and Oregon (May 20, 2014).

REPORT OF THE BOARD OF TRUSTEES

B of T Report 3-I-16

Subject: Model State Legislation Promoting the Use of Electronic Tools to Mitigate Risk
with Prescription Opioid Prescribing
(Resolution 222-I-15)

Presented by: Patrice A. Harris, MD, MA, Chair

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 INTRODUCTION

2
3 At the 2015 Interim Meeting, the House of Delegates referred Resolution 222-I-15, “Model State
4 Legislation Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid
5 Prescribing,” introduced by the Virginia Delegation, which asked:

6
7 That our American Medical Association develop model state legislation that improves
8 workflow for using state based prescription monitoring programs by enhancing information
9 available including automated alert notification of doctor shopping, real time EHR-PMP
10 integration, and e-prescribing of schedule II and III drugs which should be essential parts of a
11 state based risk mitigation strategy with identification and correction of any workflow or
12 technological barriers a high priority; and

13
14 That Stage 3 of the federal government’s meaningful use program should be delayed until the
15 following are accomplished: a) real time integration of EHRs and state based PMPs, and b)
16 electronic prescribing of schedule II and III drugs are available for meaningful use certified
17 EHR’s in the United States.

18
19 Reference committee testimony broadly supported the concept of prescription drug monitoring
20 program (PDMP) integration with electronic health records (EHRs). There was concern, however,
21 about how well PDMPs and EHRs are integrated in actual practice. Testimony noted that in clinical
22 situations where PDMPs and EHRs work well together, there are positive benefits to data retrieval
23 and information that can help with clinical decision making. On the other hand, testimony also
24 noted that not all PDMPs currently have the ability to provide real-time data or are effectively
25 integrated into clinical workflow systems. In addition, testimony noted that EHR integration into
26 PDMPs varies greatly, and there are considerable technological and practical challenges to such
27 integration.

28
29 The reference committee cited work being done by several medical societies as well as the AMA
30 Task Force to Reduce Opioid Abuse in support of physicians registering for and using PDMPs.
31 When PDMPs contain relevant, real-time data that can be accessed as part of a physician’s
32 workflow, physicians often have important information that can help improve patient care and
33 make more informed prescribing decisions. This report will discuss issues surrounding automated
34 alerts of so-called “doctor shopping,” which raise several questions, including who should receive
35 the alerts and what action(s) should be taken based on those alerts. In addition, it is not clear how

state legislation, by itself, could improve the technological functionality of a PDMP, but such legislation could be a factor in requirements of using PDMPs. This includes tying such requirements to when PDMPs and EHRs may be, in fact, integrated. In addition, this report will provide a brief update on electronic prescribing of controlled substances and an update on relevant issues concerning Stage 3 of the federal government's Meaningful Use program.

This report will recommend that existing policy be reaffirmed and recommends new policies be adopted to guide AMA advocacy.

AUTOMATED ALERTS IN A PRESCRIPTION DRUG MONITORING PROGRAM

Proponents of automated alerts to prescribers using PDMPs frequently cite the ability of such alerts to provide information about "doctor shopping." While not a legal term of art or clinical description, "doctor shopping" generally—and often pejoratively—seeks to define individuals who seek to fraudulently obtain a prescription¹ or who seek multiple prescriptions for controlled substances from multiple prescribers and/or pharmacies in a short time frame. State laws and regulation define the parameters differently. Being deemed a "doctor shopper" typically means that the patient has received one or more prescriptions for a controlled substance from 3-5 prescribers and filled it at 3-5 pharmacies within a 30-90 day time frame. This also is referred to as a Multiple Prescription Event (MPE). Many states and other stakeholders have touted their PDMPs as being able to reduce the number of MPEs. Commonly cited examples are New York and Tennessee, which have reported significant reductions in MPEs.²

The Board supports efforts to identify individuals who use fraudulent means to obtain controlled substances from prescribers and dispensers either for their own use or for diversion to others. It is not a straightforward issue, however, to separate: (1) patients who unintentionally receive multiple prescriptions that may represent dangerous drug combinations from; (2) patients with substance use disorders who are seeking more controlled substance prescriptions than would generally be prescribed for their medical condition; or from (3) individuals who misrepresent their health conditions in order to obtain controlled substance prescriptions for purposes of misuse or diversion. For this reason, the broad application of criteria for identifying MPEs may not meet the goal of reducing opioid misuse, overdose or diversion. For example, if a patient sees multiple physicians for multiple conditions, and each physician prescribes a controlled substance—and the patient fills each prescription at a different pharmacy, then technically that patient may be flagged as a "doctor shopper." The automated alert in the PDMP may be set to highlight that patient in yellow, red or some other distinctive color. The technology and functionality for communicating these types of alerts vary by state, but there is little discussion about what the physician is supposed to do when the PDMP identifies a patient as having an MPE.

If it becomes clear that an individual is fraudulently seeking prescriptions for nonmedical use or diversion, these efforts should be resisted and denied and potentially referred to law enforcement. Patients seeking more controlled substances than their health condition warrants may need to be screened, assessed for a possible opioid use disorder, and counseled and/or referred for treatment.

Patients who are unintentionally receiving dangerous drug quantities or combinations need better care coordination. If, for example, the patient is receiving an opioid analgesic, a benzodiazepine and a muscle relaxant from three different physicians, the combination could be deadly. Depending on how the PDMP allows a physician to set up an alert—or if the PDMP default is to flag such an MPE—when a patient is flagged as a potential doctor shopper, what should the physician do in such a situation?

As stated by E-10.01, “Fundamental Elements of the Patient-Physician Relationship,” “the physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient.” Yet, to prescribe a controlled substance to this patient raises the practical concern whether that prescription will be seen by regulatory bodies, law enforcement or others as contributing to further MPEs. Even if the physician documents the reasons why the patient is not a “doctor shopper,” it is unlikely that the PDMP has the sophistication to distinguish between patients. All the PDMP (and others who have access to the PDMP) know is that the physician continued to prescribe controlled substances to an alleged “doctor shopper.”

Ethical policy E-10.01 further states that “the physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care.” In an MPE situation, physicians and pharmacists are under intense pressure to reduce the number of MPEs. The balance is ensuring that the PDMP alert does not create a barrier to care. Therefore, the Board recommends that the AMA advocate to key stakeholders, including the National Association of State Controlled Substances Authorities, the National Association of Boards of Pharmacy, and the National Governors Association, to ensure that efforts to reduce MPEs are done in a manner that supports continuity of care and does not adversely affect the patient-physician relationship.

INTEGRATION OF PDMPs AND EHRs

There are many benefits to integrating PDMP data into EHRs in a seamless manner. A seamless integration process would allow physicians to have a patient’s prescription history as part of the medical record, eliminate having to sign in to separate systems, improve workflow, and other benefits that could improve patient care.

The AMA supports this type of technological improvement. For example, Policy H-95.945, “Prescription Drug Diversion, Misuse and Addiction,” provides a recommendation “that PDMPs be designed such that data is immediately available when clinicians query the database and are considering a decision to prescribe a controlled substance.” PDMPs, while they vary on whether data is input by pharmacists from within 24 hours to a week or more, arguably contain helpful information for physicians and other health care professionals about a patient’s controlled substances prescription history.

In addition, a 2016 AMA national survey found that, when asked “what would make PDMPs more effective and useful,” the number one response (66 percent of respondents) was “integration with EHR/EMR.”³ Such integration, moreover, has been studied in several pilot programs by the federal Office of the National Coordinator across multiple states and in clinical settings ranging from the emergency department to ambulatory settings to pharmacies and opioid treatment programs.⁴ This is consistent with AMA policy and its considerable support for the interoperability of EHRs and other systems. This includes D-478.972, “EHR Interoperability,” D-478.994, “Health Information Technology,” and D-478.996, “Information Technology Standards and Costs.”

UPDATE ON EPCS AND MEANINGFUL USE

Electronic prescribing of controlled substances (EPCS) has not become a major component of the U.S. health care system. Although all states allow for EPCS, according to Sure Scripts, approximately 6.0 percent of physicians and other health care providers are enabled for EPCS.⁵ New York has the highest percentage (37 percent)—almost certainly due to the fact that as of March 27, 2016, New York requires mandatory electronic prescribing for all prescriptions.⁶

1 As the AMA wrote to the U.S. Drug Enforcement Administration in 2015, “a well-designed
2 electronic medication prescription (eRx) system adds value to [physicians’] practice of medicine
3 and supports better patient care. We believe expanding the utility of EPCS to match that of current
4 eRx capabilities will benefit physicians and patients alike.”⁷

5
6 A number of reasons continue to limit the ability of those physicians, however, who would like to
7 prescribe controlled substances electronically, including the DEA “two-factor authentication”
8 requirement, verification requirements, vendor incompatibility and readiness, technological and
9 workflow barriers and other reasons, whose full discussion are beyond the scope of this report. If
10 these issues can be resolved, however, then it is hopeful that EPCS can truly become a helpful
11 component of risk mitigation strategies at the clinical, systems-wide and state-based levels.
12

13 Yet, significant barriers remain. With CMS’ release of the Stage 3 Meaningful Use proposed rule
14 in 2015, CMS signaled their intent to increase the complexity of the program and to further
15 physicians’ burden on the interoperability of electronic health information. While the majority of
16 the Stage 3 objectives and measures were recycled from Stage 2, the proposed rule increased the
17 bar for physician success and set a high initial threshold for all new objectives. Many health care
18 systems and state and medical associations, including the AMA, provided CMS detailed comments
19 focused on reducing the physician reporting burden and methods to increase flexibility in the
20 program.
21

22 Specifically relating to the electronic prescription of medications, the AMA asked CMS to allow
23 physicians the option to include or exclude controlled substances in the calculation of Meaningful
24 Use electronic prescribing measure. In the final Stage 3 rule CMS accepted AMA’s comments,
25 stating:
26

27 After consideration of the public comments received, we are finalizing changes to the
28 language to continue to allow providers the option to include or exclude controlled
29 substances in the denominator where such medications can be electronically
30 prescribed. For the purposes of this objective, we are adopting that prescriptions for
31 controlled substances may be included in the definition of permissible prescriptions
32 where the electronic prescription of a specific medication or schedule of medications
33 is permissible under state and federal law.⁸
34

35 While a number of suggested changes by the AMA were adopted, CMS stated that further program
36 adjustments could be made in future rulemaking. For many in the industry, the forthcoming
37 MACRA proposed rule in early 2016 was seen as an opportunity for CMS to rethink Stage 3
38 requirements.
39

40 Health IT development is largely guided by federal certification and reporting requirements. Prior
41 to commenting on CMS’ Stage 3 proposed rule, the AMA provided detailed comments to ONC on
42 their 2015 Edition Health IT Certification—with a focus on improving EHR interoperability and
43 usability. By taking a two-pronged approach of reducing prescriptive federal reporting demands
44 while seeking a more focused health IT certification, the AMA, along with many other
45 organizations, believes physician EHR satisfaction and participation in new payment models will
46 increase. However, due to the EHR development timeline, even before a Stage 3 final rule was
47 released, health IT developers began working on new EHRs. Although the MACRA proposed rule
48 incorporated many aspects of Meaningful Use through the Advancing Care Information (ACI)
49 component of MIPS, CMS has acknowledged health IT must improve and adapt to the needs of
50 physicians and patients.⁹

The AMA views MACRA as an opportunity to align the development of health IT with the evolving demands of health care. Value-based reimbursement models will require physicians to have at their disposal a robust health IT toolbox. While the EHR will still play a major role going forward, physicians and patients must have the ability to optimize care using both certified and non-certified technology. CMS has already identified 2015 Edition health IT products as one component for successful participation in MIPS; however, requirements on the use of EHRs will not be finalized until late 2016.

Additionally, CMS has proposed a flexible approach to the use of EHRs in APMs. The AMA views the proposed APM requirements as a logical starting point for MIPS. The AMA has supplied detailed and constructive feedback outlining how physicians can optimize the use of EHRs while achieving success in multiple MIPS components.¹⁰ This holistic approach to CMS' quality payment program provides the flexibility physicians will need to successfully participate in MIPS, and may also act as a glide path for those who wish to migrate to APMs. Furthermore, because this approach focuses less on the process and more on patient outcomes, health IT developers will benefit by increased development freedom—focusing less on federal reporting demands and creating tools that better integrate with physician workflows.

2015 Edition EHRs are already in development and some have already been certified. Many health IT developers will have products in the market by mid-2017. Advanced functionality like real-time integration between EHRs and PDMPs is not included in certification, nor are EHR vendors incentivized to focus on this type of functionality. Furthermore, there are no national standards for EHR-PDMP communication, and each state has established their own requirements around PDMP interoperability. While this capability is highly desirable by physicians, health IT developers are driven to meet federal certification requirements before developing other functionality.

Going forward, CMS and ONC must create a way to better incorporate feedback from physicians into the development of their programs. By restructuring CMS programs to focus on outcomes and focusing ONC certification on testing for product safety, security, usability, and interoperability—including with PDMPs—a physicians will encounter greater choice and better functioning products in health IT going forward.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 222-I-15, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the ability of prescription drug monitoring programs (PDMPs) to have the capability for physicians to know when their patients have received a prescription for controlled substances from multiple prescribers or multiple pharmacies within a short time frame; (New HOD Policy)
2. That our AMA advocate to key stakeholders, including the National Association of State Controlled Substances Authorities, the National Association of Boards of Pharmacy, and the National Governors Association, to ensure that efforts to reduce Multiple Provider Events (MPEs) are done in a manner that supports continuity of care; (Directive to Take Action)
3. That our AMA work with the Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA) and other relevant federal agencies, to better understand the factors that lead to MPEs and develop medically and ethically appropriate strategies for reducing them; (Directive to Take Action)

- 1 4. That our AMA support the interoperability of state PDMPs with electronic health records
2 (EHRs); (New HOD Policy)
3
- 4 5. That Policies D-478.972, "EHR Interoperability," D-478.994, "Health Information
5 Technology," and D-478.996, "Information Technology Standards and Costs," be reaffirmed;
6 (Reaffirm HOD Policy)
7
- 8 6. That our AMA advocate for the Centers for Medicaid and Medicare Services (CMS) and
9 Office of the National Coordinator for Health Information Technology (ONC) to better
10 incorporate feedback from physicians to focus on outcomes and focusing ONC certification on
11 testing for product safety, security, usability, and interoperability. (New HOD Policy)

Fiscal Note: Less than \$2,500.

REFERENCES

- ¹ For a good discussion of statutory and regulatory requirements related to fraud, misrepresentation and other illicit means of obtaining a prescription, see “Doctor Shopping Laws” from the Public Health Law Program in the Office for State, Tribal, Local and Territorial Support at the Centers for Disease Control and Prevention. Available at <https://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf>
- ² Mandating PDMP participation by medical providers: current status and experience in selected states Prescription Drug Monitoring Program Center of Excellence at Brandeis COE Briefing states States, Prescription Drug Monitoring Program Center of Excellence at Brandeis COE Briefing. Revision 1, February 2014. Available at http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf
- ³ Physician perceptions and practices on opioid prescribing, education, barriers to care, naloxone. AMA national survey conducted by TNS Global Research, Nov. 13–23, 2015. The survey had 2,130 respondents who are practicing U.S. physicians who provide a minimum of 20 hours per week in direct patient care, have a current DEA license to prescribe Schedule II controlled substances, and prescribe opioids on a weekly, or more frequent, basis. See more at <http://www.ama-assn.org/ama/pub/news/news/2016/2016-02-18-barriers-non-opioid-therapy.page>
- ⁴ See “Connecting for Impact: Linking Potential Prescription Drug Monitoring Programs (PDMPs) to Patient Care Using Health IT,” available at <https://www.healthit.gov/PDMP>
- ⁵ EPCS Provider Enablement by State. <http://surescripts.com/products-and-services/e-prescribing-of-controlled-substances>
- ⁶ See New York State Department of Health website: http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/ which also lists exceptions to the mandate.
- ⁷ August 11, 2015 letter from AMA CEO James L. Madara, MD, to Barbara J. Boockholdt, Chief, Regulatory Section, U.S. Drug Enforcement Administration Office of Diversion Control. <http://www.ama-assn.org/resources/doc/washington/x-pub/2015-8-11-ama-letter-dea-epcs.PDF>
- ⁸ CMS. Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017. October 2015. Accessed August 2016 from: <https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications>
- ⁹ Acting CMS Administrator Andy Slavitt. Remarks by Andy Slavitt, CMS Acting Administrator before the American Medical Association 2016 Annual Meeting Chicago, IL. June 2016. Accessed August 2016 from: <https://blog.cms.gov/2016/06/13/remarks-by-andy-slavitt-cms-acting-administrator-before-the-american-medical-association-2016-annual-meeting-chicago-il/>
- ¹⁰ AMA comments to CMS on the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS–5517–P). June 2016. Accessed August 2016 from: <https://download.ama-assn.org/resources/doc/washington/ama-macra-comments-27june2016.pdf>

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 201
(I-16)

Introduced by: Medical Student Section

Subject: Removing Restrictions on Federal Funding for Firearm Violence Research

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

Whereas, Firearm violence is responsible for over 32,000 deaths and 84,000 injuries annually, is one of the top three causes of death in American youth, and costs the U.S. at least \$174 billion annually;^{1,2,3,4,5} and

Whereas, The federal budgetary law, "Congressional Appropriations Act," has effectively barred the CDC, NIH, and other federal agencies from conducting necessary research on firearm violence since 1996; for example, CDC funding for firearm injury prevention fell 96% in 1996 to only \$100,000 annually;^{1,6,7,8,9} and

Whereas, Our AMA, along with over 100 other medical organizations, recently sent a joint letter to Congress urging federal funding for research on firearm violence;¹⁰ and

Whereas, Pursuant to AMA policy H-145.975, our AMA supports federal and state research on firearm-related injuries and deaths and increased funding for and the use of state and national firearms injury databases, including the expansion of the National Violent Death Reporting System to all 50 states and U.S. territories, to inform state and federal health policy; and

Whereas, Existing AMA policy urges the Centers for Disease Control and Prevention to research firearm violence from a public health standpoint (H-145.997, D-145.999) and at the 2016 Annual Meeting, our House of Delegates adopted policy to actively lobby Congress to lift the gun violence research ban (D-145.995); therefore be it

¹ Taichman DB and Laine C. (2015). Reducing Firearm-Related Harms: Time for Us to Study and Speak Out. *Ann Intern Med*, 162(7), 520.

² McCarthy M. (2013). Reviving research into US gun violence. *BMJ*. 346:f980. Available at <http://www.bmj.com/content/346/bmj.f980>.

³ Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. (2015). Web-based Injury Statistics Query and Reporting Systems: Fatal Injury Reports. Available at http://www.cdc.gov/injury/wisqars/fatal_injury_reports.html.

⁴ Siegel M, Ross CS, King C. (2014). Examining the relationship between the prevalence of guns and homicide rates in the USA using a new and improved state-level gun ownership proxy. *Injury Prevention*, 20(6), 424-426.

⁵ Children's Safety Network. (2012). "The Cost of Firearm Violence." Available at <https://www.childrenssafetynetwork.org/publications/cost-firearm-violence>.

⁶ Centers for Disease Control & Prevention (CDC) FY 2013 Budget Request Summary," CDC, <http://1.usa.gov/13sPK4Y>.

⁷ S. H.R.2029, 114th Cong. (2015) (enacted).

⁸ Frankel TC. (2015). "Why the CDC still isn't researching gun violence, despite the ban being lifted two years ago." Available at <https://www.washingtonpost.com/news/storyline/wp/2015/01/14/why-the-cdc-still-isnt-researching-gun-violence-despite-the-ban-being-lifted-two-years-ago/>.

⁹ Anglemeyer A, Horvath T, Rutherford G. (2014). The Accessibility of Firearms and Risk for Suicide and Homicide Victimization Among Household Members. *Ann Intern Med*, 160(2), 101-110.

¹⁰ Doctors for America. (2016). "Over 100 Medical and Public Health Organizations Call for Federal Gun Research." Available at http://files.drsforamerica.org/blog/blogs-from-dc-climate-change-and-health-at-the-white-house/CDC_letter_4-6_FINAL.pdf.

- 1 RESOLVED, That our American Medical Association provide an informational report on recent
- 2 and current organizational actions taken on our existing AMA policies (e.g. H-145.997)
- 3 regarding removing the restrictions on federal funding for firearms violence research, with
- 4 additional recommendations on any ongoing or proposed upcoming actions. (Directive to Take
- 5 Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 08/29/16

RELEVANT AMA POLICY

Gun Violence as a Public Health Crisis D-145.995

Our AMA: (1) will immediately make a public statement that gun violence represents a public health crisis which requires a comprehensive public health response and solution; and (2) will actively lobby Congress to lift the gun violence research ban.

Citation: Res. 1011, A-16

Firearms as a Public Health Problem in the United States - Injuries and Death H-145.997

Our AMA recognizes that uncontrolled ownership and use of firearms, especially handguns, is a serious threat to the public's health inasmuch as the weapons are one of the main causes of intentional and unintentional injuries and deaths. Therefore, the AMA: (1) encourages and endorses the development and presentation of safety education programs that will engender more responsible use and storage of firearms;

(2) urges that government agencies, the CDC in particular, enlarge their efforts in the study of firearm-related injuries and in the development of ways and means of reducing such injuries and deaths;

(3) urges Congress to enact needed legislation to regulate more effectively the importation and interstate traffic of all handguns;

(4) urges the Congress to support recent legislative efforts to ban the manufacture and importation of nonmetallic, not readily detectable weapons, which also resemble toy guns; (5) encourages the improvement or modification of firearms so as to make them as safe as humanly possible;

(6) encourages nongovernmental organizations to develop and test new, less hazardous designs for firearms;

(7) urges that a significant portion of any funds recovered from firearms manufacturers and dealers through legal proceedings be used for gun safety education and gun-violence prevention; and

(8) strongly urges US legislators to fund further research into the epidemiology of risks related to gun violence on a national level.

Citation: (CSA Rep. A, I-87; Reaffirmed: BOT Rep. I-93-50; Appended: Res. 403, I-99; Reaffirmation A-07; Reaffirmation A-13; Appended: Res. 921, I-13)

Epidemiology of Firearm Injuries D-145.999

Our AMA will: (1) strongly urge the Administration and Congress to encourage the Centers for Disease Control and Prevention to conduct an epidemiological analysis of the data of firearm-related injuries and deaths; and (2) urge Congress to provide sufficient resources to enable the CDC to collect and analyze firearm-related injury data and report to Congress and the nation via a broadly disseminated document, so that physicians and other health care providers, law enforcement and society at large may be able to prevent injury, death and the other costs to society resulting from firearms.

Citation: (Res. 424, A-03; Reaffirmation A-13; Modified: CSAPH Rep. 1, A-13)

AMA Campaign to Reduce Firearm Deaths H-145.988

The AMA supports educating the public regarding methods to reduce death and injury due to keeping guns, ammunition and other explosives in the home.

Citation: (Res. 410, A-93; Reaffirmed: CLRPD Rep. 5, A-03; Reaffirmation A-13; Modified: CSAPH Rep. 1, A-13)

Physicians and the Public Health Issues of Gun Safety D-145.997

Our AMA will request that the US Surgeon General develop a report and campaign aimed at reducing gun-related injuries and deaths.

Citation: (Res. 410, A-13)

Guns in Hospitals H-215.977

1. The policy of the AMA is to encourage hospitals to incorporate, within their security policies, specific provisions on the presence of firearms in the hospital. The AMA believes the following points merit attention:

A. Given that security needs stem from local conditions, firearm policies must be developed with the cooperation and collaboration of the medical staff, the hospital security staff, the hospital administration, other hospital staff representatives, legal counsel, and local law enforcement officials. Consultation with outside experts, including state and federal law enforcement agencies, or patient advocates may be warranted.

B. The development of these policies should begin with a careful needs assessment that addresses past issues as well as future needs.

C. Policies should, at minimum, address the following issues: a means of identification for all staff and visitors; restrictions on access to the hospital or units within the hospital, including the means of ingress and egress; changes in the physical layout of the facility that would improve security; the possible use of metal detectors; the use of monitoring equipment such as closed circuit television; the development of an emergency signaling system; signage for the facility regarding the possession of weapons; procedures to be followed when a weapon is discovered; and the means for securing or controlling weapons that may be brought into the facility, particularly those considered contraband but also those carried in by law enforcement personnel.

D. Once policies are developed, training should be provided to all members of the staff, with the level and type of training being related to the perceived risks of various units within the facility. Training to recognize and defuse potentially violent situations should be included.

E. Policies should undergo periodic reassessment and evaluation.

F. Firearm policies should incorporate a clear protocol for situations in which weapons are brought into the hospital.

2. Our AMA will advocate that hospitals and other healthcare delivery settings limit guns and conducted electrical weapons in units where patients suffering from mental illness are present

Citation: BOT Rep. 23, I-94; Reaffirmation I-03; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 2, I-10; Appended: Res. 426, A-16

Firearm Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care H-145.975

1. Our AMA supports: a) federal and state research on firearm-related injuries and deaths; b) increased funding for and the use of state and national firearms injury databases, including the expansion of the National Violent Death Reporting System to all 50 states and U.S. territories, to inform state and federal health policy; c) encouraging physicians to access evidence-based data regarding firearm safety to educate and counsel patients about firearm safety; d) the rights of physicians to have free and open communication with their patients regarding firearm safety and the use of gun locks in their homes; e) encouraging local projects to facilitate the low-cost distribution of gun locks in homes; f) encouraging physicians to become involved in local firearm

safety classes as a means of promoting injury prevention and the public health; and g) encouraging CME providers to consider, as appropriate, inclusion of presentations about the prevention of gun violence in national, state, and local continuing medical education programs

2. Our AMA supports initiatives to enhance access to mental and cognitive health care, with greater focus on the diagnosis and management of mental illness and concurrent substance abuse disorders, and work with state and specialty medical societies and other interested stakeholders to identify and develop standardized approaches to mental health assessment for potential violent behavior.

Citation: Sub. Res. 221, A-13; Appended: Res. 416, A-14; Reaffirmed: Res. 426, A-16

Data on Firearm Deaths and Injuries H-145.984

The AMA supports legislation or regulatory action that: (1) requires questions in the National Health Interview Survey about firearm related injury as was done prior to 1972; (2) mandates that the Centers for Disease Control and Prevention develop a national firearm fatality reporting system; and (3) expands activities to begin tracking by the National Electronic Injury Surveillance System.

Citation: (Res. 811, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmation A-13)

Gun Control H-145.991

The AMA supports using its influence in matters of health to effect passage of legislation in the Congress of the U.S. mandating a national waiting period that allows for a police background and positive identification check for anyone who wants to purchase a handgun from a gun dealer anywhere in our country.

Citation: (Sub. Res. 34, I-89; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-07)

Firearm Availability H-145.996

Our AMA: (1) Advocates a waiting period and background check for all firearm purchasers; (2) encourages legislation that enforces a waiting period and background check for all firearm purchasers; and (3) urges legislation to prohibit the manufacture, sale or import of lethal and non-lethal guns made of plastic, ceramics, or other non-metallic materials that cannot be detected by airport and weapon detection devices.

Citation: Res. 140, I-87; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Modified: BOT Rep. 12, A-16

Gun Regulation H-145.999

Our AMA supports stricter enforcement of present federal and state gun control legislation and the imposition of mandated penalties by the judiciary for crimes committed with the use of a firearm, including the illegal possession of a firearm.

Citation: (Sub. Res. 31, I-81; Reaffirmed: CLRPD Rep. F, I-91; Amended: BOT Rep. I-93-50; Reaffirmed: Res. 409, A-00; Reaffirmation A-07)

Waiting Period Before Gun Purchase H-145.992

The AMA supports legislation calling for a waiting period of at least one week before purchasing any form of firearm in the U.S.

Citation: (Res. 171, A-89; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-07)

Gun Safety H-145.978

Our AMA: (1) recommends and promotes the use of trigger locks and locked gun cabinets as safety precautions; and (2) endorses standards for firearm construction reducing the likelihood of accidental discharge when a gun is dropped and that standardized drop tests be developed.

Citation: (Res. 425, I-98; Reaffirmed: Res. 409, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-13)

Ban on Handguns and Automatic Repeating Weapons H-145.985

It is the policy of the AMA to: (1) Support interventions pertaining to firearm control, especially those that occur early in the life of the weapon (e.g., at the time of manufacture or importation, as opposed to those involving possession or use). Such interventions should include but not be limited to:

(a) mandatory inclusion of safety devices on all firearms, whether manufactured or imported into the United States, including built-in locks, loading indicators, safety locks on triggers, and increases in the minimum pressure required to pull triggers;

(b) bans on the possession and use of firearms and ammunition by unsupervised youths under the age of 18;

(c) the imposition of significant licensing fees for firearms dealers;

(d) the imposition of federal and state surtaxes on manufacturers, dealers and purchasers of handguns and semiautomatic repeating weapons along with the ammunition used in such firearms, with the attending revenue earmarked as additional revenue for health and law enforcement activities that are directly related to the prevention and control of violence in U.S. society; and

(e) mandatory destruction of any weapons obtained in local buy-back programs.

(2) Support legislation outlawing the Black Talon and other similarly constructed bullets.

(3) Support the right of local jurisdictions to enact firearm regulations that are stricter than those that exist in state statutes and encourage state and local medical societies to evaluate and support local efforts to enact useful controls.

Citation: (BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-14)

Restriction of Assault Weapons H-145.993

Our AMA supports appropriate legislation that would restrict the sale and private ownership of inexpensive handguns commonly referred to as "Saturday night specials," and large clip, high-rate-of-fire automatic and semi-automatic firearms, or any weapon that is modified or redesigned to operate as a large clip, high-rate-of-fire automatic or semi-automatic weapon.

Citation: (Sub. Res. 264, A-89; Reaffirmed: BOT Rep. 50, I-93; Amended: Res. 215, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmation A-07)

Guns in School Settings H-60.947

Our AMA recommends: (1) all children who take guns or other weapons to school should receive an evaluation by a psychiatrist or an appropriately trained mental health professional; and (2) that children who are determined by such evaluation to have a mental illness should receive appropriate treatment.

Citation: (Res. 402, I-98; Reaffirmed: CSAPH Rep. 2, A-08)

Prevention of Unintentional Shooting Deaths Among Children H-145.979

Our AMA supports legislation at the federal and state levels making gun owners legally responsible for injury or death caused by a child gaining unsupervised access to a gun, unless it can be shown that reasonable measures to prevent child access to the gun were taken by the gun owner, and that the specifics, including the nature of "reasonable measures," be determined by the individual constituencies affected by the law.

Citation: (Res. 204, I-98; Reaffirmed: BOT Rep. 23, A-09)

Prevention of Firearm Accidents in Children H-145.990

Our AMA (1) supports increasing efforts to reduce pediatric firearm morbidity and mortality by encouraging its members to (a) inquire as to the presence of household firearms as a part of childproofing the home; (b) educate patients to the dangers of firearms to children; (c) encourage patients to educate their children and neighbors as to the dangers of firearms; and (d) routinely remind patients to obtain firearm safety locks, to store firearms under lock and key, and to store ammunition separately from firearms; (2) encourages state medical societies to work with other organizations to increase public education about firearm safety; and (3) encourages organized medical staffs and other physician organizations, including state and local medical societies, to recommend programs for teaching firearm safety to children.

Citation: (Res. 165, I-89; Reaffirmed: Sunset Report and Appended: Sub. Res. 401, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-13)

Preventing Firearm-Related Injury and Morbidity in Youth D-145.996

Our American Medical Association will identify and support the distribution of firearm safety materials that are appropriate for the clinical setting.

Citation: (Res. 216, A-15)

Firearm Safety Counseling in Physician-Led Health Care Teams H-145.976

Our AMA: (1) will oppose any restrictions on physicians' and other members of the physician-led health care team's ability to inquire and talk about firearm safety issues and risks with their patients; (2) will oppose any law restricting physicians' and other members of the physician-led health care team's discussions with patients and their families about firearms as an intrusion into medical privacy; and (3) encourages dissemination of educational materials related to firearm safety to be used in undergraduate medical education.

Citation: (Res. 219, I-11; Reaffirmation A-13; Modified: Res. 903, I-13)

Safety of Nonpowder (Gas-Loaded/Spring-Loaded) Guns H-145.989

It is the policy of the AMA to encourage the development of appropriate educational materials designed to enhance physician and general public awareness of the safe use of as well as the dangers inherent in the unsafe use of nonpowder (gas-loaded/spring-loaded) guns.

Citation: (Res. 423, I-91; Modified: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11)

Control of Non-Detectable Firearms H-145.994

The AMA supports a ban on the manufacture, importation, and sale of any firearm which cannot be detected by ordinary airport screening devices.

Citation: (Sub. Res. 79, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CLRPD Rep. 1, A-08)

Firearm Availability H-145.996

Our AMA: (1) Advocates a waiting period and background check for all firearm purchasers; (2) encourages legislation that enforces a waiting period and background check for all firearm purchasers; and (3) urges legislation to prohibit the manufacture, sale or import of lethal and non-lethal guns made of plastic, ceramics, or other non-metallic materials that cannot be detected by airport and weapon detection devices.

Citation: Res. 140, I-87; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Modified: BOT Rep. 12, A-16

School Violence H-145.983

The AMA encourages states to adopt legislation enabling schools to limit and control the possession and storage of weapons or potential weapons on school property.

Citation: (Sub. Res. 402, I-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15)

Preventing Firearm-Related Injury and Morbidity in Youth D-145.996

Our American Medical Association will identify and support the distribution of firearm safety materials that are appropriate for the clinical setting.

Citation: (Res. 216, A-15)

Workplace Violence Prevention H-215.978

Our AMA: (1) supports the efforts of the International Association for Healthcare Security and Safety, the AHA, and The Joint Commission to develop guidelines or standards regarding hospital security issues and recognizes these groups' collective expertise in this area. As standards are developed, the AMA will ensure that physicians are advised; and (2) encourages physicians to: work with their hospital safety committees to address the security issues within particular hospitals; become aware of and familiar with their own institution's policies and procedures; participate in training to prevent and respond to workplace violence threats; report all incidents of workplace violence; and promote a culture of safety within their workplace.

Citation: BOT Rep. 16, A-94; Reaffirmation I-99; Reaffirmation I-03; Modified: CSAPH Rep. 1, A-13; Modified: CSAPH Rep. 07, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 202
(I-16)

Introduced by: Resident and Fellow Section

Subject: Inclusion of Sexual Orientation and Gender Identity Information in Electronic Health Records

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

Whereas, The Institute of Medicine¹ and The Joint Commission² have recommended that health care professionals ask patients about their sexual orientation and gender identity (SOGI) status in clinical settings and including such data in Electronic Health Records (EHRs);³ and

Whereas, SOGI data collection is increasingly viewed as a critical step toward systematically documenting and addressing health disparities affecting lesbian, gay, bisexual, and transgender (LGBT) people;⁴ and

Whereas, New rules from the Centers for Medicare & Medicaid Services and the Office of the National Coordinator of Health Information Technology require all electronic health record systems (EHRs) certified under Stage 3 of the Meaningful Use program to allow users to record, change, and access structured data on sexual orientation and gender identity; and

Whereas, An Institute of Medicine report, “The Health of Lesbian, Gay, Bisexual, and Transgender People: Building a Foundation for Better Understanding,” aptly points out “Although a modest body of knowledge on LGBT health has been developed, these populations, stigmatized as sexual and gender minorities, have been the subject of relatively little health research”; and

Whereas, Research supports the use of a two-question process in collecting gender identity data by asking sex assigned at birth and current gender;^{5,6,7} and

Whereas, Within standardized nomenclature there are a variety of terminology standards (e.g. Systematized Nomenclature of Medicine - Clinical Terms⁸) that do not provide for gender identity to be collected as a two-step process; therefore be it

¹ Committee on Lesbian, Gay, Bisexual, and Transgender Health Issues and Research Gaps and Opportunities; Board on the Health of Select Populations; Institute of Medicine (2011) The health of lesbian, gay, bisexual, and transgender people: Building a foundation for better understanding. Washington, DC: National Academies Press. Available: http://www.nap.edu/catalog.php?record_id=13128. Accessed 2015 Oct 14.

² The Joint Commission (2011) Advancing effective communication, cultural competence, and patient- and family-centered care for the lesbian, gay, bisexual, and transgender community: A field guide. Oakbrook Terrace, IL: The Joint Commission.

³ U.S. Department of Health and Human Services (29 June 2011) Affordable Care Act to improve data collection, reduce health disparities. News release.

⁴ U.S. Department of Health and Human Services (no date) Healthy People 2020. Lesbian, gay, bisexual and transgender health. Available: <http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=25>. Accessed 2015 Oct 14.

⁵ The GenIUSS Group. (2014). Best Practices for Asking Questions to Identify Transgender and Other Gender Minority Respondents on Population-Based Surveys. J.L. Herman (Ed.). Los Angeles, CA: The Williams Institute

⁶ Bradford, J.B., Cahill, S., Grasso, C., Makadon, H.J. Policy Focus: How to Gather Data on Sexual Orientation and Gender Identity in Clinical Settings. The Fenway Institute. 2012

⁷ National LGBT Health Education Center. Collecting Sexual Orientation and Gender Identity Data in Electronic Health Records: Taking the Next Steps. The Fenway Institute. August 2015

⁸ Wikipedia contributors. SNOMED CT. Wikipedia, The Free Encyclopedia. March 23, 2016, 17:46 UTC. Available at: https://en.wikipedia.org/w/index.php?title=SNOMED_CT&oldid=711567365. Accessed April 29, 2016.

- 1 RESOLVED, That our American Medical Association advocate for inclusion of sexual
- 2 orientation and gender in electronic health records (EHRs). (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/12/16

RELEVANT AMA POLICY

PROSPECTIVE PATIENTS E-1.1.2

As professionals dedicated to protecting the well-being of patients, physicians have an ethical obligation to provide care in cases of medical emergency. Physicians must also uphold ethical responsibilities not to discriminate against a prospective patient on the basis of race, gender, sexual orientation or gender identity, or other personal or social characteristics that are not clinically relevant to the individual's care. Nor may physicians decline a patient based solely on the individual's infectious disease status. Physicians should not decline patients for whom they have accepted a contractual obligation to provide care.

However, physicians are not ethically required to accept all prospective patients. Physicians should be thoughtful in exercising their right to choose whom to serve.

A physician may decline to establish a patient-physician relationship with a prospective patient, or provide specific care to an existing patient, in certain limited circumstances:

- (a) The patient requests care that is beyond the physician's competence or scope of practice; is known to be scientifically invalid, has no medical indication, or cannot reasonably be expected to achieve the intended clinical benefit; or is incompatible with the physician's deeply held personal, religious, or moral beliefs in keeping with ethical guidelines on exercise of conscience.
- (b) The physician lacks the resources needed to provide safe, competent, respectful care for the individual. Physicians may not decline to accept a patient for reasons that would constitute discrimination against a class or category of patients
- (c) Meeting the medical needs of the prospective patient could seriously compromise the physician's ability to provide the care needed by his or her other patients. The greater the prospective patient's medical need, however, the stronger is the physician's obligation to provide care, in keeping with the professional obligation to promote access to care.
- (d) The individual is abusive or threatens the physician, staff, or other patients, unless the physician is legally required to provide emergency medical care. Physicians should be aware of the possibility that an underlying medical condition may contribute to this behavior.

AMA Principles of Medical Ethics: I,VI,VIII,X

Nondiscriminatory Policy for the Health Care Needs of LGBT Populations H-65.976

Our AMA encourages physician practices, medical schools, hospitals, and clinics to broaden any nondiscriminatory statement made to patients, health care workers, or employees to include "sexual orientation, sex, or gender identity" in any nondiscrimination statement.

Res. 414, A-04 Modified: BOT Rep. 11, A-07 Modified: Res. 08, A-16

Eliminating Health Disparities - Promoting Awareness and Education of Lesbian, Gay, Bisexual, and Transgender (LGBT) Health Issues in Medical Education H-295.878

Our AMA: (1) supports the right of medical students and residents to form groups and meet on-site to further their medical education or enhance patient care without regard to their gender,

gender identity, sexual orientation, race, religion, disability, ethnic origin, national origin or age; (2) supports students and residents who wish to conduct on-site educational seminars and workshops on health issues in Lesbian, Gay, Bisexual, and Transgender communities; and (3) encourages the Liaison Committee on Medical Education (LCME), the American Osteopathic Association (AOA), and the Accreditation Council for Graduate Medical Education (ACGME) to include LGBT health issues in the cultural competency curriculum for both undergraduate and graduate medical education; and (4) encourages the LCME, AOA, and ACGME to assess the current status of curricula for medical student and residency education addressing the needs of pediatric and adolescent LGBT patients.

Citation: Res. 323, A-05; Modified in lieu of Res. 906, I-10; Reaffirmation A-11; Reaffirmation A-12; Reaffirmation A-16

Health Disparities Among Gay, Lesbian, Bisexual and Transgender Families D-65.995

Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and same sex parents in same sex households by supporting equality in laws affecting health care of members in same sex partner households and their dependent children. (Res. 445, A-05; Modified: CSAPH Rep. 1, A-15)

National Health Survey H-440.885

Our AMA supports a national health survey that incorporates a representative sample of the U.S. population of all ages (including adolescents) and includes questions on sexual orientation, gender identity, and sexual behavior. (CSA Rep. 4, A-03; Modified: BOT Rep. 11, A-07)

Goal of Health Care Data Collection H-406.999

The AMA (1) continues to advocate that health care data collected by government and third party payers be used for education of both consumers and providers; and (2) believes that government, third party payers and self-insured companies should make physician-specific utilization information available to medical societies.

BOT Rep. W, A-92 Reaffirmed: Res. 719, A-93 BOT Rep. Y, I-85 Reaffirmed CLRPD Rep. 2, I-95 CMS Rep. 10, A-96 Reaffirmed: CMS Rep. 8, A-06 Reaffirmed: CMS Rep. 01, A-16

National Health Information Technology D-478.995

1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden to the physician and maintaining the art of medicine without compromising patient care.

2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C) advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care.; and (D) advocates for more research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems.

3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians' practices; and (B) develop minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs.

4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery.
5. Our AMA will seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology's (ONC) certification process.
6. Our AMA will collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability.
7. Our AMA will directly engage the EHR vendor community to promote improvements in EHR usability.(Res. 730, I-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation A-10; Reaffirmed: BOT Rep. 16, A-11; Modified: BOT Rep. 16, A-11; Modified: BOT Rep. 17, A-12; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed: BOT Rep. 24, A-13; Reaffirmed in lieu of Res. 724, A-13; Appended: Res. 720, A-13; Appended: Sub. Res. 721, A-13; Reaffirmed: CMS Rep. 4, I-13; Reaffirmation I-13; Appended: BOT Rep. 18, A-14; Appended: BOT Rep. 20, A-14; Reaffirmation A-14; Reaffirmed: BOT Rep. 17, A-15; Reaffirmed in lieu of Res. 208, A-15; Reaffirmed in lieu of Res. 223, A-15)

Health Information Technology D-478.994

Our AMA will:

- (1) support legislation and other appropriate initiatives that provide positive incentives for physicians to acquire health information technology (HIT);
- (2) pursue legislative and regulatory changes to obtain an exception to any and all laws that would otherwise prohibit financial assistance to physicians purchasing HIT;
- (3) support initiatives to ensure interoperability among all HIT systems; and
- (4) support the indefinite extension of the Stark Law exception and the Anti-Kickback Statute safe harbor for the donation of Electronic Health Record (EHR) products and services, and will advocate for federal regulatory reform that will allow for indefinite extension of the Stark Law exception and the Anti-Kickback Statute safe harbor for the donation of EHR products and services.(Res. 723, A-05; Reaffirmation A-07; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed: Res. 726, A-08; Reaffirmation I-08; Reaffirmation I-09; Reaffirmation A-10; Reaffirmation I-10; Reaffirmed: Res. 205, A-11; Appended: Res. 220, A-12; Reaffirmed in lieu of Res. 218, I-12; Reaffirmed in lieu of Res. 219, I-12; Reaffirmed in lieu of Res. 226, I-12; Reaffirmed in lieu of Res. 228, I-12; Reaffirmed in lieu of Res. 228, I-13; Reaffirmation A-14)

Patient Information in the Electronic Medical Record H-315.971

AMA Guidelines for Patient Access to Physicians' Electronic Medical Record Systems:

- (1) Online interactions are best conducted over a secure network, with provisions for privacy and security, including encryption.
- (2) Physicians should take reasonable steps to authenticate the identity of correspondent(s) in electronic communication and to ensure that recipients of information are authorized to receive it. Physicians are encouraged to follow the following guidelines for patient authentication: (a) Have a written patient authentication protocol for all practice personnel and require all members of the physician's staff to understand and adhere to the protocol. (b) Establish minimum standards for patient authentication when a patient is new to a practice or not well known. (c) Keep a written record, electronic or paper, of each patient authenticated.
- (3) Prior to granting a patient access to his or her EMR, informed consent should be obtained regarding the appropriate use of and limitations to access of personal health information

contained in the EMR. Physicians should develop and adhere to specific guidelines and protocols for online communications and/or patient access to the EMR for all patients, and make these guidelines known to the patient as part of the informed consent process. Such guidelines should specify mechanisms for emergency access to the EMR and protection for and limitation of access to, highly sensitive medical information.

(4) If the patient is allowed to make annotations to his or her EMR (i.e., over-the-counter drug treatments, family medical history, other health information), the annotation should be indicated as authored by the patient with sourcing information (i.e., date and time stamp, login and IP address if applicable). A permanent record of all allowed annotations and communications relevant to the ongoing medical care of the patient should be maintained as part of the patient's medical record.

(5) Physicians retain the right to determine which information they do and/or do not import from a PHR into their EHR/EMR and to set parameters based on the clinical relevance of data contained within personal health records.

(6) Any data imported into a physician's EMR/EHR from a patient's personal health record (PHR) must preserve the source information of the original data and be further identified as to the PHR from which it was imported as additional source information to preserve an accurate audit trail.

(7) In order to maintain the legitimate recording of clinical events, patients should not be able to delete any health information in the record. Rather, in order to maintain the forensic nature of the record, patients should only be able to add notations when appropriate.

(8) Disclosures of Personal Health Information should comply with all applicable federal and state laws, privileges recognized in federal or state law, including common law, and the ethical requirements of physicians. (BOT Rep. 19, A-07; Modified: BOT Rep. 16, A-10)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 203
(I-16)

Introduced by: Resident and Fellow Section

Subject: Universal Prescriber Access to Prescription Drug Monitoring Programs

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

Whereas, The United States has been facing a rise in the number of opioid-related deaths over the past several years a phenomenon known as “the opioid epidemic”, with over 47,000 overdose deaths nationwide in 2014 compared to roughly 17,400 in 2000;^{1,2} and

Whereas, Our AMA recognizes the role prescribing practices play in contributing to drug abuse, and supports training in appropriate practices to students and residents (AMA Policy H-95.990); and

Whereas, Prescription drug monitoring programs (PDMPs) are state-run programs that can allow prescribers to securely see a patient’s recently filled prescriptions for controlled substances; and

Whereas, In an otherwise highly fragmented healthcare system, PDMPs are central databases that allow prescribers to better monitor for inappropriate medication doses, abuse of controlled substances, or diversion of controlled substances for street sale; and

Whereas, Our AMA supports the creation and voluntary use of state-run PDMPs by physicians (H-95.945), and our AMA and AMA-RFS support the creation of a national PDMP; and

Whereas, PDMPs exist in 49 states, though the structure and administration of the programs differ throughout the country; and

Whereas, Resident and fellow physicians made up roughly 10.9% of the physician workforce in 2014 and can write prescriptions for controlled substances in most states;³ and

Whereas, Midlevel providers including nurse practitioners and physician’s assistants can also write prescriptions for controlled substances; and

Whereas, Resident physicians routinely prescribe controlled substances for their patients including opioid pain medications, yet they do not universally have access to their state’s PDMP;⁴ and

¹ Centers for Disease Control and Prevention. CDC Grand Rounds: Prescription Drug Overdoses—A US Epidemic. Atlanta, GA: Centers for Disease Control and Prevention; 2012. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm>. Accessed March 30, 2016.

² Center for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Mortality File. (2015). Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014. Atlanta, GA: Center for Disease Control and Prevention. Available at http://www.cdc.gov/nchs/data/health_policy/AADR_drug_poisoning_involving_OA_Heroin_US_2000-2014.pdf. Accessed April 26, 2016.

³ American Association of Medical Colleges. 2015 State Physician Workforce Data Book. Washington, D.C. 2015. Available at: <https://www.aamc.org/data/workforce/reports/442830/statedataandreports.html>. Accessed March 30, 2016.

⁴ Freyer, F. “Doctors in training gain access to prescription database.” Boston Globe. Boston, MA. December 14, 2015. Available at: <https://www.bostonglobe.com/metro/2015/12/13/medical-residents-gain-access-prescription-database/uqrbMC9kfsZX5SjAU8Snck/story.html>. Accessed April 26, 2016.

1 Whereas, Many of the existing 49 state laws responsible for the creation of PDMPs do not
2 explicitly grant resident physicians access to PDMPs; therefore be it
3

4 RESOLVED, That our American Medical Association support legislation and regulatory action
5 that would authorize all prescribers of controlled substances, including residents, to have
6 access to their state prescription drug monitoring program. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/12/16

RELEVANT AMA POLICY

Drug Abuse Related to Prescribing Practices H-95.990

1. Our AMA recommends the following series of actions for implementation by state medical societies concerning drug abuse related to prescribing practices:

A. Institution of comprehensive statewide programs to curtail prescription drug abuse and to promote appropriate prescribing practices, a program that reflects drug abuse problems currently within the state, and takes into account the fact that practices, laws and regulations differ from state to state. The program should incorporate these elements: (1) Determination of the nature and extent of the prescription drug abuse problem; (2) Cooperative relationships with law enforcement, regulatory agencies, pharmacists and other professional groups to identify "script doctors" and bring them to justice, and to prevent forgeries, thefts and other unlawful activities related to prescription drugs; (3) Cooperative relationships with such bodies to provide education to "duped doctors" and "dated doctors" so their prescribing practices can be improved in the future; (4) Educational materials on appropriate prescribing of controlled substances for all physicians and for medical students.

B. Placement of the prescription drug abuse programs within the context of other drug abuse control efforts by law enforcement, regulating agencies and the health professions, in recognition of the fact that even optimal prescribing practices will not eliminate the availability of drugs for abuse purposes, nor appreciably affect the root causes of drug abuse. State medical societies should, in this regard, emphasize in particular: (1) Education of patients and the public on the appropriate medical uses of controlled drugs, and the deleterious effects of the abuse of these substances; (2) Instruction and consultation to practicing physicians on the treatment of drug abuse and drug dependence in its various forms.

2. Our AMA:

A. promotes physician training and competence on the proper use of controlled substances;

B. encourages physicians to use screening tools (such as NIDAMED) for drug use in their patients;

C. will provide references and resources for physicians so they identify and promote treatment for unhealthy behaviors before they become life-threatening; and

D. encourages physicians to query a state's controlled substances databases for information on their patients on controlled substances.

3. The Council on Science and Public Health will report at the 2012 Annual Meeting on the effectiveness of current drug policies, ways to prevent fraudulent prescriptions, and additional reporting requirements for state-based prescription drug monitoring programs for veterinarians, hospitals, opioid treatment programs, and Department of Veterans Affairs facilities.

4. Our AMA opposes any federal legislation that would require physicians to check a prescription drug monitoring program (PDMP) prior to prescribing controlled substances. (CSA Rep. C, A-81; Reaffirmed: CLRPD Rep. F, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Appended: Res. 907, I-11; Appended: Res. 219, A-12; Reaffirmation A-15; Reaffirmed: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15)

Prescription Drug Diversion, Misuse and Addiction H-95.945

Our AMA: (1) supports permanent authorization of and adequate funding for the National All Schedules Prescription Electronic Reporting (NASPER) program so that every state, district and territory of the US can have an operational Prescription Drug Monitoring Program (PDMP) for use of clinicians in all jurisdictions; (2) considers PDMP data to be protected health information, and thus protected from release outside the healthcare system unless there is a HIPAA exception or specific authorization from

the individual patient to release personal health information, and recommends that others recognize that PDMP data is health information; (3) recommends that PDMP's be designed such that data is immediately available when clinicians query the database and are considering a decision to prescribe a controlled substance; (4) recommends that individual PDMP databases be designed with connectivity among each other so that clinicians can have access to PDMP controlled substances dispensing data across state boundaries; and (5) will promote medical school and postgraduate training that incorporates curriculum topics focusing on pain medicine, addiction medicine, safe prescribing practices, safe medication storage and disposal practices, functional assessment of patients with chronic conditions, and the role of the prescriber in patient education regarding safe medication storage and disposal practices, in order to have future generations of physicians better prepared to contribute to positive solutions to the problems of prescription drug diversion, misuse, addiction and overdose deaths. (Res. 223, A-12; Reaffirmed: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15; Reaffirmation A-16)

Development and Promotion of Single National Prescription Drug Monitoring Program H-95.939

Our American Medical Association (1) supports the voluntary use of state-based prescription drug monitoring programs (PDMP) when clinically appropriate; (2) encourages states to implement modernized PDMPs that are seamlessly integrated into the physician's normal workflow, and provide clinically relevant, reliable information at the point of care; (3) supports the ability of physicians to designate a delegate to perform a check of the PDMP, where allowed by state law; (4) encourage states to foster increased PDMP use through a seamless registration process; (5) encourages all states to determine how to use a PDMP to enhance treatment for substance use disorder and pain management; (6) encourages states to share access to PDMP data across state lines, within the safeguards applicable to protected health information; and (7) encourages state PDMPs to adopt uniform data standards to facilitate the sharing of information across state lines. (BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15; Reaffirmation A-16)

Prescription Drug Monitoring Program Confidentiality H-95.946

Our AMA will: (1) advocate for the placement and management of state-based prescription drug monitoring programs with a state agency whose primary purpose and mission is health care quality and safety rather than a state agency whose primary purpose is law enforcement or prosecutorial; (2) encourage all state agencies responsible for maintaining and managing a prescription drug monitoring program (PDMP) to do so in a manner that treats PDMP data as health information that is protected from release outside of the health care system; and (3) advocate for strong confidentiality safeguards and protections of state databases by limiting database access by non-health care individuals to only those instances in which probable cause exists that an unlawful act or breach of the standard of care may have occurred. (Res. 221, A-1; Reaffirmed: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 204
(I-16)

Introduced by: New York

Subject: Seamless Conversion of Medicare Advantage Programs

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The Centers for Medicare and Medicaid Services is permitting a process of "seamless
2 conversion," wherein seniors are transitioned from traditional Medicare insurance products into
3 Medicare Advantage options with seniors having little understanding of the implications, the
4 opting out process, or informed consent; and
5

6 Whereas, Many of the Medicare Advantage plans have select narrow provider panels which
7 may disrupt a patient's established doctor/patient relationship and adversely affect the patient's
8 healthcare delivery and financial wellbeing; and
9

10 Whereas, This practice of seamless conversion is projected to augment for the January 2017
11 enrollment period; and
12

13 Whereas, There is little time in the upcoming enrollment period to appropriately educate seniors
14 on these efforts and assist them in making appropriate choices for their healthcare and financial
15 needs; therefore be it
16

17 RESOLVED, That our American Medical Association collaborate with senior groups, including
18 AARP, to raise awareness among physicians and seniors regarding the implications of the
19 practice of "seamless conversion" (Directive to Take Action); and be it further
20

21 RESOLVED, That our AMA immediately begin to advocate with Congress and the Centers for
22 Medicare and Medicaid Services to implement an immediate moratorium on the practice of
23 seamless conversion. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/21/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 205
(I-16)

Introduced by: District of Columbia

Subject: AMA Study of the Affordable Care Act

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The Patient Protection and Affordable Care Act (PPACA or ACA) was supported by
2 our AMA; and
3

4 Whereas, The ACA has not achieved many of the goals it intended to accomplish; and
5

6 Whereas, Only 16 states and the District of Columbia created state-based exchanges. Of that
7 number, four have failed (Hawaii, New Mexico, Nevada and Oregon) -- and Kentucky's will be
8 dismantled or shuttered next year. (The Oregon exchange received \$350 million in federal
9 funds, but never created a functional website or enrolled a single person in private insurance
10 online); and
11

12 Whereas, Premium costs in the exchanges increased about 12% nationwide from 2015 to 2016,
13 and current estimates are that the increase from 2016 to 2017 will double that; and
14

15 Whereas, Deductible costs and pharmaceutical costs are rising at alarming rates; and
16

17 Whereas, Insurers are increasingly fleeing--1/3 of counties in the U.S. will have only one option
18 in the exchanges next year, and the populace is not finding the exchanges attractive; and
19

20 Whereas, Millions of Americans remain without health insurance, or were pushed into struggling
21 Medicaid rosters; and
22

23 Whereas, Our AMA has a considerable volume of resolutions and reports pertinent to the
24 matter, and this extensive HOD Policy could guide the public debate; and
25

26 Whereas, Our AMA with its Federation is the most qualified entity to advise the health care
27 industry and Congress on what can be done to improve the current ACA model; therefore be it
28

29 RESOLVED, That our American Medical Association study, and using our extensive HOD
30 policy, identify what needs to be changed/fixed with the ACA (Directive to Take Action); and be
31 it further
32

33 RESOLVED, That our AMA compile a policy compendium of AMA HOD Policy or links to that
34 policy, to provide to legislators, think tanks, and the public with reliable accurate ideas and
35 knowledge (Directive to Take Action); and be it further
36

37 RESOLVED, That a comprehensive report on how to change and improve the ACA be
38 presented back to the House of Delegates at the 2017 Annual Meeting. (Directive to Take
39 Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 206
(I-16)

Introduced by: Medical Student Section

Subject: Advocacy and Studies on Affordable Care Act Section 1332
(State Innovation Waivers)

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

Whereas, Despite improvements in access to health insurance, it is projected that approximately 31 million people will remain without adequate health insurance, even with the full implementation of the Affordable Care Act (ACA);¹ and

Whereas, Many patients with health insurance purchased through the ACA state and federal healthcare exchanges continue to encounter difficulties in access and affordability of care due to rising co-pays, deductibles, out-of-pocket costs and narrow provider networks;² and

Whereas, Section 1332 of the ACA allows states³ to apply for waivers to be exempt from some of the requirements of the legislation so that they may introduce their own innovations, which they believe would better provide healthcare benefits, access and affordability for the residents of their states;⁴ and

Whereas, One of the statutory criteria of qualifying for a Section 1332 waiver is that innovations be “deficit-neutral” and, as per federal guidance, “a waiver that increases the deficit in any given year is less likely to meet the deficit neutrality requirement”;⁵ and

Whereas, The Federal guidance reducing likelihood of waiver approval based on one-year deficit neutrality will likely impair states’ abilities to obtain waivers and pursue innovations that will have initial costs in any particular year but still achieve deficit neutrality through long-term cost savings;⁶ and

Whereas, The National Governor’s Association (NGA) issued recommendations to the Department of Health and Human Services and the Department of Treasury recommending that “Section 1332 waiver applications be part of state efforts to innovate in Medicaid and reach additional populations”;^{7,8} and

¹ Effects of the Affordable Care Act on Health Insurance Coverage – Baseline Projections,” ed. Congressional Budget Office (2014)

² “State variation in narrow networks on the ACA marketplaces” Leonard Davis Institute of Health Economics. Aug 2015. Web. 20 Apr 2016. <<http://ldi.upenn.edu/sites/default/files/rte/state-narrow-networks.pdf>>

³ California, Colorado, New Mexico, Minnesota, Arkansas, Kentucky, Ohio, Hawai’i, Rhode Island, Massachusetts, and Vermont have taken steps to apply for a Section 1332 Innovation Waiver.

⁴ “SECTION 1332: STATE INNOVATION WAIVERS.” Centers for Medicare & Medicaid Services. Web. 12 Feb. 2016.

⁵ “Waivers for State Innovation.” Federal Register. Web. 12 Feb. 2016. <<https://www.federalregister.gov/articles/2015/12/16/2015-31563/waivers-for-state-innovation#p-44>>.

⁶ Howard, H. and Meuse, D. New Section 1332 Guidance A Mixed Bag for States. <http://healthaffairs.org/blog/2016/02/29/new-section-1332-guidance-a-mixed-bag-for-states/>

⁷ “NGA Recommendations Regarding 1332 State Innovation Waivers” National Governors Association. 2015. Web, April 2016 <<http://www.nga.org/files/live/sites/NGA/files/pdf/2015/1510LtrHHSTreasuryAttachment.pdf>>

⁸ “States May Find Health Reform’s Escape Hatch Is Too Small.” Modern Healthcare. Web. 21 Apr. 2016. <<http://www.modernhealthcare.com/article/20151215/NEWS/151219919>>

Whereas, Existing AMA policies (e.g. D-290.979, H-165.856, and H-290.965) support state-based innovations to improve healthcare benefits, access and affordability; therefore be it

RESOLVED, That our American Medical Association advocate that the “deficit-neutrality” component of the current HHS rule for Section 1332 waiver qualification be considered only on long-term, aggregate cost savings of states’ innovations as opposed to having costs during any particular year, including in initial “investment” years of a program, reduce the ultimate likelihood of waiver approval (New HOD Policy); and be it further

RESOLVED, That our AMA study reforms that can be introduced under Section 1332 of the Affordable Care Act in isolation and/or in combination with other federal waivers to improve healthcare benefits, access and affordability for the benefit of patients, healthcare providers and states, and encourages state societies to do the same. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

RELEVANT AMA POLICY

Medicaid Expansion D-290.979 - Our AMA, at the invitation of state medical societies, will work with state and specialty medical societies in advocating at the state level to expand Medicaid eligibility to 133% (138% FPL including the income disregard) of the Federal Poverty Level as authorized by the ACA and will advocate for an increase in Medicaid payments to physicians and improvements and innovations in Medicaid that will reduce administrative burdens and deliver healthcare services more effectively, even as coverage is expanded. Res. 809, I-12

Health Insurance Market Regulation H-165.856 - Our AMA supports the following principles for health insurance market regulation: (1) There should be greater national uniformity of market regulation across health insurance markets, regardless of type of sub-market (e.g., large group, small group, individual), geographic location, or type of health plan; (2) State variation in market regulation is permissible so long as states demonstrate that departures from national regulations would not drive up the number of uninsured, and so long as variations do not unduly hamper the development of multi-state group purchasing alliances, or create adverse selection; (3) Risk-related subsidies such as subsidies for high-risk pools, reinsurance, and risk adjustment should be financed through general tax revenues rather than through strict community rating or premium surcharges; (4) Strict community rating should be replaced with modified community rating, risk bands, or risk corridors. Although some degree of age rating is acceptable, an individual's genetic information should not be used to determine his or her premium; (5) Insured individuals should be protected by guaranteed renewability; (6) Guaranteed renewability regulations and multi-year contracts may include provisions allowing insurers to single out individuals for rate changes or other incentives related to changes in controllable lifestyle choices; (7) Guaranteed issue regulations should be rescinded; (8) Health insurance coverage of pre-existing conditions with guaranteed issue within the context of an individual mandate, in addition to guaranteed renewability. (9) Insured individuals wishing to switch plans should be subject to a lesser degree of risk rating and pre-existing conditions limitations than individuals who are newly seeking coverage; and (10) The regulatory environment should enable rather than impede private market innovation in product development and purchasing arrangements. Specifically: (a) Legislative and regulatory barriers to the formation and operation of group purchasing alliances should, in general, be removed; (b) Benefit mandates should be minimized to allow markets to determine benefit packages and

permit a wide choice of coverage options; and (c) Any legislative and regulatory barriers to the development of multi-year insurance contracts should be identified and removed.

CMS Rep. 7, A-03 Reaffirmed: CMS Rep. 6, A-05 Reaffirmation A-07 Reaffirmed: CMS Rep. 2, I-07 Reaffirmed: BOT Rep. 7, A-09 Appended: Res. 129, A-09 Reaffirmed: CMS Rep. 9, A-11 Reaffirmed in lieu of Res. 811, I-11 Reaffirmed in lieu of Res. 109, A-12 Reaffirmed in lieu of Res. 125, A-12 Reaffirmed: Res. 239, A-12 Reaffirmed: CMS Rep. 9, A-14

Medicaid Waivers for Managed Care Demonstration Projects H-290.987 - (1) Our AMA adopts the position that the Secretary of Health and Human Services should determine as a condition for granting waivers for demonstration projects under Section 1115(a) of the Medicaid Act that the proposed project: (i) assist in promoting the Medicaid Act's objective of improving access to quality medical care, (ii) has been preceded by a fair and open process for receiving public comment on the program, (iii) is properly funded, (iv) has sufficient provider reimbursement levels to secure adequate access to providers, (v) does not include provisions designed to coerce physicians and other providers into participation, such as those that link participation in private health plans with participation in Medicaid, and (vi) maintains adequate funding for graduate medical education. (2) Our AMA advocates that CMS establish a procedure which state Medicaid agencies can implement to monitor managed care plans to ensure that (a) they are aware of their responsibilities under EPSDT, (b) they inform patients of entitlement to these services, and (c) they institute internal review mechanisms to ensure that children have access to medically necessary services not specified in the plan's benefit package.

BOT Rep. 24, A-95 Reaffirmation A-99 Reaffirmation A-00 Reaffirmation I-04 Modified: CMS Rep. 1, A-14

Medicaid Expansion Options and Alternatives H-290.966 - 1. Our AMA encourages policymakers at all levels to focus their efforts on working together to identify realistic coverage options for adults currently in the coverage gap. 2. Our AMA encourages states that are not participating in the Medicaid expansion to develop waivers that support expansion plans that best meet the needs and priorities of their low income adult populations. 3. Our AMA encourages the Centers for Medicare & Medicaid Services to review Medicaid expansion waiver requests in a timely manner, and to exercise broad authority in approving such waivers, provided that the waivers are consistent with the goals and spirit of expanding health insurance coverage and eliminating the coverage gap for low-income adults. 4. Our AMA advocates that states be required to develop a transparent process for monitoring and evaluating the effects of their Medicaid expansion plans on health insurance coverage levels and access to care, and to report the results annually on the state Medicaid web site.

CMS Rep. 5, I-14 Reaffirmed: CMS Rep. 02, A-16

Medicaid Waivers and Maintenance of Effort Requirements H-290.969 - Our AMA opposes any efforts to repeal the Medicaid maintenance of effort requirements in the ACA and American Recovery and Reinvestment Act (ARRA), which mandate that states maintain eligibility levels for all existing adult Medicaid beneficiaries until 2014 and for all children in Medicaid and the Children's Health Insurance Program (CHIP) until 2019.

CMS Rep. 5, I-11 Reaffirmation A-14

Monitoring Medicaid Managed Care H-290.985 - As managed care plans increasingly become the source of care for Medicaid beneficiaries, the AMA advocates the same policies for the conduct of Medicaid managed care that the AMA advocates for private sector managed care plans. In addition, the AMA advocates that the following criteria be used in federal and/or state oversight and evaluation of managed care plans serving Medicaid beneficiaries, and insists

upon their use by the Federation in monitoring the implementation of managed care for Medicaid beneficiaries.

CMS Rep. 5 A-96 Reaffirmed and Appended: Sub. Res. 704, I-97 Reaffirmation A-00
Reaffirmation I-04 Reaffirmed: CMS Rep. 1, A-14

AMA Advocacy for Health System Reform H-165.835 - 1. Our AMA will advocate for modification of the Patient Protection and Affordable Care Act through legislation, regulation or judicial action to remove or oppose any components of the Act that are not consistent with existing AMA policy. 2. Our AMA will identify the major flaws in the Patient Protection and Affordable Care Act and advocate repair of those flaws. 3. Our AMA will educate the physicians of these United States in the details and implementation of the PPACA legislation. Res. 214, A-10 Appended: Sub. Res. 222, I-10 Appended: Res. 203, A-12 Reaffirmed in lieu of Res. 215, A-15

Affordable Care Act Medicaid Expansion H-290.965 - 1. Our AMA encourages state medical associations to participate in the development of their state's Medicaid access monitoring review plan and provide ongoing feedback regarding barriers to access. 2. Our AMA will continue to advocate that Medicaid access monitoring review plans be required for services provided by managed care organizations and state waiver programs, as well as by state Medicaid fee-for-service models. 3. Our AMA supports efforts to monitor the progress of the Centers for Medicare and Medicaid Services (CMS) on implementing the 2014 Office of Inspector General's recommendations to improve access to care for Medicaid beneficiaries. 4. Our AMA will advocate that CMS ensure that mechanisms are in place to provide robust access to specialty care for all Medicaid beneficiaries, including children and adolescents. 5. Our AMA supports independent researchers performing longitudinal and risk-adjusted research to assess the impact of Medicaid expansion programs on quality of care. 6. Our AMA supports adequate physician payment as an explicit objective of state Medicaid expansion programs. 7. Our AMA supports increasing physician payment rates in any redistribution of funds in Medicaid expansion states experiencing budget savings to encourage physician participation and increase patient access to care. 8. Our AMA will continue to advocate that CMS provide strict oversight to ensure that states are setting and maintaining their Medicaid rate structures at levels to ensure there is sufficient physician participation so that Medicaid patients can have equal access to necessary services. 9. Our AMA will continue to advocate that CMS develop a mechanism for physicians to challenge payment rates directly to CMS. 10. Our AMA supports extending to states the three years of 100 percent federal funding for Medicaid expansions that are implemented beyond 2016. 11. Our AMA supports maintenance of federal funding for Medicaid expansion populations at 90 percent beyond 2020 as long as the Affordable Care Act's Medicaid expansion exists. 12. Our AMA supports improved communication among states to share successes and challenges of their respective Medicaid expansion approaches. 13. Our AMA supports the use of emergency department (ED) best practices that are evidenced-based to reduce avoidable ED visits. CMS Rep. 02, A-16

Redefining AMA's Position on ACA and Healthcare Reform D-165.938 - 1. Our AMA will develop a policy statement clearly stating this organization's policies on the following aspects of the Affordable Care Act (ACA) and healthcare reform: A. Opposition to all P4P or VBP that fail to comply with the AMA's Principles and Guidelines; B. Repeal and appropriate replacement of the SGR; C. Repeal and replace the Independent Payment Advisory Board (IPAB) with a payment mechanism that complies with AMA principles and guidelines; D. Support for Medical Savings Accounts, Flexible Spending Accounts, and the Medicare Patient Empowerment Act ("private contracting"); E. Support steps that will likely produce reduced health care costs, lower health insurance premiums, provide for a sustainable expansion of healthcare coverage, and protect Medicare for future generations; F. Repeal the non-physician provider non-

discrimination provisions of the ACA. 2. Our AMA will immediately direct sufficient funds toward a multi-pronged campaign to accomplish these goals. 3. There will be a report back at each meeting of the AMA HOD. Res. 231, A-13 Reaffirmed in lieu of Res. 215, A-15

Health Insurance Affordability H-165.828 - 1. Our AMA supports modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered employer-sponsored coverage by lowering the threshold that determines whether an employee's premium contribution is affordable to that which applies to the exemption from the individual mandate of the Affordable Care Act (ACA). 2. Our AMA supports legislation or regulation, whichever is relevant, to fix the ACA's "family glitch," thus determining the affordability of employer-sponsored coverage with respect to the cost of family-based or employee-only coverage. 3. Our AMA encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to a health savings account (HSA) partially funded by an amount determined to be equivalent to the cost-sharing subsidy. 4. Our AMA supports capping the tax exclusion for employment-based health insurance as a funding stream to improve health insurance affordability. CMS Rep. 8, I-15 Reaffirmed in lieu of: Res. 121, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 207
(I-16)

Introduced by: New Jersey

Subject: Limitation on Reports by Insurance Carriers to the National Practitioner Data Bank Unrelated to Patient Care

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The purpose of legislation establishing the National Practitioner Data Bank (NPDB)
2 was to create a record of physicians whose medical treatment of a patient resulted in harm; and
3

4 Whereas, The regulations and NPDB Guidebook interpreting when a report should be filed have
5 expanded beyond the goal and intended purpose of the legislation to include reports by
6 malpractice carriers of physicians who were not involved in patient care; and
7

8 Whereas, Medical malpractice carriers may err on the side of reporting to the NPDB because of
9 the penalties that may be levied for failure to report; and
10

11 Whereas, Reports to the NPDB are damaging to a physician's reputation, employment status,
12 hospital medical staff privileges, and future employment opportunities; therefore be it
13

14 RESOLVED, That our American Medical Association formally request that the Health
15 Resources and Services Administration (HSRA) clarify that reports of medical malpractice
16 settlements by physicians are contingent upon treatment, the provision of or failure to provide
17 healthcare services, of the plaintiff (Directive to Take Action); and be it further
18

19 RESOLVED, That our AMA formally request that HSRA audit the National Practitioner Data
20 Bank (NPDB) for reports on physicians who were not involved in the treatment of a plaintiff, but
21 were reported as a result of a healthcare entity's settlement of a claim that included the name of
22 the physician in his/her administrative role at the entity (Directive to Take Action); and be it
23 further
24

25 RESOLVED, That HSRA should be compelled to remove the name of any physician from the
26 NPDB who was reported by a medical malpractice carrier as the result of the settlement of a
27 claim by a healthcare entity where the physician was not involved in the treatment of the
28 plaintiff. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 208
(I-16)

Introduced by: Indiana

Subject: MIPS and MACRA Exemptions

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The new payment system, merit-based incentive payment system (MIPS) and
2 Medicare Access and Chip Reauthorization Act of 2015 (MACRA), will be implemented in 2019
3 to replace the current fee-for-service systems; and
4

5 Whereas, MACRA picks a handful of screening tests and calls this a measure of quality; and
6

7 Whereas, There are no measures in MACRA for making a timely and accurate diagnosis, a core
8 expectation of primary care; and
9

10 Whereas, Eighty-seven percent of solo practices will face negative adjustments in year one of
11 MACRA (*Medical Economics*, May 25, 2015, Vol. 93 No. 10); and
12

13 Whereas, Electronic medical records are not designed for population management, a
14 requirement of MACRA; and
15

16 Whereas, Most small practices will not be able to comply with these guidelines; therefore be it
17

18 RESOLVED, That our American Medical Association support an exemption from the merit-
19 based incentive payment system (MIPS) and Medicare Access and Chip Reauthorization Act of
20 2015 (MACRA) for small practices since these rules will hasten the demise of small private
21 practice in the U.S. (New HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 209
(I-16)

Introduced by: Indiana

Subject: Affordable Care Act Revisit

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The Affordable Care Act (ACA) has and will worsen government deficit spending, in
2 spite of significant taxation under the plan and promises that it would save federal tax dollars;
3 and
4

5 Whereas, The ACA has not substantially decreased the number of uninsured; total insured
6 under the plan recently dropped below 12 million; and
7

8 Whereas, The ACA expands bureaucratization of an already over-regulated sector of the U.S.
9 economy; and
10

11 Whereas, The ACA, through its requirements related to demonstration of meaningful use,
12 transition to electronic medical records and a myriad of "red tape" rules and regulations has
13 interfered with physician productivity and satisfaction, as well as patient access; and
14

15 Whereas, The ACA infringes on religious liberties and morality through its coverage of abortion
16 on some plans and the potential for heavy fines for insurers who do not comply with the rules on
17 birth control; and
18

19 Whereas, The ACA interferes with free-market competition that would have helped lower costs
20 and improve efficiencies; and
21

22 Whereas, The ACA is limiting choice and savings through the ongoing loss of multiple
23 exchanges, co-ops and insurance plans across the country; and
24

25 Whereas, Cuts to Medicare under the ACA are unsustainable and will decrease access and
26 increase cost to seniors in the future; and
27

28 Whereas, The ACA, through its policy standardization and restrictions on policy variations, has
29 resulted in obscene premiums, deductibles and co-pays for some individuals, with most ACA
30 insureds seeing increased premiums every year; and
31

32 Whereas, The ACA largely usurps the state's authority over health insurance regulation; and
33

34 Whereas, The ACA wastes federal dollars through numerous exemptions, loopholes, subsidies
35 and other schemes; therefore be it

1 RESOLVED, That our American Medical Association House of Delegates no longer support the
2 Affordable Care Act (ACA) in its current form and to work for replacement or substantial revision
3 of the act to include these changes:

- 4
- 5 - Allowing health insurance to be sold across state lines
- 6 - Allowing all businesses to self-insure and to purchase insurance through business health
- 7 plans or association health plans
- 8 - Improving the individual mandate with a refundable tax credit that would be used to
- 9 purchase health insurance
- 10 - Improving health-related savings accounts so as to help ACA insureds afford their higher
- 11 deductibles and co-pays
- 12 - Reversing cuts to traditional Medicare and Medicare Advantage programs
- 13 - Encouraging states to develop alternatives to Medicaid by using federal funds granted
- 14 under provisions of the ACA
- 15 - Eliminating all exemptions, loopholes, discounts, subsidies and other schemes to be fair to
- 16 those who cannot access such breaks in their insurance costs (New HOD Policy); and be
- 17 it further
- 18

19 RESOLVED, That our AMA maintain the following provisions to the ACA if it is replaced:

- 20
- 21 - Full coverage of preventive services
- 22 - Family insurance coverage of children living in a household until age 26
- 23 - Elimination of lifetime benefit caps
- 24 - Guaranteed insurability (New HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 210
(I-16)

Introduced by: Indiana

Subject: Automatic Enrollment into Medicare Advantage

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, With Medicare's specific approval, a health insurance company can enroll a member
2 of its commercial plan into its Medicare Advantage Plan when the individual becomes eligible for
3 Medicare; and
4

5 Whereas, This "seamless conversion" is an opt out program; and
6

7 Whereas, Patients many times are unaware that they were automatically enrolled into a
8 Medicare Advantage plan and may end up with big bills when they get admitted to out of
9 network hospitals; therefore be it
10

11 RESOLVED, That our American Medical Association work to make seamless conversion
12 enrollment into a Medicare Advantage Plan an opt-in rather than an opt-out process. (Directive
13 to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 211
(I-16)

Introduced by: Indiana

Subject: Electronic Health Records

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The electronic health record (EHR) in the present form has been prematurely
2 mandated by the government for the medical profession with emphasis on billing (electronic
3 billing record or EBR); and
4

5 Whereas, Physicians are more vulnerable to malpractice lawsuits by:
6 - Clicking items with more detail than their usual examination
7 - Choosing a code, by mandate, that may not really reflect the true diagnosis
8 - An inability to review voluminous consultant's notes that may lead to missing important
9 recommendations; and
10

11 Whereas, Current EHR systems require too much time for the mandated useless documentation
12 causing dissatisfaction between doctors and patients and anger that is very obviously felt in
13 most waiting rooms of doctors' offices; therefore be it
14

15 RESOLVED, That our American Medical Association support federal legislation that will replace
16 current meaningful use with common sense meaningful use developed by the medical
17 profession that is user friendly and practical. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/29/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 212
(I-16)

Introduced by: Medical Student Section

Subject: Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

Whereas, There are an estimated 700,000 transgender individuals in America, not accounting for individuals who may identify with a non-conforming gender identity, who face unique obstacles to receiving healthcare;^{1,2} and

Whereas, A lack of healthcare worker awareness and sensitivity regarding different sexual orientation/gender identity (SO/GI) and/or patient intake forms that fail to accurately record a patient's preferred name, appropriate pronoun, sex, and gender identity can cause transgender individuals to delay or not seek out care at all;³ and

Whereas, The inclusion of SO/GI options with open-ended questions on patient forms validates patients' identities,² allows for a more inclusive medical environment, encourages patient disclosure leading to more complete and accurate patient health information, and recognizes that biological sex, gender identity, and sexual orientation are separate facets of a patient's identity;^{4,5} and

Whereas, Accurate SO/GI information will help physicians establish a more complete social history for all patients,^{6,7} screen for gender and lifestyle-specific disease,⁶ and identify what organs an individual may or may not have that may require preventative health screenings;⁸ and

Whereas, The Department of Health and Human Services has ruled that "providers participating in the EHR Incentive Programs will need to have certified health IT with the capability to capture SO/GI to meet the CEHRT definition in 2018 and subsequent years" and that "certification does not require that a provider collect this information, only that certified Health IT Modules enable a user to do so;"⁹ and

¹ Makadon H. Ending LGBT invisibility in health care: The first step in ensuring equitable care. *Cleve Clin J Med*. 2011; 78: 220-224.

² Gates, G. J. (2011) "How Many People are Lesbian, Gay, Bisexual, and Transgender?" The Williams Institute. Available at: <http://williamsinstitute.law.ucla.edu/research/census-lgbt-demographics-studies/how-many-people-are-lesbian-gay-bisexual-and-transgender/>

³ Mizock, L., & Lewis, T. (2008). Trauma in Transgender Populations: Risk, Resilience, and Clinical Care. *Journal of Emotional Abuse*, 8(January 2015), 335–354. <http://doi.org/10.1080/10926790802262523>

⁴ Gay and Lesbian Medical Association. Guidelines of Care for Lesbian, Gay, Bisexual, and Transgender (LGBT) Patients. New York. January 2006.

⁵ American Psychological Association. (2011). "Definition of Terms: Sex, Gender, Gender Identity, Sexual Orientation." Available at: <https://www.apa.org/pi/lgbt/resources/sexuality-definitions.pdf>

⁶ "How to Gather Data on Sexual Orientation and Gender Identity in Clinical Settings." Policy Brief by the Fenway Institute. January 09, 2012.

⁷ "Why Gather Data on Sexual Orientation and Gender Identity in Clinical Settings." Policy Brief from the Fenway Institute. January, 09, 2012.

⁸ Deutsch, M. B., Green, J., Keatley, J., Mayer, G., Hastings, J., & Hall, A. M. (2013). Electronic Medical Records and the Transgender Patient: Recommendations from the World Professional Association for Transgender Health EMR Working Group. *Journal of the American Medical Informatics Association : JAMIA*, 20(4), 700–703. <http://doi.org/10.1136/amiainl-2012-001472>

⁹ "2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications." Office of the Federal Register. Available at: <https://www.federalregister.gov/articles/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base#h-46>

Whereas, Pursuant to existing AMA policy H-160.991, our AMA believes that the physician's nonjudgmental recognition of sexual orientation and behavior enhances the ability to render optimal patient care in health as well as in illness; therefore be it

RESOLVED, That our American Medical Association support the inclusion of a patient's biological sex, gender identity, sexual orientation, preferred gender pronoun(s), and (if applicable) surrogate identifications in medical documentation and related forms in a culturally-sensitive and voluntary manner (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for collection of patient data that is inclusive of sexual orientation/gender identity for the purposes of research into patient health. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991 - 1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian gay bisexual and transgender (LGBT) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBT; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBT Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBT patients; (iii) encouraging the development of educational programs in LGBT Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBT people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBT communities to offer physicians the opportunity to better understand the medical needs of LGBT patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity. 2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for women who have sex with women to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases. 3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBT health issues. 4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBT people. CSA Rep. C, I-81 Reaffirmed: CLRPD Rep. F, I-91 CSA Rep. 8 - I-94 Appended: Res. 506, A-00 Modified and Reaffirmed: Res. 501, A-07 Modified: CSAPH Rep. 9, A-08 Reaffirmation A-12 Modified: Res. 08, A-16

Conforming Birth Certificate Policies to Current Medical Standards for Transgender Patients H-65.967 -

1. Our AMA supports policies that allow for a change of sex designation on birth certificates for transgender individuals based upon verification by a physician (MD or DO) that the individual has undergone gender transition according to applicable medical standards of care. 2. Our AMA: (a) supports elimination of any requirement that individuals undergo gender affirmation surgery in order to change their sex designation on birth certificates and supports modernizing state vital statistics statutes to ensure accurate gender markers on birth certificates; and (b) supports that any change of sex designation on an individual's birth certificate not hinder access to medically appropriate preventive care. Res. 4, A-13 Appended: BOT Rep. 26, A-14

Health Disparities Among Gay, Lesbian, Bisexual and Transgender Families D-65.995 - Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and same sex parents in same sex households by supporting equality in laws affecting health care of members in same sex partner households and their dependent children. Res. 445, A-05 Modified: CSAPH Rep. 1, A-15

Nondiscriminatory Policy for the Health Care Needs of LGBT Populations D-65.996 - Our AMA will encourage and work with state medical societies to provide a sample printed nondiscrimination policy suitable for framing, and encourage individual physicians to display for patient and staff awareness-as one example: "This office appreciates the diversity of human beings and does not discriminate based on race, age, religion, ability, marital status, sexual orientation, sex, or gender identity." Res. 414, A-04 Modified: BOT Rep. 11, A-07 Modified: Res. 08, A-16

Nondiscriminatory Policy for the Health Care Needs of LGBT Populations H-65.976 - Our AMA encourages physician practices, medical schools, hospitals, and clinics to broaden any nondiscriminatory statement made to patients, health care workers, or employees to include "sexual orientation, sex, or gender identity" in any nondiscrimination statement. Res. 414, A-04 Modified: BOT Rep. 11, A-07 Modified: Res. 08, A-16

Sexual Orientation and/or Gender Identity as Health Insurance Criteria H-180.980 - The AMA opposes the denial of health insurance on the basis of sexual orientation or gender identity. Res. 178, A-88 Reaffirmed: Sub. Res. 101, I-97 Reaffirmed: CMS Rep. 9, A-07 Modified: BOT Rep. 11, A-07

Eliminating Health Disparities - Promoting Awareness and Education of Lesbian, Gay, Bisexual, and Transgender (LGBT) Health Issues in Medical Education H-295.878 - Our AMA: (1) supports the right of medical students and residents to form groups and meet on-site to further their medical education or enhance patient care without regard to their gender, gender identity, sexual orientation, race, religion, disability, ethnic origin, national origin or age; (2) supports students and residents who wish to conduct on-site educational seminars and workshops on health issues in Lesbian, Gay, Bisexual, and Transgender communities; and (3) encourages the Liaison Committee on Medical Education (LCME), the American Osteopathic Association (AOA), and the Accreditation Council for Graduate Medical Education (ACGME) to include LGBT health issues in the cultural competency curriculum for both undergraduate and graduate medical education; and (4) encourages the LCME, AOA, and ACGME to assess the current status of curricula for medical student and residency education addressing the needs of pediatric and adolescent LGBT patients. Res. 323, A-05 Modified in lieu of Res. 906, I-10 Reaffirmation A-11 Reaffirmation A-12 Reaffirmation A-16

Strategies for Enhancing Diversity in the Physician Workforce H-200.951 - Our AMA (1) supports increased diversity across all specialties in the physician workforce in the categories of race, ethnicity, gender, sexual orientation/gender identity, socioeconomic origin and persons with disabilities; (2) commends the Institute of Medicine for its report, "In the Nation's Compelling Interest: Ensuring Diversity in the Health Care Workforce," and supports the concept that a racially and ethnically diverse educational experience results in better educational outcomes; and (3) encourages medical schools, health care institutions, managed care and other appropriate groups to develop policies articulating the value and importance of diversity as a goal that benefits all participants, and strategies to accomplish that goal. CME Rep. 1, I-06 Reaffirmed: CME Rep. 7, A-08 Reaffirmed: CCB/CLRPD Rep. 4, A-13 Modified: CME Rep. 01, A-16 Reaffirmation A-16

National Health Survey H-440.885 - Our AMA supports a national health survey that incorporates a representative sample of the U.S. population of all ages (including adolescents) and includes questions on sexual orientation, gender identity, and sexual behavior. CSA Rep. 4, A-03 Modified: BOT Rep. 11, A-07

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 213
(I-16)

Introduced by: Michigan

Subject: SOAP Notes and Chief Complaint

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, SOAP (Subjective, Objective, Assessment, and Plan) or routine visit notes start with a
2 subjective portion; and
3

4 Whereas, There are typically three key components when selecting the appropriate level of
5 evaluation and management (E/M) service provided--history, examination, and medical decision
6 making; and
7

8 Whereas, The chief complaint (CC) is a required element of history and is described in the
9 Medicare Learning Network's *Evaluation and Management Services Guide* as "a concise
10 statement that describes the symptom, problem, condition, diagnosis, or reason for the patient
11 encounter"; and
12

13 Whereas, The Medicare Learning Network's *Evaluation and Management Services Guide* states
14 that the CC may be listed as separate elements of history or they may be included in the
15 description of the history of the present illness; and
16

17 Whereas, It should be the physician's decision as to how to describe the CC or reason for the
18 patient's visit; and
19

20 Whereas, Physicians are subject to federal auditing initiatives including recovery audits
21 performed by Recovery Audit Contractors (RAC) whose primary task is to review Medicare
22 claims data and determine if a claim was appropriately paid; and
23

24 Whereas, Physician colleagues have reported the denial of visits due to the absence of specific
25 "key" words within the CC portion of the history, even though the note itself provides adequate
26 documentation of the reason for the visit and the actual services performed; therefore be it

1 RESOLVED, That our American Medical Association amend AMA Policy D-320.991, Creating a
2 Fair and Balanced Medicare and Medicaid RAC Program, by addition to read as follows:

3
4 1. Our AMA will continue to monitor Medicare and Medicaid Recovery Audit
5 Contractor (RAC) practices and recovery statistics and continue to encourage the
6 Centers for Medicare and Medicaid Services (CMS) to adopt new regulations which
7 will impose penalties against RACs for abusive practices.

8 2. Our AMA will continue to encourage CMS to adopt new regulations which require
9 physician review of all medical necessity cases in post-payment audits, as medical
10 necessity is quintessentially a physician determination and judgment.

11 3. Our AMA will encourage CMS to discontinue the denial of payments or imposition
12 of negative action during a RAC audit due to the absence of specific words in the
13 chief complaint when the note provides adequate documentation of the reason for the
14 visit and services rendered.

15 ~~3.~~ 4. Our AMA will assist states by providing recommendations regarding state
16 implementation of Medicaid RAC rules and regulations in order to lessen confusion
17 among physicians and to ensure that states properly balance the interest in
18 overpayment and underpayment audit corrections for Recovery Contractors.

19 ~~4.~~ 5. Our AMA will petition CMS to amend CMS' rules governing the use of
20 extrapolation in the RAC audit process, so that the amended CMS rules conform to
21 Section 1893 of the Social Security Act Subsection (f) (3) - Limitation on Use of
22 Extrapolation; and insists that the amended rules state that when an RAC initially
23 contacts a physician, the RAC is not permitted to use extrapolation to determine
24 overpayment amounts to be recovered from that physician by recoupment, offset, or
25 otherwise, unless (as per Section 1893 of the Social Security Act) the Secretary of
26 Health and Human Services has already determined, before the RAC audit, either
27 that (a) previous, routine pre- or post-payment audits of the physician's claims by the
28 Medicare Administrative Contractor have found a sustained or high level of previous
29 payment errors, or that (b) documented educational intervention has failed to correct
30 those payment errors.

31 ~~5.~~ 6. Our AMA, in coordination with other stakeholders such as the American Hospital
32 Association, will seek to influence Congress to eliminate the current RAC system and
33 ask CMS to consolidate its audit systems into a more balanced, transparent, and fair
34 system, which does not increase administrative burdens on physicians.

35 ~~6.~~ 7. Our AMA will: (A) seek to influence CMS and Congress to require that a
36 physician, and not a lower level provider, review and approve any RAC claim against
37 physicians or physician-decision making, (B) seek to influence CMS and Congress to
38 allow physicians to be paid any denied claim if appropriate services are rendered, and
39 (C) seek the enactment of fines, penalties and the recovery of costs incurred in
40 defending against RACs whenever an appeal against them is won in order to
41 discourage inappropriate and illegitimate audit work by RACs.

42 ~~7.~~ 8. Our AMA will advocate for penalties and interest to be imposed on the auditor
43 and payable to the physician when a RAC audit or appeal for a claim has been found
44 in favor of the physician. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

Member Education on Medicare Recovery Audit Contractors H-335.963

Our AMA: (1) will educate our membership about the effect of the program's safeguard contractor activity and Recovery Audit Contractor (RAC) audits on individual physician practices, expansion of the RAC program, and assistance that may be available through our AMA; and (2) will actively support the legislation currently before Congress to require an immediate moratorium on the expansion of the RAC program, and will seek the introduction of subsequent legislation that would limit or exclude physician billings from the authority of RAC audits altogether.

Citation: (Sub. Res. 226, A-08)

RAC Audits of E&M Codes D-330.915

1. Our AMA opposes Recovery Audit Contractor audits of E&M codes with the Centers for Medicare & Medicaid Services (CMS) and will explain to CMS and Congress why these audits as currently conducted are deleterious to the provision of care to patients with complex health needs.

2. If our AMA is unsuccessful in reversing the audits, our AMA will urge CMS and elected Washington officials to require physician reimbursement for time and expense of appeals.

3. Our AMA will urge CMS and elected Washington officials to provide statistical data regarding the audits, including the specialties most affected by these audits, and the percentage of denied claims for E&M codes which, when appealed, are reversed on appeal.

Citation: (Res. 224, I-12)

Creating a Fair and Balanced Medicare and Medicaid RAC Program D-320.991

1. Our AMA will continue to monitor Medicare and Medicaid Recovery Audit Contractor (RAC) practices and recovery statistics and continue to encourage the Centers for Medicare and Medicaid Services (CMS) to adopt new regulations which will impose penalties against RACs for abusive practices.

2. Our AMA will continue to encourage CMS to adopt new regulations which require physician review of all medical necessity cases in post-payment audits, as medical necessity is quintessentially a physician determination and judgment.

3. Our AMA will assist states by providing recommendations regarding state implementation of Medicaid RAC rules and regulations in order to lessen confusion among physicians and to ensure that states properly balance the interest in overpayment and underpayment audit corrections for Recovery Contractors.

4. Our AMA will petition CMS to amend CMS' rules governing the use of extrapolation in the RAC audit process, so that the amended CMS rules conform to Section 1893 of the Social Security Act Subsection (f) (3) - Limitation on Use of Extrapolation; and insists that the amended rules state that when an RAC initially contacts a physician, the RAC is not permitted to use extrapolation to determine overpayment amounts to be recovered from that physician by recoupment, offset, or otherwise, unless (as per Section 1893 of the Social Security Act) the Secretary of Health and Human Services has already determined, before the RAC audit, either that (a) previous, routine pre- or post-payment audits of the physician's claims by the Medicare Administrative Contractor have found a sustained or high level of previous payment errors, or that (b) documented educational intervention has failed to correct those payment errors.

5. Our AMA, in coordination with other stakeholders such as the American Hospital Association, will seek to influence Congress to eliminate the current RAC system and ask CMS to consolidate its audit systems into a more balanced, transparent, and fair system, which does not increase administrative burdens on physicians.

6. Our AMA will: (A) seek to influence CMS and Congress to require that a physician, and not a lower level provider, review and approve any RAC claim against physicians or physician-decision making, (B) seek to influence CMS and Congress to allow physicians to be paid any denied claim if appropriate services are rendered, and (C) seek the enactment of fines, penalties and the recovery of costs incurred in defending against RACs whenever an appeal against them is won in order to discourage inappropriate and illegitimate audit work by RACs.

7. Our AMA will advocate for penalties and interest to be imposed on the auditor and payable to the physician when a RAC audit or appeal for a claim has been found in favor of the physician.

Citation: Res. 215, I-11; Appended: Res. 209, A-13; Appended: Res. 229, A-13; Appended: Res. 216, I-13; Reaffirmed: Res. 223, I-13

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 214
(I-16)

Introduced by: Michigan

Subject: Firearm-Related Injury and Death: Adopt a Call to Action

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, Deaths and injuries related to firearms constitute a major public health problem in the
2 United States; and
3

4 Whereas, In response to firearm violence and other firearm-related injuries and deaths, an
5 interdisciplinary, inter-professional group of leaders from eight national health professional
6 organizations and the American Bar Association, representing the official policy positions of
7 their organizations, advocate a series of measures aimed at reducing the health and public
8 health consequences of firearms; and
9

10 Whereas, The eight national health professional organizations include the American Academy
11 of Family Physicians, American Academy of Pediatrics, American College of Emergency
12 Physicians, American Congress of Obstetricians and Gynecologists, American College of
13 Physicians, American College of Surgeons, American Psychiatric Association, and American
14 Public Health Association; and
15

16 Whereas, The American Medical Association is prominently absent; and
17

18 Whereas, The specific recommendations of this inter-disciplinary group include universal
19 background checks of gun purchasers, elimination of physician “gag laws,” restricting the
20 manufacture and sale of military-style assault weapons and large-capacity magazines for
21 civilian use, research to support strategies for reducing firearm-related injuries and deaths,
22 improved access to mental health services, and avoidance of stigmatization of persons with
23 mental and substance use disorders through blanket reporting laws; and
24

25 Whereas, The American Bar Association, acting through its Standing Committee on Gun
26 Violence, confirms that none of these recommendations conflict with the Second Amendment or
27 previous rulings of the U.S. Supreme Court; therefore be it
28

29 RESOLVED, That our American Medical Association endorse the specific recommendations
30 made by an interdisciplinary, inter-professional group of leaders from the American Academy of
31 Family Physicians, American Academy of Pediatrics, American College of Emergency
32 Physicians, American Congress of Obstetricians and Gynecologists, American College of
33 Physicians, American College of Surgeons, American Psychiatric Association, American Public
34 Health Association, and the American Bar Association in the publication “Firearm-Related Injury
35 and Death in the United States: A Call to Action From 8 Health Professional Organizations and
36 the American Bar Association,” which is aimed at reducing the health and public health
37 consequences of firearms and lobby for their adoption. (Directive to Take Action)

Reference:

1. Annals of Internal Medicine 7 April 2015, Vol 162, No.7 "Firearm-Related Injury and Death in the United States" - <http://annals.org/article.aspx?articleid=2151828>

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

Firearm Safety Counseling in Physician-Led Health Care Teams H-145.976

Our AMA: (1) will oppose any restrictions on physicians' and other members of the physician-led health care team's ability to inquire and talk about firearm safety issues and risks with their patients; (2) will oppose any law restricting physicians' and other members of the physician-led health care team's discussions with patients and their families about firearms as an intrusion into medical privacy; and (3) encourages dissemination of educational materials related to firearm safety to be used in undergraduate medical education.

Citation: (Res. 219, I-11; Reaffirmation A-13; Modified: Res. 903, I-13)

Gun Safety H-145.978

Our AMA: (1) recommends and promotes the use of trigger locks and locked gun cabinets as safety precautions; and (2) endorses standards for firearm construction reducing the likelihood of accidental discharge when a gun is dropped and that standardized drop tests be developed.

Citation: (Res. 425, I-98; Reaffirmed: Res. 409, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-13)

Data on Firearm Deaths and Injuries H-145.984

The AMA supports legislation or regulatory action that: (1) requires questions in the National Health Interview Survey about firearm related injury as was done prior to 1972; (2) mandates that the Centers for Disease Control and Prevention develop a national firearm fatality reporting system; and (3) expands activities to begin tracking by the National Electronic Injury Surveillance System.

Citation: (Res. 811, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmation A-13)

Increasing Toy Gun Safety H-145.974

Our American Medical Association (1) encourages toy gun manufacturers to take further steps beyond the addition of an orange tip on the gun to reduce the similarity of toy guns with real guns, and (2) encourages parents to increase their awareness of toy gun ownership risks.

Citation: (Res. 406, A-15)

AMA Campaign to Reduce Firearm Deaths H-145.988

The AMA supports educating the public regarding methods to reduce death and injury due to keeping guns, ammunition and other explosives in the home.

Citation: (Res. 410, A-93; Reaffirmed: CLRPD Rep. 5, A-03; Reaffirmation A-13; Modified: CSAPH Rep. 1, A-13)

Prevention of Firearm Accidents in Children H-145.990

Our AMA (1) supports increasing efforts to reduce pediatric firearm morbidity and mortality by encouraging its members to (a) inquire as to the presence of household firearms as a part of childproofing the home; (b) educate patients to the dangers of firearms to children; (c) encourage patients to educate their children and neighbors as to the dangers of firearms; and (d) routinely remind patients to obtain firearm safety locks, to store firearms under lock and key, and to store ammunition separately from firearms; (2) encourages state medical societies to work with other organizations to increase public education about firearm safety; and (3) encourages organized medical staffs and other physician organizations, including state and local medical societies, to recommend programs for teaching firearm safety to children.

Citation: (Res. 165, I-89; Reaffirmed: Sunset Report and Appended: Sub. Res. 401, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-13)

Control of Non-Detectable Firearms H-145.994

The AMA supports a ban on the manufacture, importation, and sale of any firearm which cannot be detected by ordinary airport screening devices.

Citation: (Sub. Res. 79, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CLRPD Rep. 1, A-08)

Waiting Period Before Gun Purchase H-145.992

The AMA supports legislation calling for a waiting period of at least one week before purchasing any form of firearm in the U.S.

Citation: (Res. 171, A-89; Reaffirmed: BOT Rep.50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-07)

Firearm Availability H-145.996

Our AMA: (1) Advocates a waiting period and background check for all firearm purchasers;

(2) encourages legislation that enforces a waiting period and background check for all firearm purchasers; and

(3) urges legislation to prohibit the manufacture, sale or import of lethal and non-lethal guns made of plastic, ceramics, or other non-metallic materials that cannot be detected by airport and weapon detection devices.

Citation: Res. 140, I-87; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Modified: BOT Rep. 12, A-16

Firearm Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care H-145.975

1. Our AMA supports: a) federal and state research on firearm-related injuries and deaths; b) increased funding for and the use of state and national firearms injury databases, including the expansion of the National Violent Death Reporting System to all 50 states and U.S. territories, to inform state and federal health policy; c) encouraging physicians to access evidence-based data regarding firearm safety to educate and counsel patients about firearm safety; d) the rights of physicians to have free and open communication with their patients regarding firearm safety and the use of gun locks in their homes; e) encouraging local projects to facilitate the low-cost distribution of gun locks in homes; f) encouraging physicians to become involved in local firearm safety classes as a means of promoting injury prevention and the public health; and g) encouraging CME providers to consider, as appropriate, inclusion of presentations about the prevention of gun violence in national, state, and local continuing medical education programs

2. Our AMA supports initiatives to enhance access to mental and cognitive health care, with greater focus on the diagnosis and management of mental illness and concurrent substance abuse disorders, and work with state and specialty medical societies and other interested stakeholders to identify and develop standardized approaches to mental health assessment for potential violent behavior.

Citation: Sub. Res. 221, A-13; Appended: Res. 416, A-14; Reaffirmed: Res. 426, A-16

Prevention of Unintentional Shooting Deaths Among Children H-145.979

Our AMA supports legislation at the federal and state levels making gun owners legally responsible for injury or death caused by a child gaining unsupervised access to a gun, unless it can be shown that reasonable measures to prevent child access to the gun were taken by the gun owner, and that the specifics, including the nature of "reasonable measures," be determined by the individual constituencies affected by the law.

Citation: (Res. 204, I-98; Reaffirmed: BOT Rep. 23, A-09)

School Violence H-145.983

The AMA encourages states to adopt legislation enabling schools to limit and control the possession and storage of weapons or potential weapons on school property.

Citation: (Sub. Res. 402, I-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15)

Ban on Handguns and Automatic Repeating Weapons H-145.985

It is the policy of the AMA to: (1) Support interventions pertaining to firearm control, especially those that occur early in the life of the weapon (e.g., at the time of manufacture or importation, as opposed to those involving possession or use). Such interventions should include but not be limited to:

(a) mandatory inclusion of safety devices on all firearms, whether manufactured or imported into the

United States, including built-in locks, loading indicators, safety locks on triggers, and increases in the minimum pressure required to pull triggers;

(b) bans on the possession and use of firearms and ammunition by unsupervised youths under the age of 18;

(c) the imposition of significant licensing fees for firearms dealers;

(d) the imposition of federal and state surtaxes on manufacturers, dealers and purchasers of handguns and semiautomatic repeating weapons along with the ammunition used in such firearms, with the attending revenue earmarked as additional revenue for health and law enforcement activities that are directly related to the prevention and control of violence in U.S. society; and

(e) mandatory destruction of any weapons obtained in local buy-back programs.

(2) Support legislation outlawing the Black Talon and other similarly constructed bullets.

(3) Support the right of local jurisdictions to enact firearm regulations that are stricter than those that exist in state statutes and encourage state and local medical societies to evaluate and support local efforts to enact useful controls.

Citation: (BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-14)

Gun Violence as a Public Health Crisis D-145.995

Our AMA: (1) will immediately make a public statement that gun violence represents a public health crisis which requires a comprehensive public health response and solution; and

(2) will actively lobby Congress to lift the gun violence research ban.

Citation: Res. 1011, A-16;

Safety of Nonpowder (Gas-Loaded/Spring-Loaded) Guns H-145.989

It is the policy of the AMA to encourage the development of appropriate educational materials designed to enhance physician and general public awareness of the safe use of as well as the dangers inherent in the unsafe use of nonpowder (gas-loaded/spring-loaded) guns.

Citation: (Res. 423, I-91; Modified: Sunset Report, I-01; Modified: CSAPH Rep. 1, A-11)

Restriction of Assault Weapons H-145.993

Our AMA supports appropriate legislation that would restrict the sale and private ownership of inexpensive handguns commonly referred to as "Saturday night specials," and large clip, high-rate-of-fire automatic and semi-automatic firearms, or any weapon that is modified or redesigned to operate as a large clip, high-rate-of-fire automatic or semi-automatic weapon.

Citation: (Sub. Res. 264, A-89; Reaffirmed: BOT Rep. 50, I-93; Amended: Res.215, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmation A-07)

Gun Control H-145.991

The AMA supports using its influence in matters of health to effect passage of legislation in the Congress of the U.S. mandating a national waiting period that allows for a police background and positive identification check for anyone who wants to purchase a handgun from a gun dealer anywhere in our country.

Citation: (Sub. Res. 34, I-89; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-07)

Ban Realistic Toy Guns H-145.995

The AMA supports (1) working with civic groups and other interested parties to ban the production, sale, and distribution of realistic toy guns; and (2) taking a public stand on banning realistic toy guns by various public appeal methods.

Citation: (Sub. Res. 140, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CLRPD Rep. 1, A-08)

Firearms as a Public Health Problem in the United States - Injuries and Death H-145.997

Our AMA recognizes that uncontrolled ownership and use of firearms, especially handguns, is a serious threat to the public's health inasmuch as the weapons are one of the main causes of intentional and unintentional injuries and deaths. Therefore, the AMA: (1) encourages and endorses the development and presentation of safety education programs that will engender more responsible use and storage of firearms;

(2) urges that government agencies, the CDC in particular, enlarge their efforts in the study of firearm-related injuries and in the development of ways and means of reducing such injuries and deaths;

- (3) urges Congress to enact needed legislation to regulate more effectively the importation and interstate traffic of all handguns;
- (4) urges the Congress to support recent legislative efforts to ban the manufacture and importation of nonmetallic, not readily detectable weapons, which also resemble toy guns; (5) encourages the improvement or modification of firearms so as to make them as safe as humanly possible;
- (6) encourages nongovernmental organizations to develop and test new, less hazardous designs for firearms;
- (7) urges that a significant portion of any funds recovered from firearms manufacturers and dealers through legal proceedings be used for gun safety education and gun-violence prevention; and
- (8) strongly urges US legislators to fund further research into the epidemiology of risks related to gun violence on a national level.

Citation: (CSA Rep. A, I-87; Reaffirmed: BOT Rep. I-93-50; Appended: Res. 403, I-99; Reaffirmation A-07; Reaffirmation A-13; Appended: Res. 921, I-13)

Guns in Hospitals H-215.977

1. The policy of the AMA is to encourage hospitals to incorporate, within their security policies, specific provisions on the presence of firearms in the hospital. The AMA believes the following points merit attention:

- A. Given that security needs stem from local conditions, firearm policies must be developed with the cooperation and collaboration of the medical staff, the hospital security staff, the hospital administration, other hospital staff representatives, legal counsel, and local law enforcement officials. Consultation with outside experts, including state and federal law enforcement agencies, or patient advocates may be warranted.
- B. The development of these policies should begin with a careful needs assessment that addresses past issues as well as future needs.
- C. Policies should, at minimum, address the following issues: a means of identification for all staff and visitors; restrictions on access to the hospital or units within the hospital, including the means of ingress and egress; changes in the physical layout of the facility that would improve security; the possible use of metal detectors; the use of monitoring equipment such as closed circuit television; the development of an emergency signaling system; signage for the facility regarding the possession of weapons; procedures to be followed when a weapon is discovered; and the means for securing or controlling weapons that may be brought into the facility, particularly those considered contraband but also those carried in by law enforcement personnel.
- D. Once policies are developed, training should be provided to all members of the staff, with the level and type of training being related to the perceived risks of various units within the facility. Training to recognize and defuse potentially violent situations should be included.
- E. Policies should undergo periodic reassessment and evaluation.
- F. Firearm policies should incorporate a clear protocol for situations in which weapons are brought into the hospital.

2. Our AMA will advocate that hospitals and other healthcare delivery settings limit guns and conducted electrical weapons in units where patients suffering from mental illness are present

Citation: BOT Rep. 23, I-94; Reaffirmation I-03; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 2, I-10; Appended: Res. 426, A-16

Preventing Firearm-Related Injury and Morbidity in Youth D-145.996

Our American Medical Association will identify and support the distribution of firearm safety materials that are appropriate for the clinical setting.

Citation: (Res. 216, A-15)

Gun Regulation H-145.999

Our AMA supports stricter enforcement of present federal and state gun control legislation and the imposition of mandated penalties by the judiciary for crimes committed with the use of a firearm, including the illegal possession of a firearm.

Citation: (Sub. Res. 31, I-81; Reaffirmed: CLRPD Rep. F, I-91; Amended: BOT Rep. I-93-50; Reaffirmed: Res. 409, A-00; Reaffirmation A-07)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 215
(I-16)

Introduced by: Missouri

Subject: Parental Leave

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

Whereas, The United States has one of the shortest parental leave periods in the world and is the only developed country not to mandate that the leave period is both paid and protected; and

Whereas, Only 46% of private sector employees qualify for unpaid parental leave under the Family and Medical Leave Act of 1993, which only covers individuals who work for employers with at least 50 employees within 75 miles and who have worked more than 1250 hours in the past 12 months; and

Whereas, Paid leave better facilitates parents taking a longer leave and is associated with significantly greater improvements in infant mortality compared to unpaid leave; and

Whereas, Longer use of parental leave improves health outcomes for the child by decreasing infant mortality by 10%, increasing the likelihood of vaccination, increasing the likelihood of the child having routine medical check-ups, and increasing cognitive and behavioral scores in early childhood; and

Whereas, Longer use of parental leave reduces the risk of maternal depressive symptoms and improves the physical health status of both mothers and fathers; therefore be it

RESOLVED, That our American Medical Association study the health implications among patients if the United States were to modify one or more of the following aspects of the Family and Medical Leave Act (FMLA):

- a reduction in the number of employees from 50 employees;
- an increase in the number of covered weeks from 12 weeks; and
- creating a new benefit of paid parental leave (Directive to Take Action); and be it further

RESOLVED, That our AMA study the effects of FMLA expansion on physicians in varied practice environments. (Directive to Take Action)

Fiscal Note: Estimated cost of \$31,000 to implement resolution.

Received: 09/30/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 216
(I-16)

Introduced by: Florida

Subject: Ending Medicare Advantage "Auto-Enrollment"

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The Centers for Medicare and Medicaid Services now allows commercial healthcare
2 insurers to “auto-enroll” their insured into that carrier’s Medicare Advantage Plan with a single
3 letter of notification during that insured’s pre-Medicare enrollment period; and
4

5 Whereas, During the pre-Medicare enrollment period each individual will receive dozens of
6 communications from multiple healthcare insurers regarding a wide variety of Medicare
7 insurance products that many Medicare-eligible individuals find confusing; and
8

9 Whereas, The insured receiving notification by their healthcare carrier of “auto-enrollment” in
10 that carrier’s Medicare Advantage Plan must actively “opt-out” of that plan within 60 days or lose
11 their ability to enroll in traditional Medicare for a year; therefore be it
12

13 RESOLVED, The our American Medical Association work with the Centers for Medicare and
14 Medicaid Services and/or Congress to end the procedure of “auto-enrollment” of individuals into
15 Medicare Advantage Plans. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/05/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 217
(I-16)

Introduced by: American Society of Ophthalmic Plastic and Reconstructive Surgery
American Academy of Ophthalmology
American Academy of Facial Plastic and Reconstructive Surgery
American Society for Aesthetic Plastic Surgery
American Society of Cataract and Refractive Surgery
American Society of Retinal Specialists
American Society of Plastic Surgeons

Subject: The Rights of Patients, Providers and Facilities to Contract for Non-Covered Services

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, Blepharoplasty and blepharoptosis repair are distinct surgical procedures directed at
2 correcting different pathology of the upper eyelids; and
3

4 Whereas, Each may be performed for medically necessary (functional) or aesthetic indications;
5 and
6

7 Whereas, These distinctions are dictated by coverage rules of third party payers regarding
8 medical necessity; and
9

10 Whereas, In 2009, NCCI bundled payments for blepharoplasty and ptosis repair and the
11 bundling applied to procedures that met medical necessity criteria but aesthetic procedures
12 would be performed per agreement between patients, surgeons and facilities in accordance with
13 current practice and regulations; and
14

15 Whereas, In May, 2016, CMS issued a guidance that interpreted the bundles to include all
16 ptosis procedures and all functional and aesthetic aspects of blepharoplasty (CMS MLN Matters
17 Number M9658); and
18

19 Whereas, This guidance makes it a violation of policy for aesthetic surgery to be done on the
20 same eyelid, at the same time as functional surgery or at any time by the initial surgeon or by a
21 second surgeon at the same time or at any future time; and
22

23 Whereas, This prohibits the rights of a patient to contract with a surgeon to obtain aesthetic
24 surgery involving an eyelid once any functional surgery has been performed on that lid at the
25 time of the functional surgery or at any time in the future by the same or any surgeon; and
26

27 Whereas, Medical third party payers are not obligated to pay for procedures that do not meet
28 their medical necessity criteria but DO NOT have authority to regulate choices made by patients
29 and providers regarding procedures that do not meet their criteria for medical necessity and
30 decisions regarding non-covered benefits are to be made by agreement between patients,
31 providers and facilities (AMA Policy D-380.997); and

1 Whereas, CMS Matter Number MM9658 violates the rights of patients, facilities and providers to
2 privately contract for non-covered services; and
3

4 Whereas, This regulation sets a bad precedent for future CMS guidance that could affect private
5 contracting between patients and providers in any area of medicine; therefore be it
6

7 RESOLVED, That our American Medical Association reaffirm Policy D-380.997 and any other
8 applicable policies (Reaffirm HOD Policy); and be it further
9

10 RESOLVED, That our AMA engage in efforts to convince the CMS to rescind the CMS guidance
11 that bundled all blepharoptosis procedures with all functional and aesthetic aspects of
12 blepharoplasty and to abstain from bundling other situations in which functional and aesthetic
13 considerations should be able to be considered separately (Directive to Take Action); and be it
14 further
15

16 RESOLVED, That our AMA actively oppose further regulations that would interfere with the
17 rights of patients, providers, and facilities to privately contract for non-covered services. (New
18 HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/13/16

RELEVANT AMA POLICY

Private Contracting by Medicare Patients D-380.997

1. It is the policy of the AMA: (a) that any patient, regardless of age or health care insurance coverage, has both the right to privately contract with a physician for wanted or needed health services and to personally pay for those services; (b) to pursue appropriate legislative and legal means to permanently preserve that patient's basic right to privately contract with physicians for wanted or needed health care services; (c) to continue to expeditiously pursue regulatory or legislative changes that will allow physicians to treat Medicare patients outside current regulatory constraints that threaten the physician/patient relationship; and (d) to seek immediately suitable cases to reverse the limitations on patient and physician rights to contract privately that have been imposed by CMS or the private health insurance industry.

2. Our AMA strongly urge CMS to clarify the technical and statutory ambiguities of the private contracting language contained in Section 4507 of the Balanced Budget Act of 1997.

3. Our AMA reaffirms its position in favor of a pluralistic health care delivery system to include fee-for-service medicine, and will lobby for the elimination of any restrictions and physician penalties for provision of fee-for-service medicine by a physician to a consenting patient, including patients covered under Medicare.

CMS Rep. 6, A-99 Reaffirmation A-04 Reaffirmation A-08 Reaffirmation I-13 Modified: CMS Rep. 1, A-15

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 218
(I-16)

Introduced by: American Academy of Orthopaedic Surgeons, North American Spine Society, American Association for Hand Surgery, American Orthopaedic Foot and Ankle Society, American Congress of Obstetricians and Gynecologists, American Association of Hip and Knee Surgeons, Kansas

Subject: Support for Prescription Drug Monitoring Programs

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, State prescription drug monitoring programs (PDMPs) have been established to
2 collect and monitor prescribing and dispensing data of controlled substances; and
3

4 Whereas, PDMPs are currently established in 49 states, the District of Columbia, and Guam;
5 and
6

7 Whereas, Data from PDMPs help physicians to assess risks of abuse or diversion of controlled
8 substances; and
9

10 Whereas, Patients may acquire controlled substances from health care providers and/or
11 pharmacies in more than one state; and
12

13 Whereas, State-based PDMPs currently are not interactive across state lines, limiting the data
14 to which physicians have access, thereby limiting their ability to determine individual patients'
15 risks for addiction or diversion; and
16

17 Whereas, The National All Schedules Prescription Electronic Reporting Act (NASPER) was first
18 passed by Congress in 2005 and last re-authorized in the Comprehensive Addiction and
19 Recovery Act of 2016; and
20

21 Whereas, NASPER contains the initial mandate that PDMPs be interactive between states; and
22

23 Whereas, NASPER does not remain fully funded; and
24

25 Whereas, Our AMA has been supportive of full appropriations for NASPER; therefore be it
26

27 RESOLVED, That our American Medical Association continue to encourage Congress to assure
28 that the National All Schedules Prescription Electronic Reporting Act (NASPER) and/or similar
29 programs be fully funded to allow state prescription drug monitoring programs (PDMPs) to
30 remain viable and active (New HOD Policy); and be it further
31

32 RESOLVED, That our AMA work to assure that interstate operability of PDMPs in a manner that
33 allows data to be easily accessed by physicians and does not place an onerous burden on their
34 practices. (Directive to Take Action)

¹ <http://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq>

² <https://www.govtrack.us/congress/bills/109/hr1132/summary>

Fiscal Note: Minimal - less than \$1,000.

Received: 10/11/16

RELEVANT AMA POLICY

Prescription Drug Monitoring Program Confidentiality H-95.946

Our AMA will: (1) advocate for the placement and management of state-based prescription drug monitoring programs with a state agency whose primary purpose and mission is health care quality and safety rather than a state agency whose primary purpose is law enforcement or prosecutorial; (2) encourage all state agencies responsible for maintaining and managing a prescription drug monitoring program (PDMP) to do so in a manner that treats PDMP data as health information that is protected from release outside of the health care system; and (3) advocate for strong confidentiality safeguards and protections of state databases by limiting database access by non-health care individuals to only those instances in which probable cause exists that an unlawful act or breach of the standard of care may have occurred.

Res. 221, A-12 Reaffirmed: BOT Rep. 12, A-15 Reaffirmed: BOT Rep. 5, I-15

Development and Promotion of Single National Prescription Drug Monitoring Program H-95.939

Our American Medical Association (1) supports the voluntary use of state-based prescription drug monitoring programs (PDMP) when clinically appropriate; (2) encourages states to implement modernized PDMPs that are seamlessly integrated into the physician's normal workflow, and provide clinically relevant, reliable information at the point of care; (3) supports the ability of physicians to designate a delegate to perform a check of the PDMP, where allowed by state law; (4) encourage states to foster increased PDMP use through a seamless registration process; (5) encourages all states to determine how to use a PDMP to enhance treatment for substance use disorder and pain management; (6) encourages states to share access to PDMP data across state lines, within the safeguards applicable to protected health information; and (7) encourages state PDMPs to adopt uniform data standards to facilitate the sharing of information across state lines.

BOT Rep. 12, A-15 Reaffirmed: BOT Rep. 5, I-15 Reaffirmation A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 219
(I-16)

Introduced by: American Academy of Allergy, Asthma and Immunology

Subject: Protect Individualized Compounding in Physicians' Offices
as Practice of Medicine

Referred to: Reference Committee B
(Ann R. Stroink, MD, Chair)

1 Whereas, The AMA has adopted policy that encourages the United States Pharmacopeia (USP)
2 to retain special rules for compounding in physician offices for allergen immunotherapy and
3 potentially other kinds of small-volume physician office-based compounding, including engaging
4 with the U.S. Congress and the Food and Drug Administration (FDA); that the AMA shall form a
5 coalition of specialties impacted by rules related to physician in-office compounding; that
6 regulation of physician in-office compounding should be regulated by state medical boards
7 rather than state pharmacy boards; and that the AMA supports current 2008 USP General
8 Chapter <797> sterile compounding rules as pertaining to allergen extracts; and
9

10 Whereas, AMA Washington office staff have recently convened medical specialties affected by
11 recent proposed actions by the USP and FDA as they relate to physician office compounding
12 and are initiating a survey of the potential impact of proposed requirements on each specialty,
13 as well as assisting with outreach regarding broad concerns on this issue; and
14

15 Whereas, The USP's revisions to Chapter <797> are not anticipated until at least 2018; and
16

17 Whereas, In August 2016, the FDA issued a draft guidance entitled "Insanitary Conditions at
18 Compounding Facilities" that effectively circumvents the USP Chapter <797> revision process
19 by indicating that states should enforce a set of standards for compounding facilities, including
20 considering to be insanitary any compounded material not mixed under those standards, and
21 specifically including physician in-office compounding in its definition of "compounding facilities";
22 and
23

24 Whereas, The draft guidance specifically cites the 60 tragic deaths and 750 fungal meningitis
25 infections in 2012 resulting from contaminated products produced by a compounding pharmacy
26 and indicates that other adverse events have resulted from contaminated drug products
27 produced in commercial compounding facilities, but as yet the FDA has not provided evidence
28 or indication of any adverse events resulting from individually compounded medications
29 produced in physician offices; and specifically the FDA has not produced any data that allergen
30 extract compounding in physician offices has resulted in any infectious complications in
31 patients; and
32

33 Whereas, Any physician in the practice of Allergy/Immunology would have to consider
34 immediately halting treatment already underway for patients on allergen immunotherapy,
35 including those in treatment for allergies with a significant risk of life threatening anaphylaxis,
36 under threat of potential recourse by states implementing these standards as soon as a finalized
37 guidance might be issued, thereby putting these patients at serious risk of physical harm; and

1 Whereas, Allergen immunotherapy, which has been provided in the U.S. for more than 100
2 years with no known documented adverse infectious events, requires the allergist to compound
3 not only initial individualized treatment sets, but sometimes also to make modifications to a
4 patients' allergen extract over the course of this highly personalized treatment; and this
5 generally would not be possible under the standards suggested in the draft guidance, therefore
6 creating a significant barrier to the physician's ability to practice evidence based medicine; and
7

8 Whereas, The FDA's draft guidance, if made final, would thus have significant detrimental
9 impact on patients' access to optimal individualized care by limiting their physicians' ability to
10 practice medicine; and
11

12 Whereas, There is no known evidence that this effort by the FDA to expand compounding
13 pharmacy-level precautionary measures is indicated or necessary for small-volume physician in-
14 office compounding, and if FDA has such evidence that has not been shared then it is acting
15 without sufficient transparency for such an extraordinary regulatory over-reach; therefore be it
16

17 RESOLVED, That our American Medical Association strongly request that the US Food and
18 Drug Administration (FDA) withdraw its draft guidance "Insanitary Conditions at Compounding
19 Facilities" and that no further action be taken by the agency until revisions to the USP Chapter
20 <797> on Sterile Compounding, have been finalized (Directive to Take Action); and be it further
21

22 RESOLVED, That our AMA work with the US Congress to adopt legislation that would preserve
23 physician office-based compounding as the practice of medicine and codify in law that
24 physicians compounding medications in their offices for immediate or subsequent use in the
25 management of their patients are not compounding facilities under the jurisdiction of the FDA.
26 (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/13/16

Reference Committee C

CME Report(s)

01 Access to Confidential Health Services for Medical Students and Physicians

Resolution(s)

- 301 Expanding the Treatment of Opioid Dependence Using Medication-Assisted Treatment by Physicians in Residency Training Programs
- 302 Protecting the Rights of Breastfeeding Residents and Fellows
- 303 Primary Care and Mental Health Training in Residency
- 304 Improving Access to Care and Health Outcomes
- 305 Privacy, Personal Use and Funding of Mobile Devices
- 306 Formal Leadership Training During Medical Education
- 307 Inappropriate Uses of Maintenance of Certification
- 308 Promoting and Reaffirming Domestic Medical School Clerkship Education
- 309 Development of Alternative Competency Assessment Models
- 310 Maintenance of Certification and Insurance Plan Participation
- 311 Prevent Maintenance of Certification Licensure and Hospital Privileging Requirements
- 312* Eliminating the Tax Liability for Payment of Student Loans

REPORT 1 OF THE COUNCIL ON MEDICAL EDUCATION (I-16)
Access to Confidential Health Services for Medical Students and Physicians
(Resolution 901-I-15, Resolution 913-I-15, Resolution 304-A-16)
(Reference Committee C)

EXECUTIVE SUMMARY

This report is in response to AMA Policy D-405.983, “Medical Students and Residents as Patients,” and to Resolution 901-I-15, “Access to Mental Health Care for Medical Trainees”; Resolution 913-I-15, “Mental Health Services for Medical Staff”; and Resolution 304-A-16, “Evaluation of Factors During Residency and Fellowship that Impact Routine Health Maintenance.”

To ensure a holistic approach to this issue, the scope of this report has been expanded beyond access to mental health care services to encompass confidential access to all health services. That said, it should be emphasized that the provision of mental health services, and the confidentiality of this care, is a critical need throughout medical education training and practice and presents some challenges in the inherently imbalanced relationship(s) between and among teachers and learners.

This report provides an overview of the issue and its challenges vis-à-vis the culture of medicine writ large and then examines potential solutions by a number of key stakeholders, including: 1) accrediting agencies, 2) medical institutions, including medical schools, residency/fellowship programs, employers, hospitals, and 3) professional associations, particularly the AMA.

Issues cited include 1) The mental and physical toll that medical education exacts on medical students and physicians, as they seek to balance their personal lives with the need to master a growing body of knowledge and develop the needed skills to practice medicine; 2) The “hidden curriculum” of medical education, which can expose students/learners to an unhealthy emotional environment and contribute to burnout; 3) The long-standing and deeply ingrained stigma against physicians seeking care for either physical or mental health issues, partly due to concerns of career and licensure implications; 4) Issues with confidentiality of care, particularly in training or practice settings in more isolated, rural areas or small towns, as a significant barrier to seeking needed services; and 5) Acculturation during medical education and training to ignore one’s own personal health needs rather than expose colleagues and team members to an even more onerous work load.

Through the work of two of its strategic focus areas, 1) Accelerating Change in Medical Education and 2) Professional Satisfaction and Practice Sustainability, the AMA can play a key role, alongside other stakeholders, in addressing these systemic issues in medical education and practice and ensuring a healthier health care environment, to the ultimate benefit not only of medical students and physicians but patients as well.

The report’s recommendations include revisions to existing AMA policy on medical student and physician health, to streamline and consolidate this policy into a more cohesive, coherent body. These recommendations do not reflect new policy directives for the AMA.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 1-I-16

Subject: Access to Confidential Health Services for Medical Students and Physicians
(Resolution 901-I-15, Resolution 913-I-15, Resolution 304-A-16)

Presented by: Patricia L. Turner, MD, Chair

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

INTRODUCTION

This report of the Council on Medical Education is in response to the following American Medical Association (AMA) Policy and to the three resolutions noted below, which were referred by the House of Delegates:

- Policy D-405.983, “Medical Students and Residents as Patients,” which directs the American Medical Association (AMA) to study ways to address the power dichotomy between physicians and medical students, residents and fellows as it relates to these trainees’ care as patients.
- Resolution 901-I-15, “Access to Mental Health Care for Medical Trainees” (introduced by the Indiana Delegation), which asks that the AMA: 1) Support the provision of on-campus mental health care in medical schools and residency programs that goes beyond supportive counseling; and 2) Encourage ongoing and future initiatives by medical schools and residency programs to provide urgent and emergent access for all medical trainees to psychiatrists that could include an in-house board-certified psychiatrist.
- Resolution 913-I-15, “Mental Health Services for Medical Staff” (introduced by the Resident and Fellow Section), which asks that the AMA encourage health systems, hospitals, and medical schools to offer physicians and medical students access to confidential and comprehensive mental health services not affiliated with their place of employment.
- Resolution 304-A-16, “Evaluation of Factors During Residency and Fellowship that Impact Routine Health Maintenance” (introduced by the Resident and Fellow Section), which asks that the AMA study ways to improve access and reduce barriers to seeking preventive and routine physical and mental health care for trainees in graduate medical education programs.

For Resolutions 901-I-15 and 913-I-15, testimony before Reference Committee K at the 2015 Interim Meeting emphasized the importance of making confidential and comprehensive mental health services available to medical students and resident/fellow physicians. It was noted that Liaison Committee on Medical Education (LCME) accreditation standards require medical schools to provide medical services at sites in reasonable proximity to the locations of their required educational experiences, and that the LCME collects data on access to psychiatric services and

1 student satisfaction with mental health services. It was also noted that this item is consistent with
2 the work being done by the Accreditation Council for Graduate Medical Education (ACGME) to
3 support trainee well-being, through such efforts as the ACGME Clinical Learning Environment
4 Review process. There was concern expressed during testimony about providing students and
5 residents access to in-house psychiatrists for urgent and emergent care. It was noted that a
6 psychiatrist located in reasonable proximity to training sites would be the most appropriate
7 caregiver so that students and residents would not be obligated to receive care from a physician
8 who is involved in their academic assessment and advancement. Other factors related to
9 Occupational Safety and Health Administration (OSHA) standards and occupational health care
10 regulations also need to be considered, as well as the health of physicians beyond training years.

11
12 For Resolution 304-A-16, significant testimony was provided to Reference Committee C at the
13 2016 Annual Meeting, reflecting the importance of this timely issue, as the epidemic of physician
14 burnout and suicide continues unabated. Testimony noted the work of the AMA in exploring and
15 disseminating solutions, through its Professional Satisfaction and Practice Sustainability strategic
16 focus area, for example, and educational sessions on the topic during the 2016 Annual Meeting. It
17 was also noted that the Accreditation Council for Graduate Medical Education, through its
18 Physician Well-Being initiative (as described further below), is actively addressing the issues of
19 physician burnout, wellness and resiliency. Additional testimony noted issues of confidentiality in
20 accessing needed care, especially in smaller cities and towns; the reluctance among trainees to seek
21 care due to fear of burdening their residency colleagues with having to cover for their absence; and
22 the need to change the culture of medicine to enhance physician well-being and work-life balance.

23 24 BACKGROUND

25
26 To ensure a holistic approach to this issue (and in light of the need to respond to Resolution 304-A-
27 16), the scope of this report has been expanded beyond access to mental health care services to
28 encompass confidential access to all health services. That said, it is important to emphasize that the
29 provision of mental health services, and the confidentiality of this care, is a critical need throughout
30 medical education training and practice and presents some challenges in the inherently imbalanced
31 relationship(s) between and among teachers and learners. Although Policy D-405.983 calls for
32 studying this imbalance, the real priority (and the objective for this report) is how to address this
33 imbalance so that medical students and resident/fellow physicians can receive appropriate care
34 without fear of stigma or repercussions.

35
36 This report provides an overview of the issue and its challenges vis-à-vis the culture of medicine
37 writ large and then examines potential solutions by a number of key stakeholders, including:
38 1) accrediting agencies; 2) medical institutions, including medical schools, residency/fellowship
39 programs, employers, hospitals; and 3) professional associations, particularly the AMA.

40 41 THE NEED FOR MEDICAL STUDENT AND PHYSICIAN ACCESS TO CARE

42
43 Interest in physician health and wellness has increased significantly over the last few years, as
44 stressors in medical education and practice exact a mental and physical toll on medical students and
45 physicians. Those at the early stages of their careers—medical students and resident/fellow
46 physicians—are undergoing the challenges of balancing their personal lives with the need to master
47 a growing body of knowledge and develop the needed skills to practice in a changing health care
48 environment. What is often called the “hidden curriculum” of medical education can expose
49 students/learners to an unhealthy emotional environment and can contribute to burnout. Residency
50 training, in particular, can be a daunting endeavor for many, despite the implementation of duty

hour limits. For some, the personal and professional stresses become too great, leading to emotional distress, burnout, major depression, and, in extreme cases, suicide.

Indeed, a study in the Dec. 8, 2015 issue of *JAMA* found that nearly one-third of interns and residents experience depressive symptoms or full-blown depression at some point during their training. The prevalence of depression among trainees is significantly higher among medical residents than the general population (about 7 percent of all U.S. adults had at least one major depressive episode during the previous year, according to the National Institute of Mental Health).

Similarly, more than half of U.S. physicians “experienced at least one symptom of burnout in 2014, compared to about 46 percent of doctors in 2011,” notes coverage of a *Mayo Clinic Proceedings* study released on Dec. 1, 2015. These data point to the need for interventions for all physicians and physicians-in-training to learn techniques for ensuring wellness, managing burnout when symptoms arise, and improving emotional resiliency to professional and personal challenges.

Without serious attention to physician wellness, physicians may retire earlier or leave medicine for another field, further exacerbating medical workforce shortages and reducing access to needed care among patients. Even for those who remain in practice, burnout can have substantial professional and patient safety implications. An extensive body of research has demonstrated a strong link between physicians’ personal well-being and the quality of care they provide patients, as well as a positive relation between physicians’ and patients’ preventive health practices.¹ Finally, as role models and mentors to those who will serve as the nation’s future physicians, academic physicians must develop a better understanding of the importance of and need for wellness so that they can help their mentees succeed.

From a systemic perspective, the stigma against physicians seeking care for either physical or mental health issues is long-standing and deeply ingrained. Generalizations about generational differences come into play as well, with a commonly held stereotype in medicine that today’s “kids” (the Millennials, for example) are not as committed to medicine and their patients as their predecessors and lack the requisite work ethic to be physicians. Long hours and commitment to patients are praised, and attention to self-care or healthy lifestyles/prevention may be seen as self-indulgent or indicative of a lack of dedication. Little or no confidentiality, particularly in training or practice settings in more isolated, rural areas or small towns, can be a barrier to seeking needed services. During training, many resident/fellow physicians are acculturated to ignore their own personal health needs (sleep, for example) and are loath to miss a shift and expose colleagues and team members to an even more onerous work load. Many physicians develop a “survival” mentality during medical school and training, which extends throughout their careers, with unfortunate consequences for personal health and well-being as well as work-life balance and interpersonal and family relationships.

Physicians who continue to work when sick and who routinely ignore their own health needs to provide care to their patients may be unintentionally endangering those very patients—e.g., by exposing them to contagions or infection if they come to work while sick, or to unintentional injury if they are not well-rested. As noted in the *AMA Code of Medical Ethics* 9.3.1, “Physician Health & Wellness” (included in the appendix of this report), “When physician health or wellness is compromised, so may the safety and effectiveness of the medical care provided. To preserve the quality of their performance, physicians have a responsibility to maintain their health and wellness, broadly construed as preventing or treating acute or chronic diseases, including mental illness, disabilities, and occupational stress.” The policy also notes that physicians should take “appropriate measures to protect patients, including measures to minimize the risk of transmitting infectious disease commensurate with the seriousness of the disease.”

These attitudes and behaviors may be gradually shifting—particularly as more physicians enter into employment versus solo practice—but the enduring power of the “medical-institutional complex” and the attitudes of attending physicians and faculty (upon whose approval/satisfaction one’s career rests) may ensure the perpetuation of an ultimately unhealthy hidden curriculum and culture. For example, one medical student, who decided to be outspoken about her own personal mental health struggles, wrote, “Dealing with academic administration is an awful part of med school. It’s a medieval-like process of judgment and punishment to ask for help or find yourself struggling with all the exams.”²

In addition, a significant number of mental health professionals do not accept insurance. A recent news report notes, “[N]early half of therapists in California don’t take insurance, according to a recent survey from the California Association of Marriage and Family Therapists. The same is true of psychiatrists.”³ This widespread lack of insurance coverage presents another barrier to medical students and resident/fellow physicians seeking mental care services and counseling.

The extent of these pernicious issues and challenges throughout medical education and practice call for a variety of individual, institutional, and systemic (cultural) solutions. When learners/employees access medical/behavioral services from teachers/employers, the potential exists for troublesome conflicts of interest, confidentiality concerns, and related issues. As noted in the following sections, key stakeholders in this process include: 1) accrediting agencies; 2) medical institutions, including medical schools, residency/fellowship programs, employers, hospitals; and 3) the AMA and other professional associations and related bodies.

THE WORK OF ACCREDITING AGENCIES

Liaison Committee on Medical Education (LCME)

Relevant LCME standards (now called “Elements”) are included below (note that the LCME defines personal counseling to include psychiatric and psychological services):

12.5 Non-Involvement of Providers of Student Health Services in Student Assessment/ Location of Student Health Records

The health professionals who provide health services, including psychiatric/psychological counseling, to a medical student have no involvement in the academic assessment or promotion of the medical student receiving those services. A medical school ensures that medical student health records are maintained in accordance with legal requirements for security, privacy, confidentiality, and accessibility.

12.4 Student Access to Health Care Services

A medical school provides its medical students with timely access to needed diagnostic, preventive, and therapeutic health services at sites in reasonable proximity to the locations of their required educational experiences and has policies and procedures in place that permit students to be excused from these experiences to seek needed care.

12.3 Personal Counseling/Well-Being Programs

A medical school has in place an effective system of personal counseling for its medical students that includes programs to promote their well-being and to facilitate their adjustment to the physical and emotional demands of medical education.

Commission on Osteopathic College Accreditation (COCA)

Relevant standards from the COCA are as follows:

5.5.7 The COM [College of Medicine] and/or its parent institution must make available to students confidential resources for physical healthcare services.

5.5.8 The COM and/or its parent must make available to students on a 24 hour per day 7 days a week (“24/7”) basis, confidential resources for behavioral healthcare services.⁴

Accreditation Council for Graduate Medical Education (ACGME)

Through its Physician Well-Being initiative, the ACGME is engaging in a national dialogue on this issue to ensure positive, transformational change in the learning environment. Beginning with a symposium in November 2015, medical education organizations representing accreditation, assessment, and certification, along with the AMA, have joined the ACGME in prioritizing this issue. As noted on the initiative’s website, the following areas of focus have been identified:

- Physician well-being is an individual and a system issue, and needs to be addressed on both levels.
- Alignment between institutional leadership and faculty members in the learning environment is necessary to create a culture of respect and accountability for physician well-being.
- The well-being of physicians as caregivers is crucial to their ability to deliver the safest, best possible care to patients.

Although the ACGME does not have specific accreditation standards on resident wellness and confidential access to health care services, certain standards are relevant to this topic. For example, its Institutional Requirements⁵ state:

Behavioral Health: The Sponsoring Institution must provide residents/fellows with access to confidential counseling and behavioral health services.

Physician Impairment: The Sponsoring Institution must have a policy, not necessarily GME-specific, which addresses physician impairment.

The Sponsoring Institution must ensure a healthy and safe learning and working environment that provides for:

- access to food while on duty at all participating sites;
- safe, quiet, and private sleep/rest facilities available and accessible for residents/fellows to support education and safe patient care; and
- security and safety measures appropriate to the participating site.

Meanwhile, the ACGME Common Program Requirements,⁶ in the section “Resident Duty Hours in the Learning and Working Environment,” state:

Programs and sponsoring institutions must educate residents and faculty members concerning the professional responsibilities of physicians to appear for duty appropriately rested and fit to provide the services required by their patients.

The program must be committed to and responsible for promoting patient safety and resident well-being in a supportive educational environment.

In addition, these requirements state that residents and faculty members “must demonstrate an understanding and acceptance of their personal role in the following,” including “recognition of impairment, including illness and fatigue, in themselves and in their peers.”

The ACGME is in the process of updating the Common Program Requirements. Revision of section VI of these requirements was in process at the time this report was written. These new Common Program Requirements are likely to include a section on resident well-being. The ACGME supports the fact that well-being is critical to the development of physicians and that self-care is an important component of a physician’s professional life.

Finally, one of the six focus areas that is part of the ACGME’s Clinical Learning Environment Review (CLER) program has been renamed to reflect a broader emphasis on physician well-being. The ACGME Board of Directors approved the recommendation of the Executive Committee for the CLER Evaluation Committee, such that the CLER focus area currently called “Duty Hours/Fatigue Mitigation and Management” has been renamed “Well-Being,” effective July 1, 2017. This focus area will concentrate primarily on the Clinical Learning Environment’s systems-based approaches to creating and maintaining an environment of well-being. It is anticipated that the new focus area will include a number of pathways and properties that address fatigue, burnout, work-life balance, and support of residents and faculty at risk or demonstrating self-harm. The other five CLER focus areas are patient safety, health care quality, care transitions, supervision, and professionalism.

The Joint Commission

Joint Commission standard MS.11.01.01 requires that medical staffs create a non-disciplinary process by which licensed independent practitioners’ health issues can be identified and managed. When the standard was first created, many hospitals implemented wellness committees with the primary focus of detecting and reprimanding physicians struggling with addiction, stress, or other issues that could negatively impact patient safety. More recently, however, an increased focus on physician burnout by the medical community at large has led many of these groups to shift their thinking and proactively offer tools and resources meant to alleviate stress and promote resiliency.

THE WORK OF MEDICAL INSTITUTIONS

Academic medical centers and regional health systems, medical schools, residency/fellowship programs, teaching hospitals, and physician groups all have a role to play in addressing medical student and physician health. Each type of organization can take action on this topic in different ways.

For example, as described by the authors of a 2012 study in *Academic Medicine*,⁷ one teaching hospital’s graduate medical education division has sought to address obstacles to resident/fellow well-being by implementing a policy “that requires programs to assign residents four half-days off per academic year for health care and wellness (physical and mental well-being).” The study, which detailed gaps in personal health care practices of resident/fellow physicians, noted that this population may be less likely than demographically similar non-physician peers to have a primary care physician or seek routine health or dental care. Some of the concerns identified in the study include a perception of lack of time to see a physician, lack of access to an appropriate physician, and concerns about confidentiality and stigmatization (particularly as it relates to seeking mental

health services). In addition, with the introduction of the 16-hour work day requirements for first-year resident physicians, many residency programs have gone to week- or month-long night float rotations. The residents on night float, therefore, have additional time for personal well-being visits. Residents on a more traditional day-work schedule, who in the past had part of their post-call days free, now no longer take call. As a result, their post-call flexibility may be limited except when they are assigned to the night float service.

For medical students and physicians seeking care, particularly those in more remote communities, telemedicine may offer one way to supersede some of these issues—particularly the confidentiality, access, and time/scheduling concerns that an on-site, face-to-face visit might present. As reflected in Council on Medical Education Report 6-A-16, “Telemedicine in Medical Education,” this modality offers multiple benefits and is growing in popularity. Indeed, a recent news article describes how telemedicine kiosks are becoming more common, with an increasing number of employers offering insurance coverage for telemedicine services and installing telemedicine kiosks at work sites so employees can receive on-the-job medical advice.⁸

Another possible solution for institutions to consider, as described in a recent article in *Academic Medicine*,⁹ is to apply the principles of the patient-centered medical home to improving care for resident/fellow physicians. The authors suggest several interventions to improve access to care, including “confidential care without perceived conflicts of interest in the training environment, co-location of medical and mental health care, and accommodations for schedule constraints.” These types of resources and support may be particularly useful for first-year resident physicians, who are not as familiar as their senior colleagues with seeking and obtaining health care services in the specific hospital/health system in which they are training.

Finally, as noted earlier in this report, a significant number of psychiatrists and other mental health professionals do not accept insurance, which presents another barrier to medical students and resident/fellow physicians obtaining needed care and counseling services. In Manhattan, for example, and other large cities, mental health/counseling services are prohibitively expensive for residents and fellows—\$350 to \$450 a session is common. To address this issue, New York-Presbyterian, a sponsoring institution for 135 residency/fellowship programs, has developed Housestaff Mental Health Services.¹⁰ Through this program, resident/fellow physicians can access up to eight free, confidential sessions from a pool of attending psychiatrists who have been identified as having a particular interest in and aptitude for working with housestaff. The institution pays for the services; insurance is not billed. A director (who is a psychiatrist) triages the residents, manages the program, and maintains a firewall of confidentiality between the trainees and anyone in the graduate medical education enterprise. Program directors and institutional leadership (to include the designated institutional official, for example) do not know who accesses these services; the human resources department processes the billing. As for usage, currently about 10% of housestaff access these services each year. The program is offered on each of New York-Presbyterian’s two GME campuses. Aside from helping individual residents access needed care, the program is also available as a resource for crisis management and promoting well-being among trainees.

THE WORK OF THE AMA

The AMA has a number of policies on this topic, as noted in the Appendix to this report:

1. H-95.955, “Physician Impairment”
2. H-225.961, “Medical Staff Development Plans”

- 1 3. H-225.966, “Medical Staff Role in the Development of Substance Abuse Policies and
- 2 Procedures”
- 3 4. H-235.977, “Medical Staff Committees to Assist Impaired or Distressed Physicians”
- 4 5. H-295.872, “Expansion of Student Health Services”
- 5 6. H-295.955, “Teacher-Learner Relationship in Medical Education”
- 6 7. H-295.999, “Medical Student Support Groups”
- 7 8. H-310.907, “AMA Duty Hours Policy”
- 8 9. H-310.912, “Residents and Fellows’ Bill of Rights”
- 9 10. H-310.979, “Resident Physician Working Hours and Supervision”
- 10 11. H-345.973, “Mental Health Services for Medical Students and Resident and Fellow
- 11 Physicians”
- 12 12. H-345.981, “Access to Mental Health Services”
- 13 13. H-405.961, “Physician Health Programs”
- 14 14. D-405.990, Educating Physicians about Physician Health Programs”
- 15 15. D-405.992, “Physician Health and Wellness”
- 16 16. D-405.996, “Physician Well-Being and Renewal”
- 17 17. H-440.905, “Confidentiality, Counseling and Treatment in the Tuberculosis Screening of
- 18 Health Care Workers”
- 19 18. E-9.0305, “Physician Health and Wellness”
- 20 19. E-8.191, “Peers as Patients”

21
22 Included in the recommendations of this report are several items to consolidate existing AMA
23 policy on this topic. For example, a portion of AMA Policy H-345.973, “Mental Health Services
24 for Medical Students and Resident and Fellow Physicians,” is proposed for recission, as it is
25 already reflected in LCME element 12.4, Student Access to Health Care Services (part of LCME
26 standard 12, Medical Student Health Services, Personal Counseling, and Financial Aid Services),
27 which reads: “A medical school provides its medical students with timely access to needed
28 diagnostic, preventive, and therapeutic health services at sites in reasonable proximity to the
29 locations of their required educational experiences and has policies and procedures in place that
30 permit students to be excused from these experiences to seek needed care.”

31
32 Aside from policy, the AMA has several ongoing projects/initiatives that address many aspects of
33 medical student and physician health. One example is the biennial International Conference on
34 Physician Health, a collaborative effort of the AMA, Canadian Medical Association, and British
35 Medical Association. The theme for the 2016 conference was “Increasing Joy in Medicine,” with a
36 focus on research about and perspectives into physicians’ health.

37
38 Similarly, the work of AMA member sections, including the Resident and Fellow Section, Young
39 Physicians Section, Organized Medical Staff Section, and others often touches on issues of
40 wellness, burnout, and physician health.

41
42 The AMA Academic Physicians Section (APS), for example, featured wellness/burnout throughout
43 the medical education and practice continuum as its educational focus during the 2016 Annual
44 Meeting. In his talk, Tait Shanafelt, MD, director of the Mayo Clinic Department of Medicine
45 Program on Physician Well-being at the Mayo School of Medicine in Rochester, Minn., reviewed
46 the literature on physician satisfaction and burnout and discussed the personal and professional
47 repercussions of physician distress. He also reviewed the individual and organizational approaches
48 to promoting physician well-being. Next, an interactive, hands-on session provided the opportunity
49 for medical education leaders to learn how creative expression—designing and constructing a mask
50 and drawing a comic—can mitigate the impacts of an unhealthy emotional environment, which can

lead to burnout. A third session on burnout was co-sponsored by the APS and the AMA Senior Physicians Section, featuring Richard Gunderman, MD, a professor at Indiana University.

AMA Medical Student Section

Another AMA section that is addressing wellness/burnout is the AMA Medical Student Section. The AMA-MSS works to represent the interests of medical students, improve medical education, develop leadership, and promote activism for the health of America. Related to improving accessibility to confidential health care services, the MSS can work to publicize, disseminate, and advocate for all efforts undertaken by the AMA on this topic. As reflected in MSS policy on this topic, some concrete recommendations for action at the medical school level include:

1. Creating a mental health awareness and suicide prevention screening program that would be available to all medical students on an opt-out basis; ensure anonymity, confidentiality, and protection from administration; provide proactive intervention for identified at-risk students by mental health professionals; and educate students and faculty about personal mental health and factors that may contribute to suicidal ideation.
2. Increasing or enhancing existing collaborations between university mental health specialists and local health centers to provide a larger pool of mental health resources.
3. Basing actions to improve access to confidential health services for medical students (e.g., on-campus programs, local campaigns) on the concepts of accessibility and de-stigmatization.

Accelerating Change in Medical Education

The AMA's Accelerating Change in Medical Education consortium comprises 32 medical schools working together to create the medical school of the future and transform physician training. An estimated 19,000 medical students—18% of all U.S. allopathic and osteopathic medical students—study at medical schools that are consortium members. The projects of several member schools of the consortium are focused on medical student wellness, including Eastern Virginia Medical School and Mayo Medical School. Further, the consortium has a newly formed student wellness interest group to share ideas across schools as to best practices to ensure wellness and counter burnout. Finally, several submissions to the 2015 AMA Medical Education Innovation Challenge focused on medical student wellness, including the third place winner, submitted by a team from the University of Louisville School of Medicine.

Professional Satisfaction and Practice Sustainability, Steps Forward modules

As one of the AMA's three key strategic focus areas, the Professional Satisfaction and Practice Sustainability initiative is addressing issues that practicing physicians face, including concerns with electronic health records and the rising wave of documentation requirements from insurers and regulators, by providing useful and user-friendly tools and apps to help ease the burdens of the administrative side of medicine. Indeed, for many physicians, dealing with regulatory, certification, licensure, insurer, and other rules and dictates represent a challenging and unfulfilling aspect of medicine. It is not surprising, then, that data from the AMA's Steps Forward website show that the Preventing Physician Burnout module is among the most popular modules that have been accessed via the site.

1 *AMA Council on Ethical and Judicial Affairs (CEJA)*

2
3 The AMA Council on Ethical and Judicial Affairs (CEJA) works to maintain and update the *Code*
4 *of Medical Ethics*, through its policy development function, and to promote adherence to the
5 professional ethical standards set out in the *Code*, through its judicial function. Related to the topic
6 of this report, CEJA may wish to review its guidance so that AMA ethics policy addresses conflicts
7 of interest involving confidential health services for medical students and resident/fellow
8 physicians, in addition to that of physicians.

9
10 THE WORK OF PROFESSIONAL ASSOCIATIONS AND OTHER ENTITIES

11
12 Other entities involved in this issue include the Association of American Medical Colleges and
13 American Osteopathic Association. In addition, through its role in identifying major issues in
14 education and focusing national attention on these issues, the U.S. Department of Education should
15 be a major stakeholder in any kind of education reform (e.g., de-stigmatization of mental health
16 services). The Department's role might include allocating funds to research on this topic, releasing
17 data on what successful de-stigmatization efforts would entail (and encouraging states to
18 implement those efforts), and, more generally, informing the public on the importance of access to
19 mental health services in post-secondary education.

20
21 *Federation of State Medical Boards (FSMB) and State Medical Boards*

22
23 Physician burnout is a key topic of interest for the Federation of State Medical Boards (FSMB).
24 Currently, an FSMB workgroup, appointed by FSMB chair Art Hengerer, MD is studying burnout
25 on behalf of the nation's state medical and osteopathic boards. In addition, the FSMB participated
26 in a planning meeting in July at the National Academy of Medicine—at the invitation of its
27 president, Victor Dzau, MD—to explore the issue of physician burnout and the role of the National
28 Academies of Sciences, Engineering and Medicine in advancing a solution. The meeting was co-
29 hosted by Darrell Kirch, MD, CEO of the Association of American Medical Colleges, and Tom
30 Nasca, MD, CEO of the Accreditation Council for Graduate Medical Education.

31
32 Meanwhile, the state medical licensing boards can work to de-stigmatize treatment for mental
33 illness. In this regard, the FSMB and the state boards should consider a reevaluation of the scope of
34 boards' access to applicants' health records during the medical licensure application process,
35 including the need for applicants to disclose treatment received by a mental health professional.
36 This disclosure may have a chilling effect on medical students who would like to seek treatment for
37 their mental illness; students may fear being perceived as professionally impaired and/or
38 discriminated against by medical boards.

39
40 One example, from the Illinois Application for Physician Licensure, Question 4 of Personal
41 History,¹¹ is illustrative of the scope of licensing boards' queries related to mental health; it asks
42 for:

43
44 A report from any and all physicians, counselors, or therapists from whom you have received
45 treatment for any chronic disease or condition (i.e., chemical/ alcohol dependency, depression,
46 etc.). The report must include dates of treatment, method of treatment, diagnosis, and
47 prognosis. Attach a detailed statement advising whether you are currently under treatment. If
48 you have been treated as an inpatient/outpatient at any time for any disease or condition, then it
49 will be necessary for you to have the institution(s) submit, directly to this Department, copies
50 of any and all admitting histories, physicals and discharge summaries for each
51 inpatient/outpatient stay or treatment.

Similarly, state boards of professional regulation, in their work to ensure patient protection, may consider a less punitive approach to addressing physician impairment. For example, boards could reevaluate the factors that contribute to the suspension of a medical license and determine whether these factors: (a) relate to mental illness; and (b) could be replaced with an option for treatment, rather than or in addition to a punishment (i.e., license suspension).

Physician Health Programs

Related to state physician health programs, one potential model/best practice comes from Colorado, where the Colorado Physician Health Program (CPHP) offers a safe haven for reporting of physicians with mental health issues to the medical board.¹² That is, physicians who are applying or reapplying for a Colorado medical license can ensure, under specific conditions, that certain medical and/or psychiatric matters will remain unknown to the state medical board.

As with other state medical board licensure applications, the Colorado application includes questions pertaining to medical/psychiatric health, encompassing substance use, mental health disorders, and cognitive matters. The applicant must indicate either yes or no, to acknowledge or deny the presence of a medical or psychiatric condition, respectively.

The applicant may also answer no, and keep certain personal health matters unknown to the medical board, if: 1) the CPHP has been informed of the applicant's health matter(s); 2) the applicant has attended an initial appointment with CPHP for the behavior or condition; and 3) there is compliance with all of CPHP's requirements for evaluation, treatment, and/or monitoring.

This safe haven encourages physicians to proactively seek and receive the health care services they need, confidentially, and provides assurance to the Colorado medical board (through oversight by the CPHP) that patient safety is not jeopardized.

SUMMARY AND RECOMMENDATIONS

Ensuring access to confidential health services for medical students and physicians offers many ethical, logistical, educational, and systemic/cultural challenges. Fortunately, a variety of programs/initiatives/requirements are currently in place, from accrediting agencies and medical institutions, along with the AMA and other professional associations, to ensure more attention and holistic solutions to this issue. The Council on Medical Education believes that this report and its recommendations will help raise awareness of and action on this important issue as it relates to the medical education needs of medical students and physicians throughout the continuum.

The Council on Medical Education therefore recommends that the following recommendations be adopted in lieu of Resolutions 901-I-15, 913-I-15, and 304-A-16, and the remainder of the report be filed.

1. That our American Medical Association (AMA) ask the Liaison Committee on Medical Education, Commission on Osteopathic College Accreditation, American Osteopathic Association, and Accreditation Council for Graduate Medical Education to encourage medical schools and residency/fellowship programs, respectively, to:
 - 1) Provide or facilitate the immediate availability of urgent and emergent access to low-cost, confidential health care and mental health counseling services that: a) include appropriate follow-up; b) are outside the trainees' grading and evaluation pathways; and c) are available (based on patient preference and need for assurance of confidentiality) in

reasonable proximity to the education/training site, at an external site, or through telemedicine or other virtual, online means;

2) Ensure that residency/fellowship programs are abiding by all duty hour restrictions, as these regulations exist in part to ensure the mental and physical health of trainees;

3) Encourage and promote routine health screening among medical students and resident/fellow physicians, and consider designating some segment of already-allocated personal time off (if necessary, during scheduled work hours) specifically for routine health screening and preventive services, including physical, mental, and dental care; and

4) Remind trainees and practicing physicians to avail themselves of any needed resources, both within and external to their institution, to provide for their mental and physical health and well-being, as a component of their professional obligation to ensure their own fitness for duty and the need to prioritize patient safety and quality of care by ensuring appropriate self-care, not working when sick, and following generally accepted guidelines for a healthy lifestyle. (New HOD Policy).

2. That our AMA urge state medical boards to accept “safe haven” non-reporting for physicians seeking licensure or relicensure who are undergoing treatment for mental health issues, to help ensure confidentiality of such treatment for the individual physician while providing assurance of patient safety. (New HOD Policy).

3. That Policy H-345.973, “Mental Health Services for Medical Students and Resident and Fellow Physicians,” be amended by addition and deletion, as follows.

Medical and Mental Health Services for Medical Students and Resident and Fellow Physicians

Our AMA promotes the availability of timely, confidential, accessible, and affordable medical and mental health services for medical students and resident and fellow physicians, to include needed diagnostic, preventive, and therapeutic services. Information on where and how to access these services should be readily available at all education/training sites, and these services should be provided at sites in reasonable proximity to the sites where the education/training takes place. (Modify Current HOD Policy).

4. That Policy H-295.872, “Expansion of Student Health Services,” be rescinded, as it is (in part) already reflected in current LCME standards and (in part) now incorporated into Policy H-345.973, Mental Health Services for Medical Students and Resident and Fellow Physicians. (Rescind HOD Policy).

5. That Policy D-405.992, “Physician Health and Wellness,” and D-405.996, “Physician Well-Being and Renewal,” be rescinded, as these directives have been accomplished, are superseded by other policy, or are no longer relevant. (Rescind HOD Policy).

6. That Policy D-405.983, “Medical Students and Residents as Patients,” be rescinded, as having been fulfilled by this report. (Rescind HOD Policy).

Fiscal Note: \$1,000.

APPENDIX: RELEVANT AMA POLICY

H-95.955, “Physician Impairment”

(1) The AMA defines physician impairment as any physical, mental or behavioral disorder that interferes with ability to engage safely in professional activities and will address all such conditions in its Physician Health Program. (2) The AMA encourages state medical society-sponsored physician health and assistance programs to take appropriate steps to address the entire range of impairment problems that affect physicians, to develop case finding mechanisms for all types of physician impairments, and to collect data on the prevalence of conditions affecting physician health. (3) The AMA encourages additional research in the area of physician impairment, particularly in the type and impact of external factors adversely affecting physicians, including workplace stress, litigation issues, and restructuring of the health care delivery systems.

H-225.961, “Medical Staff Development Plans”

1. All hospitals/health systems incorporate the following principles for the development of medical staff development plans: (h) Staff privileges for physicians should be based on training, experience, demonstrated competence, and adherence to medical staff bylaws. No aspect of medical staff membership or particular clinical privileges shall be denied on the basis of sex, race, age, creed, color, national origin, religion, disability, ethnic origin sexual orientation, gender identity or physical or mental impairment that does not pose a threat to the quality of patient care.

H-225.966, “Medical Staff Role in the Development of Substance Abuse Policies and Procedures”

1. Our AMA establishes the primacy of medical staff authority in substance abuse policy and procedures covering any pre-employment, credentialing, or other phases of physician evaluation. 2. Policy of the AMA states that medical staff must be involved in the development of the institution’s substance abuse policy, including: (a) selection of analytical methods to ensure scientific validity of the test results, (b) determination of measures to maintain confidentiality of the test results, (c) in for-cause post-incident/injury testing, definition of standards for determining whether cause exists and which incidents and/or injuries will result in testing, and (d) development of mechanisms to address the physical and mental health of medical staff members. 3. The AMA believes all drug and alcohol testing must be performed only with substantive and procedural due process safeguards in place.

H-235.977, “Medical Staff Committees to Assist Impaired or Distressed Physicians”

Our AMA recognizes the importance of early recognition of impaired or distressed physicians, and encourages hospital medical staffs to have provisions in their bylaws for a mechanism to address the physical and mental health of their medical staff and housestaff members.

H-295.872, “Expansion of Student Health Services”

1. It is AMA policy that medical students should have timely access to needed preventive and therapeutic medical and mental health services at sites in reasonable proximity to where their education is occurring. 2. Out AMA will encourage the LCME to develop an annotation to its standard on medical student access to preventive and therapeutic health services that includes a specification of the following: a. Medical students should have timely access to needed preventive and therapeutic medical and mental health services at sites in reasonable proximity to where their education is occurring. b. Medical students should have information about where and how to access health services at all locations where training occurs. c. Medical schools should have policies that permit students to be excused from class or clinical activities to seek needed care.

H-295.955, “Teacher-Learner Relationship in Medical Education”

CODE OF BEHAVIOR: The teacher-learner relationship should be based on mutual trust, respect, and responsibility. This relationship should be carried out in a professional manner, in a learning environment that places strong focus on education, high quality patient care, and ethical conduct... Certain behaviors are inherently destructive to the teacher-learner relationship. Behaviors such as violence, sexual harassment, inappropriate discrimination based on personal characteristics must never be tolerated. Other behavior can also be inappropriate if the effect interferes with professional development. Behavior patterns such as making habitual demeaning or derogatory remarks, belittling comments or destructive criticism fall into this category. On the behavioral level, abuse may be operationally defined as behavior by medical school faculty, residents, or students, which is consensually disapproved by society and by the academic community as either exploitive or punishing. Examples of inappropriate behavior are: physical punishment or physical threats; sexual harassment; discrimination based on race, religion, ethnicity, sex, age, sexual orientation, gender identity, and physical disabilities; repeated episodes of psychological punishment of a student by a particular superior (e.g., public humiliation, threats and intimidation, removal of privileges); grading used to punish a student rather than to evaluate objective performance; assigning tasks for punishment rather than educational purposes; requiring the performance of personal services; taking credit for another individual’s work; intentional neglect or intentional lack of communication...

H-295.999, “Medical Student Support Groups”

(1) Our AMA encourages the development of alternative methods for dealing with the problems of student-physician mental health among medical schools, such as: (a) introduction to the concepts of physician impairment at orientation; (b) ongoing support groups, consisting of students and house staff in various stages of their education; (c) journal clubs; (d) fraternities; (e) support of the concepts of physical and mental well-being by heads of departments, as well as other faculty members; and/or (f) the opportunity for interested students and house staff to work with students who are having difficulty. (2) Our AMA supports making these alternatives available to students at the earliest possible point in their medical education.

H-310.907, “AMA Duty Hours Policy”

Our AMA adopts the following Principles of Resident/Fellow Duty Hours, Patient Safety, and Quality of Physician Training: 3. Our AMA encourages publication and supports dissemination of studies in peer-reviewed publications and educational sessions about all aspects of duty hours, to include such topics as extended work shifts, handoffs, in-house call and at-home call, level of supervision by attending physicians, workload and growing service demands, moonlighting, protected sleep periods, sleep deprivation and fatigue, patient safety, medical error, continuity of care, resident well-being and burnout, development of professionalism, resident learning outcomes, and preparation for independent practice.

H-310.912, “Residents and Fellows’ Bill of Rights”

...E. Adequate compensation and benefits that provide for resident well-being and health. (3) With Regard to Benefits, Residents and Fellows Should Receive: a. Quality and affordable comprehensive medical, mental health, dental, and vision care; b. Education on the signs of excessive fatigue, clinical depression, and substance abuse and dependence; c. Confidential access to mental health and substance abuse services; d. A guaranteed, predetermined amount of paid vacation leave, sick leave, maternity and paternity leave and educational leave during each year in their training program the total amount of which should not be less than six weeks; and e. Leave in compliance with the Family and Medical Leave Act.

H-310.979, “Resident Physician Working Hours and Supervision”

(1) Our AMA supports the following principles regarding the supervision of residents and the avoidance of the harmful effects of excessive fatigue and stress: (g) The program director, with institutional support, must assure for each resident effective counseling as stated in Section II.D.4.k of the Institutional requirements: "Counseling services: The Sponsoring Institution should facilitate residents' access to confidential counseling, medical, and psychological support services."

H-345.973, “Mental Health Services for Medical Students and Resident and Fellow Physicians”

Our AMA promotes confidential, accessible, and affordable mental health services for medical students and resident and fellow physicians.

H-345.981, “Access to Mental Health Services”

Our AMA advocates the following steps to remove barriers that keep Americans from seeking and obtaining treatment for mental illness: (1) reducing the stigma of mental illness by dispelling myths and providing accurate knowledge to ensure a more informed public; (2) improving public awareness of effective treatment for mental illness; (3) ensuring the supply of psychiatrists and other well trained mental health professionals, especially in rural areas and those serving children and adolescents; (4) tailoring diagnosis and treatment of mental illness to age, gender, race, culture and other characteristics that shape a person's identity; (5) facilitating entry into treatment by first-line contacts recognizing mental illness, and making proper referrals and/or to addressing problems effectively themselves; and (6) reducing financial barriers to treatment.

H-405.961, “Physician Health Programs”

Our AMA affirms the importance of physician health and the need for ongoing education of all physicians and medical students regarding physician health and wellness.

D-405.990, “Educating Physicians about Physician Health Programs”

1) Our AMA will work closely with the Federation of State Physician Health Programs (FSPHP) to educate our members as to the availability and services of state physician health programs to continue to create opportunities to help ensure physicians and medical students are fully knowledgeable about the purpose of physician health programs and the relationship that exists between the physician health program and the licensing authority in their state or territory; 2) Our AMA will continue to collaborate with relevant organizations on activities that address physician health and wellness; 3) Our AMA will, in conjunction with the FSPHP, develop state legislative guidelines addressing the design and implementation of physician health programs; and 4) Our AMA will work with FSPHP to develop messaging for all Federation members to consider regarding elimination of stigmatization of mental illness and illness in general in physicians and physicians in training.

D-405.992, “Physician Health and Wellness”

Our AMA: (1) supports programs related to physician health and wellness, including those offered in conjunction with the Federation of State Physician Health Programs; (2) will convene those interested in medical education in an effort to bring the dialogue about healthy lifestyle and balance early in the careers of medical students and residents; and (3) considers the concept of physician wellness as an element of the AMA Strategic Plan.

D-405.996, “Physician Well-Being and Renewal”

Our AMA will work with the Federation of State Physician Health Programs to establish and promulgate a networking resource/database and web site clearinghouse for Medical Staff Physician Health Committees or their equivalents in physician groups throughout the country, and to provide resources that will allow such committees to proactively initiate programs of wellness and illness prevention for physicians.

H-440.905, “Confidentiality, Counseling and Treatment in the Tuberculosis Screening of Health Care Workers”

The AMA encourages all health care organizations that require Tuberculosis screening tests to adopt standards which guarantee health care workers and medical students the right to confidentiality, appropriate counseling, and treatment following the positive results of a tuberculosis skin test; and encourages all health care organizations that require Tuberculosis screening tests to adopt standards which guarantee prospective health care workers and volunteers confidentiality and education about treatment options following the positive results of a tuberculosis skin test.

9.3.1, “Physician Health & Wellness”

When physician health or wellness is compromised, so may the safety and effectiveness of the medical care provided. To preserve the quality of their performance, physicians have a responsibility to maintain their health and wellness, broadly construed as preventing or treating acute or chronic diseases, including mental illness, disabilities, and occupational stress.

To fulfill this responsibility individually, physicians should:

(a) Maintain their own health and wellness by:

- (i) following healthy lifestyle habits;
- (ii) ensuring that they have a personal physician whose objectivity is not compromised.

(b) Take appropriate action when their health or wellness is compromised, including:

- (i) engaging in honest assessment of their ability to continue practicing safely;
- (ii) taking measures to mitigate the problem;
- (iii) taking appropriate measures to protect patients, including measures to minimize the risk of transmitting infectious disease commensurate with the seriousness of the disease;
- (iv) seeking appropriate help as needed, including help in addressing substance abuse. Physicians should not practice if their ability to do so safely is impaired by use of a controlled substance, alcohol, other chemical agent or a health condition.

Collectively, physicians have an obligation to ensure that colleagues are able to provide safe and effective care, which includes promoting health and wellness among physicians.

AMA Principles of Medical Ethics: I,II,IV

10.3, “Peers as Patients”

The opportunity to care for a fellow physician is a privilege or physician-in-training and may represent a gratifying experience and serve as a show of respect or competence. However, physicians must recognize that providing medical care for a fellow professional can pose special challenges for objectivity, open exchange of information, privacy and confidentiality, and informed consent.

In emergencies or isolated rural settings when options for care by other physicians are limited or where there is no other qualified physician available, physicians should not hesitate to treat colleagues.

Physicians must make the same fundamental ethical commitments when treating peers as when treating any other patient. Physicians who provide medical care to a colleague should:

- (a) Exercise objective professional judgment and make unbiased treatment recommendations despite the personal or professional relationship they may have with the patient.
- (b) Be sensitive to the potential psychological discomfort of the physician-patient, especially when eliciting sensitive information or conducting an intimate examination.
- (c) Respect the physical and informational privacy of physician-patients. Discuss how to respond to inquiries about the physician-patient’s medical care from colleagues. Recognize that special measures may be needed to ensure privacy.
- (d) Provide information to enable the physician-patient to make voluntary, well-informed decisions about care. The treating physician should not assume that the physician-patient is knowledgeable about his or her medical condition.

Physicians-in-training and medical students (when they provide care as part of their supervised training) face unique challenges when asked to provide or participate in care for peers, given the circumstances of their roles in residency programs and medical schools. Except in emergency situations or when other care is not available, physicians-in-training should not be required to provide medical care for fellow trainees, faculty members, or attending physicians if they are reluctant to do so.

AMA Principles of Medical Ethics: VI

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 301
(I-16)

Introduced by: Resident and Fellow Section

Subject: Expanding the Treatment of Opiate Dependence Using Medication-Assisted Treatment by Physicians in Residency Training Programs

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

Whereas, The Centers for Disease Control and Prevention recently announced that death due to drug overdose has reached an unprecedented 14.7 per 100,000 in 2014 (45,000 people in US), with 61% of deaths involving some form of opioid;¹ and

Whereas, Buprenorphine and naloxone (suboxone) are effective components of the medication-assisted treatment of opioid use disorders which have a favorable safety and tolerability profile in numerous populations;² and

Whereas, The Department of Health and Human Services has recently announced a new rule, which expands the patient limit for qualified physicians to treat opioid use disorders using buprenorphine in order to increase access to medication-assisted treatment for opioid abuse and dependence;³ and

Whereas, The 2014 Buprenorphine Summit held by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institute on Drug Abuse (NIDA) notes that increasing resident exposure to medication-assisted treatment for addiction is a strategy to improve patient access to the medication;⁴ and

Whereas, The Drug Addiction Treatment Act of 2000 allows for a physician in a residency training program with an unrestricted license and the appropriate Drug Enforcement Administration registration to receive a waiver to prescribe buprenorphine, provided it is in accordance with state laws regarding the use of Schedule III narcotics for detoxification and maintenance therapy;⁵ and

Whereas, Addiction clinics in which residents prescribe buprenorphine are prevalent but barriers to resident prescription of the medication remain, including funding for buprenorphine waiver training, supervision and patient continuity from a certified addiction medicine physician, as well as support staff for scheduling, billing and urine drug testing;^{6,7,8} therefore be it

¹ US drug overdose deaths: a global challenge. *Lancet*. 2016;387(10017):404.

² Connery HS. Medication-assisted treatment of opioid use disorder: review of the evidence and future directions. *Harv Rev Psychiatry*. 2015;23(2):63-75.

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⁴ <https://www.whitehouse.gov/the-press-office/2016/03/29/fact-sheet-obama-administration-announces-additional-actions-address> March 29 2016.

⁵ NIDA Sa. 2014 Buprenorphine Summit: Report of Proceedings. http://www.samhsa.gov/sites/default/files/proceedings_of_2014_buprenorphine_summit_030915_508.pdf. 2014;1(1):2-20.

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1 RESOLVED, That our American Medical Association encourage the expansion of residency and
 2 fellowship training opportunities to provide clinical experience in the medication-assisted
 3 treatment of opioid use disorders, under the supervision of an appropriately trained physician
 4 (New HOD Policy); and be it further

5
 6 RESOLVED, That our AMA support additional funding to overcome the financial barriers that
 7 exist for trainees seeking clinical experience in the medication-assisted treatment of opioid use
 8 disorders. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/12/16

RELEVANT AMA POLICY

Methadone Maintenance in Private Practice H-95.957

Our AMA: (1) reaffirms its position that, "the use of properly trained practicing physicians as an extension of organized methadone maintenance programs in the management of those patients whose needs for allied services are minimal" (called "medical" maintenance) should be evaluated further;
 (2) supports the position that "medical" methadone maintenance may be an effective treatment for the subset of opioid dependent patients who have attained a degree of behavioral and social stability under standard treatment and thereby an effective measure in controlling the spread of infection with HIV and other blood-borne pathogens but further research is needed;
 (3) encourages additional research that includes consideration of the cost of "medical" methadone maintenance relative to the standard maintenance program (for example, the cost of additional office security and other requirements for the private office-based management of methadone patients) and relative to other methods to prevent the spread of blood-borne pathogens among intravenous drug users;
 (4) supports modification of federal and state laws and regulations to make newly approved anti-addiction medications available to those office-based physicians who are appropriately trained and qualified to treat opiate withdrawal and opiate dependence in accordance with documented clinical indications and consistent with sound medical practice guidelines and protocols; and
 (5) urges that guidelines and protocols for the use of newly approved anti-addiction medications be developed jointly by appropriate national medical specialty societies in association with relevant federal agencies and that continuing medical education courses on opiate addiction treatment be developed by these specialty societies to help designate those physicians who have the requisite training and qualifications to provide therapy within the broad context of comprehensive addiction treatment and management. (CSA Rep. 2, I-94; Reaffirmed: CSA Rep. 12 and Append Res. 412, A-99; Reaffirmation I-00; Modified: CSAPH Rep. 1, A-10)

Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
 2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose. (Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16)

Third Party Payer Quantity Limits H-185.942

1. Our AMA supports the protection of the patient-physician relationship from interference by payers via various utilization control mechanisms, including medication and testing and treatment supply quantity limits.
2. Our AMA will work with third party payers to ensure that if they use quantity limits for prescription drugs or testing and treatment supplies, an exceptions process must be in place to ensure that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, and that any such process should place a minimum burden upon patients, physicians and their staff.
3. Our AMA supports interested state legislative efforts and federal action and will develop model state legislation to ensure that third party payers that institute quantity limits for prescription drugs or testing and treatment supplies include an exceptions process so that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, including provisions such as the following:
 - physicians can specify limited supplies of medications during initial trials of a medication, or if a larger quantity of medication would expose an at-risk patient to potential harm (e.g., opioids, benzodiazepines, or psychostimulants)- physicians can appeal adverse determinations regarding quantity limitations;- payers must provide an easily accessible list of all medications and testing and treatment supplies with quantity limits and the requirements for the exception process on the payer's Web site;- payers must indicate, what, if any, clinical criteria (e.g., evidence-based guidelines, FDA label, scientific literature) support the plan's quantity limitations;- physicians with specialized qualifications may not be subject to quantity limits;- payers cannot charge patients for an additional co-pay if an exception request for a higher medication or testing and treatment supply quantity has been approved based on medical necessity;- payer decisions on exception, and subsequent appeal requests, of quantity limits must be made within two working days in nonurgent situations and one working day in urgent cases; and- physicians or patients can submit any denied appeals to an independent review body for a final, binding decision. (BOT Rep. 12, A-12)

Protection for Physicians Who Prescribe Pain Medication H-120.960

Our AMA supports the following:

- (1) the position that physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines protecting physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection;
- (2) education of medical students and physicians to recognize addictive disorders in patients, minimize diversion of opioid preparations, and appropriately treat or refer patients with such disorders; and
- (3) the prevention and treatment of pain disorders through aggressive and appropriate means, including the continued education of doctors in the use of opioid preparations.

Our AMA opposes harassment of physicians by agents of the Drug Enforcement Administration in response to the appropriate prescribing of controlled substances for pain management. (BOT Rep. 1, I-97; Reaffirm: Res. 237, A-99; Appended: Res. 506, A-01; Appended: Sub. Res. 213, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Reaffirmed: BOT Rep. 3, I-13; Reaffirmation A-15)

Opioid Treatment and Prescription Drug Monitoring Programs D-95.980

Our AMA will seek changes to allow states the flexibility to require opioid treatment programs to report to prescription monitoring programs. (BOT Rep. 11, A-10)

Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone D-120.985

1. Our AMA will incorporate into its web site a directory consolidating available information on the safe and effective use of opioid analgesics in clinical practice.
2. Our AMA, in collaboration with Federation partners, will collate and disseminate available educational and training resources on the use of methadone for pain management. (Sub. Res. 508, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Append: Res. 515, A-14; Reaffirmed: BOT Rep. 14, A-15)

Drug Abuse Related to Prescribing Practices H-95.990

1. Our AMA recommends the following series of actions for implementation by state medical societies concerning drug abuse related to prescribing practices:

A. Institution of comprehensive statewide programs to curtail prescription drug abuse and to promote appropriate prescribing practices, a program that reflects drug abuse problems currently within the state, and takes into account the fact that practices, laws and regulations differ from state to state. The program should incorporate these elements: (1) Determination of the nature and extent of the prescription drug abuse problem; (2) Cooperative relationships with law enforcement, regulatory agencies, pharmacists and other professional groups to identify "script doctors" and bring them to justice, and to prevent forgeries, thefts and other unlawful activities related to prescription drugs; (3) Cooperative relationships with such bodies to provide education to "duped doctors" and "dated doctors" so their prescribing practices can be improved in the future; (4) Educational materials on appropriate prescribing of controlled substances for all physicians and for medical students.

B. Placement of the prescription drug abuse programs within the context of other drug abuse control efforts by law enforcement, regulating agencies and the health professions, in recognition of the fact that even optimal prescribing practices will not eliminate the availability of drugs for abuse purposes, nor appreciably affect the root causes of drug abuse. State medical societies should, in this regard, emphasize in particular: (1) Education of patients and the public on the appropriate medical uses of controlled drugs, and the deleterious effects of the abuse of these substances; (2) Instruction and consultation to practicing physicians on the treatment of drug abuse and drug dependence in its various forms.

2. Our AMA:

A. promotes physician training and competence on the proper use of controlled substances;

B. encourages physicians to use screening tools (such as NIDAMED) for drug use in their patients;

C. will provide references and resources for physicians so they identify and promote treatment for unhealthy behaviors before they become life-threatening; and

D. encourages physicians to query a state's controlled substances databases for information on their patients on controlled substances.

3. The Council on Science and Public Health will report at the 2012 Annual Meeting on the effectiveness of current drug policies, ways to prevent fraudulent prescriptions, and additional reporting requirements for state-based prescription drug monitoring programs for veterinarians, hospitals, opioid treatment programs, and Department of Veterans Affairs facilities.

4. Our AMA opposes any federal legislation that would require physicians to check a prescription drug monitoring program (PDMP) prior to prescribing controlled substances. (CSA Rep. C, A-81; Reaffirmed: CLRPD Rep. F, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Appended: Res. 907, I-11; Appended: Res. 219, A-12; Reaffirmation A-15; Reaffirmed: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15)

Reduction of Medical and Public Health Consequences of Drug Abuse: Update D-95.999

Our AMA encourages state medical societies to advocate for the expansion of and increased funding for needle and syringe-exchange programs and methadone maintenance and other opioid treatment services and programs in their states. (CSA Rep. 12, A-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 302
(I-16)

Introduced by: Resident and Fellow Section

Subject: Protecting the Rights of Breastfeeding Resident and Fellows

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

1 Whereas, Many female medical students, residents and fellows are of childbearing age, with
2 many having children during medical school, residency or fellowship; and
3

4 Whereas, Many hospital and clinical work environments do not support protected times or
5 places in which medical students, residents or fellows may express breast milk or safely store
6 pumped milk; and
7

8 Whereas, The medical benefits of breast milk have been widely studied and supported by
9 physicians and researchers; and
10

11 Whereas, Studies have demonstrated that a majority of physician mothers want to exclusively
12 breastfeed for up to 12 months, but many were unable to do so due to work-related factors that
13 influence physician mothers' breastfeeding behavior; and
14

15 Whereas, The Fair Labor Standards Act of 1938 was amended with Section 4207 to require an
16 employer to provide reasonable break time for an employee to express breast milk for her
17 nursing child for one year after the child's birth, at each time such employee has need to
18 express milk; and
19

20 Whereas, Our AMA, in policy H-245.982, "encourages all medical schools and graduate medical
21 education programs to support all residents, medical students and faculty who provide breast
22 milk for their infants, including appropriate time and facilities to express and store breast milk
23 during the working day;" and
24

25 Whereas, Section VI "Resident Duty Hours in the Learning and Working Environment"
26 of Accreditation Council for Graduate Medical Education Common Program Requirements for
27 July 2016 does not include any protective provisions for breast expression for residents or
28 fellows; therefore be it
29

30 RESOLVED, That our American Medical Association work with appropriate bodies, such as the
31 Accreditation Council for Graduate Medical Education (ACGME), to mandate language in
32 housestaff manuals or similar policy references of all training programs on the protected time
33 and locations for milk expression and storage of breast milk (Directive to Take Action); and be it
34 further
35

36 RESOLVED, That our AMA work with appropriate bodies, such as the ACGME and the
37 Association of American Medical Colleges, to include language related to the learning and work
38 environments for breast feeding mothers in regular program reviews. (Directive to Take Action)

References:

<http://pediatrics.aappublications.org/content/131/2/387>

<http://online.liebertpub.com/doi/abs/10.1089/bfm.2009.0090>

<https://www.change.org/p/accreditation-council-for-graduate-medical-education-request-the-acgme-to-develop-standard-maternity-leave-and-nursing-break-policies>

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/12/16

RELEVANT AMA POLICY

AMA Support for Breastfeeding H-245.982

1. Our AMA: (a) recognizes that breastfeeding is the optimal form of nutrition for most infants; (b) endorses the 2012 policy statement of American Academy of Pediatrics on Breastfeeding and the use of Human Milk, which delineates various ways in which physicians and hospitals can promote, protect, and support breastfeeding practices; (c) supports working with other interested organizations in actively seeking to promote increased breastfeeding by Supplemental Nutrition Program for Women, Infants, and Children (WIC Program) recipients, without reduction in other benefits; (d) supports the availability and appropriate use of breast pumps as a cost-effective tool to promote breast feeding; and (e) encourages public facilities to provide designated areas for breastfeeding and breast pumping; mothers nursing babies should not be singled out and discouraged from nursing their infants in public places.
2. Our AMA: (a) promotes education on breastfeeding in undergraduate, graduate, and continuing medical education curricula; (b) encourages all medical schools and graduate medical education programs to support all residents, medical students and faculty who provide breast milk for their infants, including appropriate time and facilities to express and store breast milk during the working day; (c) encourages the education of patients during prenatal care on the benefits of breastfeeding; (d) supports breastfeeding in the health care system by encouraging hospitals to provide written breastfeeding policy that is communicated to health care staff; (e) encourages hospitals to train staff in the skills needed to implement written breastfeeding policy, to educate pregnant women about the benefits and management of breastfeeding, to attempt early initiation of breastfeeding, to practice "rooming-in," to educate mothers on how to breastfeed and maintain lactation, and to foster breastfeeding support groups and services; (f) supports curtailing formula promotional practices by encouraging perinatal care providers and hospitals to ensure that physicians or other appropriately trained medical personnel authorize distribution of infant formula as a medical sample only after appropriate infant feeding education, to specifically include education of parents about the medical benefits of breastfeeding and encouragement of its practice, and education of parents about formula and bottlefeeding options; and (g) supports the concept that the parent's decision to use infant formula, as well as the choice of which formula, should be preceded by consultation with a physician.
3. Our AMA: (a) supports the implementation of the WHO/UNICEF Ten Steps to Successful Breastfeeding at all birthing facilities; (b) endorses implementation of the Joint Commission Perinatal Care Core Measures Set for Exclusive Breast Milk Feeding for all maternity care facilities in the US as measures of breastfeeding initiation, exclusivity and continuation which should be continuously tracked by the nation, and social and demographic disparities should be addressed and eliminated; (c) recommends exclusive breastfeeding for about six months, followed by continued breastfeeding as complementary food are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant; (d) recommends the adoption of employer programs which support breastfeeding mothers so that they may safely and privately express breast milk at work or take time to feed their infants; and (e) encourages employers in all fields of healthcare to serve as role models to improve the public health by supporting mothers providing breast milk to their infants beyond the postpartum

period. (CSA Rep. 2, A-05; Res. 325, A-05; Reaffirmation, A-07; Reaffirmation, A-12; Modified in lieu of Res. 409, A-12 and Res. 410, A-12; Appended: Res. 410, A-16)

Breast Milk Banking H-245.972

Our AMA encourages breast milk banking. (Res. 443, A-07)

Lodging, Meeting Venues, and Social Functions G-630.140

AMA policy on lodging and accommodations includes the following: (1) Our AMA supports choosing hotels for its meetings, conferences, and conventions based on size, service, location, cost, and similar factors. (2) Our AMA shall attempt, when allocating meeting space, to locate the Section Assembly Meetings in the House of Delegates Meeting hotel or in a hotel in close proximity. (3) All meetings and conferences organized and/or primarily sponsored by our AMA will be held in a town, city, county, or state that has enacted comprehensive legislation requiring smoke-free worksites and public places (including restaurants and bars), unless intended or existing contracts or special circumstances justify an exception to this policy, and our AMA encourages state and local medical societies, national medical specialty societies, and other health organizations to adopt a similar policy. (4) It is the policy of our AMA not to hold meetings or pay member, officer or employee dues in any club, restaurant, or other institution that has exclusionary policies based on gender, race, color, religion, national origin, gender identity, or sexual orientation. (5) Our AMA staff will work with facilities where AMA meetings are held to designate an area for breastfeeding and breast pumping. (Res. 2, I-87; Reaffirmed: Sunset Report, I-97; Res. 512, I-98; Consolidated: CLRPD Rep. 3, I-01; Reaffirmation A-04; Modified CCB/CLRPD Rep. 3, A-12; Modified: CCB/CLRPD Rep. 2, A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 303
(I-16)

Introduced by: Resident and Fellow Section

Subject: Primary Care and Mental Health Training in Residency

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

Whereas, 50% of primary care visits involve concerns about behavioral health comorbidities and 60% of mental illness is treated by primary care providers;¹ and

Whereas, Child and adolescent psychiatry is one of the most underserved medical subspecialties;² and

Whereas, Primary care physicians often feel unprepared to manage patients with complex psychiatric comorbidities;³ and

Whereas, Internal medicine, family medicine, and pediatric residents do not receive collaborative psychiatric supervision during their residency, nor do psychiatry residents and fellows receive training in how to liaise with primary care offices; and

Whereas, Our AMA has policy which encourages practicing physicians to seek out continuing medical education opportunities on integrated physical and behavioral health care and promotes the development of sustainable payment models that would be used to fund the necessary services inherent in integrating behavioral health care services into primary care settings (AMA Policy H-385.915); therefore be it

RESOLVED, That our American Medical Association advocate for the incorporation of integrated mental health and primary care services into existing psychiatry and primary care training programs' clinical settings (New HOD Policy); and be it further

RESOLVED, That our AMA encourage primary care and psychiatry residency training programs to create and expand opportunities for residents to obtain clinical experience working in an integrated mental health and primary care model, such as the collaborative care model (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for appropriate reimbursement to support the practice of integrated physical and mental health care in clinical care settings. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/12/16

¹ Pirl W.F., Beck B.J., Safren, S. A., Kim H (2001). "A descriptive study of psychiatric consultations in a community primary care center". Primary Care Companion Journal of Clinical Psychiatry 3 (5): 190–194. doi:10.4088/PCC.v03n0501.

² Simpson G.A., Bloom B., Cohen R.A., et al. U.S. children with emotional and behavioral difficulties: Data from the 2001, 2002, and 2003 National Health Interview Surveys. Adv Data 2005; 23: 1–13.

³ Loeb D.F., Bayliss E.A., Binswanger I.A., et al. (2012). "Primary care physician perceptions on caring for complex patients with medical and mental illness". Journal of General Internal Medicine. 2012 Aug; 27 (8):945-52. doi: 10.1007/s11606-012-2005-9

RELEVANT AMA POLICY

Integrating Physical and Behavioral Health Care H-385.915

Our American Medical Association: (1) encourages private health insurers to recognize CPT codes that allow primary care physicians to bill and receive payment for physical and behavioral health care services provided on the same day; (2) encourages all state Medicaid programs to pay for physical and behavioral health care services provided on the same day; (3) encourages state Medicaid programs to amend their state Medicaid plans as needed to include payment for behavioral health care services in school settings; (4) encourages practicing physicians to seek out continuing medical education opportunities on integrated physical and behavioral health care; and (5) promotes the development of sustainable payment models that would be used to fund the necessary services inherent in integrating behavioral health care services into primary care settings. (CMS Rep. 6, A-15)

Prevention of Unnecessary Hospitalization and Jail Confinement of the Mentally Ill H-345.995

Our AMA urges physicians to become more involved in pre-crisis intervention, treatment and integration of chronic mentally ill patients into the community in order to prevent unnecessary hospitalization or jail confinement. (Res. 16, I-81; Reaffirmed: CLRPD Rep. F, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Reaffirmation, A-15)

Access to Mental Health Services D-345.997

Our AMA will: (1) continue to work with relevant national medical specialty societies and other professional and patient advocacy groups to identify and eliminate barriers to access to treatment for mental illness; (2) advocate that psychiatrists and other physicians who provide treatment for mental illness be paid by both private and public payers for the provision of evaluation and management services, for case management and coordination efforts, and for interpretive and indirect services; and (3) advocate that all insurance entities facilitate direct access to a psychiatrist in the referral process. (CMS Rep. 9, A-01; Reaffirmed: CMS Rep., A-11; Reaffirmed in lieu of Res. 804, I-13; Reaffirmed in lieu of res. 808, I-14)

Mental Health Crisis Interventions H-345.972

Our AMA: (1) continues to support jail diversion and community based treatment options for mental illness; (2) supports implementation of law enforcement-based crisis intervention training programs for assisting those individuals with a mental illness, such as the Crisis Intervention Team model programs; and (3) supports federal funding to encourage increased community and law enforcement participation in crisis intervention training programs. (Res. 923, I-15)

Awareness, Diagnosis and Treatment of Depression and other Mental Illnesses H-345.984

Awareness, Diagnosis and Treatment of Depression and Other Mental Illnesses: (1) Our AMA encourages: (a) medical schools, primary care residencies, and other training programs as appropriate to include the appropriate knowledge and skills to enable graduates to recognize, diagnose, and treat depression and other mental illnesses, either as the chief complaint or with another general medical condition; (b) all physicians providing clinical care to acquire the same knowledge and skills; and (c) additional research into the course and outcomes of patients with depression and other mental illnesses who are seen in general medical settings and into the development of clinical and systems approaches designed to improve patient outcomes. Furthermore, any approaches designed to manage care by reduction in the demand for services should be based on scientifically sound outcomes research findings. (2) Our AMA will work with the National Institute on Mental Health and appropriate medical specialty and mental health advocacy groups to increase public awareness about depression and other mental illnesses, to reduce the stigma associated with depression and other mental illnesses, and to increase

patient access to quality care for depression and other mental illnesses. (Res. 502, I-96; Reaffirm & Append: CSA Rep. 7, I-97; Reaffirmation A-00; Modified: CSAPH Rep. 1, A-10; Modified: Res. 301, A-12)

Access to Mental Health Services H-345.981

Our AMA advocates the following steps to remove barriers that keep Americans from seeking and obtaining treatment for mental illness:

- (1) reducing the stigma of mental illness by dispelling myths and providing accurate knowledge to ensure a more informed public;
- (2) improving public awareness of effective treatment for mental illness;
- (3) ensuring the supply of psychiatrists and other well trained mental health professionals, especially in rural areas and those serving children and adolescents;
- (4) tailoring diagnosis and treatment of mental illness to age, gender, race, culture and other characteristics that shape a person's identity;
- (5) facilitating entry into treatment by first-line contacts recognizing mental illness, and making proper referrals and/or to addressing problems effectively themselves; and
- (6) reducing financial barriers to treatment. (CMS Rep. 9, A-01; Reaffirmation, A-11; Reaffirmed: CMS Rep. 7, A-11; Reaffirmed: BOT action in response to referred for decision Res. 403, A-12; Reaffirmed in lieu of Res. 804, I-13; Reaffirmed in lieu of Res. 808, I-14)

Statement of Principles on Mental Health H-345.999

- (1) Tremendous strides have already been made in improving the care and treatment of the emotionally disturbed, but much remains to be done. The mental health field is vast and includes a network of factors involving the life of the individual, the community and the nation. Any program designed to combat mental illness and promote mental health must, by the nature of the problems to be solved, be both ambitious and comprehensive.
- (2) The AMA recognizes the important stake every physician, regardless of type of practice, has in improving our mental health knowledge and resources. The physician participates in the mental health field on two levels, as an individual of science and as a citizen. The physician has much to gain from a knowledge of modern psychiatric principles and techniques, and much to contribute to the prevention, handling and management of emotional disturbances. Furthermore, as a natural community leader, the physician is in an excellent position to work for and guide effective mental health program.
- (3) The AMA will be more active in encouraging physicians to become leaders in community planning for mental health.
- (4) The AMA has a deep interest in fostering a general attitude within the profession and among the lay public more conducive to solving the many problems existing in the mental health field. (A-62; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation, A-99; Reaffirmed: CSAPH Rep. 1, A-09)

Increasing Detection of Mental Illness and Encouraging Education D-345.994

1. Our AMA will work with: (A) mental health organizations, state, specialty, and local medical societies and public health groups to encourage patients to discuss mental health concerns with their physicians; and (B) the Department of Education and state education boards and encourage them to adopt basic mental health education designed specifically for preschool through high school students, as well as for their parents, caregivers and teachers.
2. Our AMA will encourage the National Institute of Mental Health and local health departments to examine national and regional variations in psychiatric illnesses among immigrant, minority, and refugee populations in order to increase access to care and appropriate treatment. (Res. 412, A-06; Appended: Res. 907, I-12)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 304
(I-16)

Introduced by: Resident and Fellow Section

Subject: Improving Access to Care and Health Outcomes

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

Whereas, The U.S has higher prevalence of chronic diseases compared to other nations with poorer health outcomes, large disparities with varying access and utilization of health care services across populations;¹ and

Whereas, Chronic diseases are the leading cause of mortality and morbidity as well as high cost of care in the U.S.;¹ and

Whereas, The American Public Health Association defines a community health worker (CHW) as “a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery. A CHW also builds individual and community capacity by increasing health knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy”;² and

Whereas, CHWs are effective in promoting health and improving health outcomes in their communities;^{3,4} and

Whereas, CHWs are community builders that are culturally competent^{2,3,4} at understanding the socioeconomic challenges of the community they work in; and

Whereas, CHWs deliver cost benefit caring for chronic diseases;^{3,4} therefore be it

RESOLVED, That our American Medical Association support training opportunities for students and residents to learn cultural competency from community health workers. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/12/16

¹ US Department of Health and Human Services. *Chronic diseases: The leading causes of death*.

² Brown 3rd H, Wilson KJ, Pagán JA, et al. Cost-effectiveness analysis of a community health worker intervention for low-income hispanic adults with diabetes. *Prev Chronic Dis*. 2012;9:E140.

³ Ryabov I. Cost-effectiveness of community health workers in controlling diabetes epidemic on the US–Mexico border. *Public Health*. 2014;128(7):636-642.

⁴ Alvillar M, Quinlan J, Rush CH, Dudley DJ. Recommendations for developing and sustaining community health workers. *J Health Care Poor Underserved*. 2011;22(3):745-750.

RELEVANT AMA POLICY

Incorporating Community Health Workers into the US Health Care System H-440.828

1. Our AMA encourages states and other appropriate stakeholders to establish that community health workers work under a strict protocol for any activity that relates to clinical matters and that this protocol be developed by the physician-led health care team.
2. Our AMA encourages states and other appropriate stakeholders to conduct background checks on community health workers prior to the community health worker providing services and take the background check results into appropriate consideration.
3. Our AMA encourages states and other appropriate stakeholders to develop a set of defined core competencies and skills of community health workers.
4. Our AMA encourages states to support or establish the training, certification, and continuing education of community health workers that allow for multiple points of entry into the profession.
5. Our AMA encourages health insurers and other appropriate stakeholders to promote sustainable funding mechanisms such as public and private insurance to finance community health worker services and that this funding not be part of funds allocated for physician payment.
6. Our AMA encourages states and other appropriate stakeholders to engage in collaborative efforts with community health workers and their professional organizations in the development and implementation of policies related to community health workers.
7. Our AMA encourages states to consider privacy and liability issues related to the inclusion of community health workers in the physician-led health care team. (CMS Rep. 7, I-15)

Transforming Medicaid and Long-Term Care and Improving Access to Care for the Uninsured H-290.982

AMA policy is that our AMA:

- (1) urges that Medicaid reform not be undertaken in isolation, but rather in conjunction with broader health insurance reform, in order to ensure that the delivery and financing of care results in appropriate access and level of services for low-income patients;
- (2) encourages physicians to participate in efforts to enroll children in adequately funded Medicaid and State Children's Health Insurance Programs using the mechanism of "presumptive eligibility," whereby a child presumed to be eligible may be enrolled for coverage of the initial physician visit, whether or not the child is subsequently found to be, in fact, eligible.
- (3) encourages states to ensure that within their Medicaid programs there is a pluralistic approach to health care financing delivery including a choice of primary care case management, partial capitation models, fee-for-service, medical savings accounts, benefit payment schedules and other approaches;
- (4) calls for states to create mechanisms for traditional Medicaid providers to continue to participate in Medicaid managed care and in State Children's Health Insurance Programs;
- (5) calls for states to streamline the enrollment process within their Medicaid programs and State Children's Health Insurance Programs by, for example, allowing mail-in applications, developing shorter application forms, coordinating their Medicaid and welfare (TANF) application processes, and placing eligibility workers in locations where potential beneficiaries work, go to school, attend day care, play, pray, and receive medical care;
- (6) urges states to administer their Medicaid and SCHIP programs through a single state agency;
- (7) strongly urges states to undertake, and encourages state medical associations, county medical societies, specialty societies, and individual physicians to take part in, educational and outreach activities aimed at Medicaid-eligible and SCHIP-eligible children. Such efforts should be designed to ensure that children do not go without needed and available services for which they are eligible due to administrative barriers or lack of understanding of the programs;

- (8) supports requiring states to reinvest savings achieved in Medicaid programs into expanding coverage for uninsured individuals, particularly children. Mechanisms for expanding coverage may include additional funding for the SCHIP earmarked to enroll children to higher percentages of the poverty level; Medicaid expansions; providing premium subsidies or a buy-in option for individuals in families with income between their state's Medicaid income eligibility level and a specified percentage of the poverty level; providing some form of refundable, advanceable tax credits inversely related to income; providing vouchers for recipients to use to choose their own health plans; using Medicaid funds to purchase private health insurance coverage; or expansion of Maternal and Child Health Programs. Such expansions must be implemented to coordinate with the Medicaid and SCHIP programs in order to achieve a seamless health care delivery system, and be sufficiently funded to provide incentive for families to obtain adequate insurance coverage for their children;
- (9) advocates consideration of various funding options for expanding coverage including, but not limited to: increases in sales tax on tobacco products; funds made available through for-profit conversions of health plans and/or facilities; and the application of prospective payment or other cost or utilization management techniques to hospital outpatient services, nursing home services, and home health care services;
- (10) supports modest co-pays or income-adjusted premium shares for non-emergent, non-preventive services as a means of expanding access to coverage for currently uninsured individuals;
- (11) calls for CMS to develop better measurement, monitoring, and accountability systems and indices within the Medicaid program in order to assess the effectiveness of the program, particularly under managed care, in meeting the needs of patients. Such standards and measures should be linked to health outcomes and access to care;
- (12) supports innovative methods of increasing physician participation in the Medicaid program and thereby increasing access, such as plans of deferred compensation for Medicaid providers. Such plans allow individual physicians (with an individual Medicaid number) to tax defer a specified percentage of their Medicaid income;
- (13) supports increasing public and private investments in home and community-based care, such as adult day care, assisted living facilities, congregate living facilities, social health maintenance organizations, and respite care;
- (14) supports allowing states to use long-term care eligibility criteria which distinguish between persons who can be served in a home or community-based setting and those who can only be served safely and cost-effectively in a nursing facility. Such criteria should include measures of functional impairment which take into account impairments caused by cognitive and mental disorders and measures of medically related long-term care needs;
- (15) supports buy-ins for home and community-based care for persons with incomes and assets above Medicaid eligibility limits; and providing grants to states to develop new long-term care infrastructures and to encourage expansion of long-term care financing to middle-income families who need assistance;
- (16) supports efforts to assess the needs of individuals with intellectual disabilities and, as appropriate, shift them from institutional care in the direction of community living;
- (17) supports case management and disease management approaches to the coordination of care, in the managed care and the fee-for-service environments;
- (18) urges CMS to require states to use its simplified four-page combination Medicaid / Children's Health Insurance Program (CHIP) application form for enrollment in these programs, unless states can indicate they have a comparable or simpler form; and
- (19) urges CMS to ensure that Medicaid and CHIP outreach efforts are appropriately sensitive to cultural and language diversities in state or localities with large uninsured ethnic populations. (BOT Rep. 31, I-97; Reaffirmed by CMS Rep. 2, A-98; Reaffirmation A-99 and Reaffirmed: Res. 104, A-99; Appended: CMS Rep 2, A-99; Reaffirmation A-00; Appended: CMS Rep. 6, A-01; Reaffirmation, A-02; Modified: CMS Rep 2, A-99; Reaffirmation A-00; Appended: CMS Rep. 6,

A-01; Reaffirmation A-02; Modified: CMS Rep. 8, A-03; Reaffirmed: CMS Rep. 1, A-05; Reaffirmation, A-05; Reaffirmation, A-07; Modified: CMS Rep. 8, A-08; Reaffirmation, A-11; Modified: CMS Rep. 3, I-11)

Strategies to Increase Diabetes Awareness D-440.935

Our AMA will organize a series of activities for the public in collaboration with health care workers and community organizations to bring awareness to the severity of diabetes and measures to decrease its incidence. (Res. 412, A-13)

Patient Navigation Programs H-373.994

1. Our AMA recognizes the increasing use of patient navigator and patient advocacy services to help improve access to care and help patients manage complex aspects of the health care system. In order to ensure that patient navigator services enhance the delivery of high-quality patient care, our AMA supports the following guidelines for patient navigator programs:

- a) The primary role of a patient navigator should be to foster patient empowerment, and to provide patients with information that enhances their ability to make appropriate health care choices and to receive medical care with an enhanced sense of confidence about risks, benefits, and responsibilities.
- b) Patient navigator programs should establish procedures to ensure direct communication between the navigator and the patient's medical team.
- c) Patient navigators should refrain from any activity that could be construed as clinical in nature, including interpreting test results or medical symptoms, offering second opinions, or making treatment recommendations. Patient navigators should provide a supportive role for patients and, when necessary, help them understand medical information provided by physicians and other members of their medical care team.
- d) Patient navigators should fully disclose relevant training, experience, and credentials, in order to help patients understand the scope of services the navigator is qualified to provide.
- e) Patient navigators should fully disclose potential conflicts of interest to those whom they serve, including employment arrangements.

2. Our AMA will work with the American College of Surgeons and other entities and organizations to ensure that patient navigators are free of bias, do not have any role in directing referrals, do not usurp the physician's role in and responsibility for patient education or treatment planning, and act under the direction of the physician or physicians primarily responsible for each patient's care.

3. Policy provisions for patient navigators are also relevant for community health workers and other non-clinical public health workers. (CMS Rep. 7, I-11; Appended: CMS Rep. 7, I-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 305
(I-16)

Introduced by: Resident and Fellow Section

Subject: Privacy, Personal Use and Funding of Mobile Devices

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

Whereas, The technological revolution of the past decades launched a wave of unprecedented growth and portability in electronic and information technology; and

Whereas, Personal mobile devices, such as, netbooks, personal digital assistants, tablets, phone-tablet hybrids (“phablets”), and smartphones, have become almost ubiquitous in any workplace, including the healthcare environment; and

Whereas, Healthcare staffs use personal mobile devices for both personal and professional reasons, ranging from sending emails and text messages to remotely accessing medical records on Virtual Private Networks and virtual desktops, in an effort to improve communications, clinical services, and patient care; and

Whereas, Specialty training programs, such as family medicine, radiology, general surgery, and internal medicine, have used a variety of mobile devices to improve the learning process and clinical training environment;^{1,2,3,4} and

Whereas, Studies have indicated that using medical apps on mobile devices has resulted in improvement in learning for medical students, residents, and faculty;^{5,6,7} and

Whereas, Integration of mobile devices and mobile platforms has resulted in increased connectedness among residents and attending, which led to more efficient care and safety checks, as well as better real-time report of clinically significant events;⁶ and

¹ Archibald D, Macdonald CJ, Plante J, Hogue RJ, Fiallos J. Residents' and preceptors' perceptions of the use of the iPad for clinical teaching in a family medicine residency program. *BMC Med Educ*. 2014;14:174. doi:10.1186/1472-6920-14-174.

² Berkowitz SJ, Kung JW, Eisenberg RL, Donohoe K, Tsai LL, Slanetz PJ. Resident iPad use: has it really changed the game? *J Am Coll Radiol JACR*. 2014;11(2):180-184. doi:10.1016/j.jacr.2013.04.017.

³ Gandsas A, McIntire K, Montgomery K, Bumgardner C, Rice L. The personal digital assistant (PDA) as a tool for telementoring endoscopic procedures. *Stud Health Technol Inform*. 2004;98:99-103.

⁴ Patel BK, Chapman CG, Luo N, Woodruff JN, Arora VM. Impact of mobile tablet computers on internal medicine resident efficiency. *Arch Intern Med*. 2012;172(5):436-438. doi:10.1001/archinternmed.2012.45.

⁵ Boruff JT, Storie D. Mobile devices in medicine: a survey of how medical students, residents, and faculty use smartphones and other mobile devices to find information. *J Med Libr Assoc JMLA*. 2014;102(1):22-30. doi:10.3163/1536-5050.102.1.006.

⁶ Nabors C, Peterson SJ, Aronow WS, et al. Mobile physician reporting of clinically significant events-a novel way to improve handoff communication and supervision of resident on call activities. *J Patient Saf*. 2014;10(4):211-217. doi:10.1097/PTS.0b013e31829952ff.

⁷ Wu RC, Tzanetos K, Morra D, Quan S, Lo V, Wong BM. Educational impact of using smartphones for clinical communication on general medicine: more global, less local. *J Hosp Med*. 2013;8(7):365-372. doi:10.1002/jhm.2037.

Whereas, Studies have indicated that common advantages of mobile device integration are improved access to research and medical journals⁸, increased learning through medical apps and online resources,¹ reduced administrative burden,^{4,9,10} increased efficiency in clinical care, decreased rounding times, and increased face-to-face patient care;¹¹ and

Whereas, While there are advantages of integrating mobile devices in medical education and clinical training, risks include reducing resident autonomy, creating possible Health Insurance Portability and Accountability Act violations, and increasing nosocomial infections; therefore be it

RESOLVED, That our American Medical Association encourage further research in integrating mobile devices in clinical care, particularly to address challenges of reducing work burden while maintain clinical autonomy for residents and fellows (New HOD Policy); and be it further

RESOLVED, That our AMA collaborate with the Accreditation Council for Graduate Medical Education to develop germane policies, especially with consideration of potential financial burden and personal privacy of trainees, to ensure a more uniform regulation of mobile devices in medical education and clinical training (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage medical schools and residency programs to educate all trainees on proper hygiene and professional guidelines in using personal devices in clinical environment. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/12/16

⁸ Niehaus W, Boimbo S, Akuthota V. Physical Medicine and Rehabilitation Resident Use of iPad Mini Mobile Devices. PM R. 2015;7(5):512-518. doi:10.1016/j.pmrj.2015.01.017.

⁹ Schooley B, Walczak S, Hikmet N, Patel N. Impacts of mobile tablet computing on provider productivity, communications, and the process of care. Int J Med Inf. 2016;88:62-70. doi:10.1016/j.ijmedinf.2016.01.010.

¹⁰ Lobo MJ, Crandley EF, Rumph JS, et al. Pilot Study of iPad Incorporation Into Graduate Medical Education. J Grad Med Educ. 2013;5(1):142-144. doi:10.4300/JGME-D-12-00007.1.

¹¹ Crowson MG, Kahmke R, Ryan M, Scher R. Utility of Daily Mobile Tablet Use for Residents on an Otolaryngology Head & Neck Surgery Inpatient Service. J Med Syst. 2016;40(3):55. doi:10.1007/s10916-015-0419-8.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 306
(I-16)

Introduced by: International Medical Graduates Section

Subject: Formal Leadership Training During Medical Education

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

1 Whereas, Current training curriculums for physicians are designed to ensure the development of
2 clinical skills necessary to become competent practitioners, yet there is no clearly defined
3 process to encourage and sustain leadership skills acquisition essential to successful transition
4 to independent practice; and

5
6 Whereas, Effective leadership is vital to creation of an optimal environment for providing high-
7 quality patient care with consistency; and

8
9 Whereas, Physicians who acquire insufficient leadership qualities and skills within the clinical,
10 operational and financial spheres of practice may face greater challenges in navigating the ever-
11 changing United States healthcare environment and in maintaining high standards of care while
12 minimizing healthcare disparities; therefore be it

13
14 RESOLVED, That our American Medical Association advocate for and support the creation of
15 programs and curricula that emphasize experiential and active learning models which are
16 inclusive of leadership knowledge, skills and the qualities utilized in the clinical setting through
17 direct observation and which foster a shared learning environment with the entire
18 interdisciplinary care team (Directive to Take Action); and be it further

19
20 RESOLVED, That our AMA advocate for and support the creation of programs and curricula to
21 develop the leadership competencies and foundational skills for medical practitioners necessary
22 to effectively understand and navigate current and future policy changes from the Center for
23 Medicare and Medicaid Services, while continuing to maintain said practitioners fiduciary
24 responsibility and high-quality patient care (Directive to Take Action); and be it further

25
26 RESOLVED, That our AMA advocate with the Liaison Committee for Medical Education,
27 Association of American Medical Colleges and other governing bodies responsible for the
28 education of future physicians to implement programs early in medical training to promote the
29 development of leadership capabilities, so that all doctors obtain a minimum standard of
30 leadership and management skills. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/20/16

References:

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5. Pullen ML. Developing clinical leadership skills in student nurses. *Nurse Education Today*. 2003; 23(1): 34-39.
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RELEVANT AMA POLICY**AMA Mission and Vision G-625.010**

Mission: To promote the art and science of medicine and the betterment of public health.

Core Values: (1) Leadership; (2) Excellence; and (3) Integrity and Ethical Behavior.

Vision: To be an essential part of the professional life of every physician.

BOT Rep. 1, A-01, Consolidated: CLPRD Rep. 3, I-01, Modified: BOT Rep. 2, A-02, Reaffirmed, BOT Rep. 1, A-03, Modified: BOT Rep. 14, I-03, Modified: BOT Rep. 22, I-06, Reaffirmed: BOT Rep. 5, A-11, Reaffirmation A-11, Reaffirmed: BOT Rep. 4, I-11

AMA Sponsored Leadership Training for Hospital Medical Staff Officers and Committee Chairs H-225.972

It is the policy of the AMA (1) to offer, both regionally and locally, extensive training and skill development for emerging medical staff leaders to assure that they can effectively perform the duties and responsibilities associated with medical staff self-governance; and (2) that training and skill development programs for medical staff leaders be as financially self-supporting as feasible.

Res. 808, I-91, Reaffirmed: Sunset Report, I-01, Reaffirmed: CMS Rep. 7, A-11

Management and Leadership for Physicians D-295.316

1. Our AMA will study advantages and disadvantages of various educational options on management and leadership for physicians with a report back to the House of Delegates; and develop an online report and guide aimed at physicians interested in management and leadership that would include the advantages and disadvantages of various educational options.

2. Our AMA will work with key stakeholders to advocate for collaborative programs between medical schools and related schools of business and management to better prepare physicians for administrative and leadership responsibilities in medical management.

Sub. Res. 918, I-14

Initiative to Transform Medical Education: Strategies for Medical Education Reform H-295.871

Our AMA continues to recognize the need for transformation of medical education across the continuum from premedical preparation through continuing physician professional development and the need to involve multiple stakeholders in the transformation process, while taking an appropriate leadership and coordinating role.

CME Rep. 13, A-07

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 307
(I-16)

Introduced by: Organized Medical Staff Section

Subject: Inappropriate Uses of Maintenance of Certification

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

1 Whereas, Many hospitals and health care organizations impose Maintenance of Certification
2 (MOC) as a requirement for medical staff membership, credentialing, and/or hospital privileges,
3 essentially making MOC mandatory for all physician members on the medical staff; and
4

5 Whereas, Most insurance companies not only impose MOC requirements for physicians who
6 wish to participate in and maintain their insurance panel membership, but may also require that
7 physicians be board certified in order to receive any reimbursement for services rendered,
8 regardless of their network status; and
9

10 Whereas, There remain widespread and valid concerns relating to the occurrence of legislative
11 efforts that would require all physicians to participate in "time-limited" board certification and other
12 associated MOC programs in order to maintain their state medical license; and
13

14 Whereas, The MOC process is expensive, time-consuming, disruptive to physicians' lives and
15 practices, and decreases the time available for patient care; and
16

17 Whereas, There is little evidence that the MOC process is effective in accomplishing the goal of
18 improved clinical outcomes based upon improved professional performance; therefore be it
19

20 RESOLVED, That our American Medical Association, through legislative, regulatory, and
21 collaborative efforts, advocate that Maintenance of Certification not be a requirement for: (1)
22 medical staff membership, privileging, or credentialing; (2) insurance panel participation; or (3)
23 state medical licensure. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

The topic of this resolution is currently under study by the Council on Medical Education.

RELEVANT AMA POLICY**H-230.997 Recertification and Hospital or Health Plan Network Privileges**

(1) The fact that a board certified practitioner fails to undergo the recertification examination shall not be adequate reason to modify or withhold hospital privileges or health plan network status from a physician. (2) Modification or withholding of hospital privileges or health plan network status shall be purely on the basis of assessment of performance. (Res. 26, A-77; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Modified: Res. 727, A-06; Reaffirmed: CMS Rep. 01, A-16)

H-275.924 Maintenance of Certification

AMA Principles on Maintenance of Certification (MOC)

1. Changes in specialty-board certification requirements for MOC programs should be longitudinally stable in structure, although flexible in content.
2. Implementation of changes in MOC must be reasonable and take into consideration the time needed to develop the proper MOC structures as well as to educate physician diplomates about the requirements for participation.
3. Any changes to the MOC process for a given medical specialty board should occur no more frequently than the intervals used by that specialty board for MOC.
4. Any changes in the MOC process should not result in significantly increased cost or burden to physician participants (such as systems that mandate continuous documentation or require annual milestones).
5. MOC requirements should not reduce the capacity of the overall physician workforce. It is important to retain a structure of MOC programs that permits physicians to complete modules with temporal flexibility, compatible with their practice responsibilities.
6. Patient satisfaction programs such as The Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient survey are neither appropriate nor effective survey tools to assess physician competence in many specialties.
7. Careful consideration should be given to the importance of retaining flexibility in pathways for MOC for physicians with careers that combine clinical patient care with significant leadership, administrative, research and teaching responsibilities.
8. Legal ramifications must be examined, and conflicts resolved, prior to data collection and/or displaying any information collected in the process of MOC. Specifically, careful consideration must be given to the types and format of physician-specific data to be publicly released in conjunction with MOC participation.
9. Our AMA affirms the current language regarding continuing medical education (CME): "Each Member Board will document that diplomates are meeting the CME and Self-Assessment requirements for MOC Part II. The content of CME and self-assessment programs receiving credit for MOC will be relevant to advances within the diplomate's scope of practice, and free of commercial bias and direct support from pharmaceutical and device industries. Each diplomate will be required to complete CME credits (AMA PRA Category 1 Credit?, American Academy of Family Physicians Prescribed, American College of Obstetricians and Gynecologists, and/or American Osteopathic Association Category 1A)."
10. In relation to MOC Part II, our AMA continues to support and promote the AMA Physician's Recognition Award (PRA) Credit system as one of the three major credit systems that comprise the foundation for continuing medical education in the U.S., including the Performance Improvement CME (PICME) format; and continues to develop relationships and agreements that may lead to standards accepted by all U.S. licensing boards, specialty boards, hospital credentialing bodies and other entities requiring evidence of physician CME.
11. MOC is but one component to promote patient safety and quality. Health care is a team effort, and changes to MOC should not create an unrealistic expectation that lapses in patient safety are primarily failures of individual physicians.

12. MOC should be based on evidence and designed to identify performance gaps and unmet needs, providing direction and guidance for improvement in physician performance and delivery of care.
 13. The MOC process should be evaluated periodically to measure physician satisfaction, knowledge uptake and intent to maintain or change practice.
 14. MOC should be used as a tool for continuous improvement.
 15. The MOC program should not be a mandated requirement for licensure, credentialing, reimbursement, network participation or employment.
 16. Actively practicing physicians should be well-represented on specialty boards developing MOC.
 17. Our AMA will include early career physicians when nominating individuals to the Boards of Directors for ABMS member boards.
 18. MOC activities and measurement should be relevant to clinical practice.
 19. The MOC process should not be cost prohibitive or present barriers to patient care.
 20. Any assessment should be used to guide physicians' self-directed study.
 21. Specific content-based feedback after any assessment tests should be provided to physicians in a timely manner.
 22. There should be multiple options for how an assessment could be structured to accommodate different learning styles.
 23. Physicians with lifetime board certification should not be required to seek recertification.
 24. No qualifiers or restrictions should be placed on diplomates with lifetime board certification recognized by the ABMS related to their participation in MOC.
 25. Members of our House of Delegates are encouraged to increase their awareness of and participation in the proposed changes to physician self-regulation through their specialty organizations and other professional membership groups.
- (CME Rep. 16, A-09 Reaffirmed: CME Rep. 11, A-12 Reaffirmed: CME Rep. 10, A-12, Reaffirmed in lieu of Res. 313, A-12, Reaffirmed: CME Rep. 4, A-13, Reaffirmed in lieu of Res. 919, I-13, Appended: Sub. Res. 920, I-14, Reaffirmed: CME Rep. 2, A-15, Appended: Res. 314, A-15, Modified: CME Rep. 2, I-15; Reaffirmation A-16; Reaffirmed: Res. 309, A-16)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 308
(I-16)

Introduced by: Medical Student Section

Subject: Promoting and Reaffirming Domestic Medical School Clerkship Education

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

Whereas, Pursuant to existing AMA policy D-295.320, our AMA will advocate for regulations that would ensure clinical clerkship slots be given first to students of US medical schools that are Liaison Committee on Medical Education- or Commission on Osteopathic College Accreditation-approved, or schools currently given preliminary accreditation status, provisional accreditation status, or equivalent, from either of the above bodies; and

Whereas, Pursuant to existing AMA policy D-295.320, our AMA will advocate for federal and state legislation or regulations to oppose any extraordinary compensation for clinical clerkship sites by medical schools or other clinical programs that would result in displacement or otherwise limit the training opportunities of United States LCME/COCA students in clinical rotations; and

Whereas, Pursuant to existing AMA policy D-295.931, our AMA opposes any arrangements of US medical schools or their affiliated hospitals that allow the presence of visiting students to disadvantage their own students educationally or financially; and

Whereas, LCME Standard 5, Element 5.10, Resources Used by Transfer/Visiting Students, states, "The resources used by a medical school to accommodate any visiting and transfer students in its medical education program do not significantly diminish the resources available to already enrolled medical students."¹

Whereas, Data compiled from the 2012 LCME Annual Medical Questionnaire showed that in the past 2-3 years, 53 percent of medical schools have found it more difficult to find inpatient clinical placements for students in core clinical clerkships, and 18 percent attributed the increased difficulty to "competition for placement sites from offshore international medical schools";²

Whereas, To gain access, some for-profit offshore medical schools pay hospitals in the United States for their students' clinical training;² and

Whereas, The educational experience of US medical students could be compromised by their having to compete for faculty attention and access to patients with visiting students;² therefore be it

RESOLVED, That our American Medical Association pursue legislative and/or regulatory avenues that promote the regulation of the financial compensation which medical schools can provide for clerkship positions in order to facilitate fair competition amongst medical schools and prevent unnecessary increases in domestically-trained medical student debt (Directive to Take Action); and be it further

¹ 2017-2018 Functions and Structure of a Medical School. Available at: <http://lcme.org/publications/>

² CME Report 1, I-13

- 1 RESOLVED, That our AMA support the expansion of partnerships of foreign medical schools
 2 with hospitals in regions which lack local medical schools in order to maximize the cumulative
 3 clerkship experience for all students (New HOD Policy); and be it further
 4
 5 RESOLVED, That our AMA reaffirm policies D-295.320, D-295.931, and D-295.937.
 6 (Reaffirm HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

RELEVANT AMA POLICY

Factors Affecting the Availability of Clinical Training Sites for Medical Student Education

D-295.320 - Our AMA will work with the Association of American Medical Colleges and the American Association of Colleges of Osteopathic Medical Education to encourage local and state governments and the federal government, as well as private sector philanthropies, to provide additional funding to support infrastructure and faculty development for medical school expansion. 2. Our AMA will encourage medical schools and the rest of the medical community within states or geographic regions to engage in collaborative planning to create additional clinical education resources for their students. 3. Our AMA will support the expansion of medical education programs only when educational program quality, including access to appropriate clinical teaching resources, can be assured. 4. Our AMA will advocate for regulations that would ensure clinical clerkship slots be given first to students of US medical schools that are Liaison Committee on Medical Education- or Commission on Osteopathic College Accreditation- approved, or schools currently given preliminary accreditation status, provisional accreditation status, or equivalent, from either of the above bodies. 5. Our AMA will advocate for federal and state legislation or regulations to oppose any extraordinary compensation for clinical clerkship sites by medical schools or other clinical programs that would result in displacement or otherwise limit the training opportunities of United States LCME/COCA students in clinical rotations. CME Rep. 4, I-09 Appended: Sub. Res. 302, A-12 Modified: Res. 903, I-12 Modified: CME Rep. 1, I-13

Update on the Availability of Clinical Training Sites for Medical Student Education D-

295.931 - Our AMA will work with appropriate collaborators to study how to build additional institutional and faculty capacity in the US for delivering clinical education. 2. Our AMA, in collaboration with interested stakeholders, will: (a) study options to require that students from international medical schools who desire to take clerkships in US hospitals come from medical schools that are approved by an independent public or private organization, such as the Liaison Committee on Medical Education, using principles consistent with those used to accredit US medical schools; (b) advocate for regulations that will assure that international students taking clinical clerkships in US medical schools come from approved medical schools that assure educational quality that promotes patient safety; and (c) advocate that any institution that accepts students for clinical placements be required to assure that all such students are trained in programs that meet requirements for curriculum, clinical experiences and attending supervision as expected for Liaison Committee on Medical Education and American Osteopathic Association accredited programs. 3. Our AMA will study whether the public service community benefit commitment and corporate purposes of not for profit, tax exempt hospitals impose any legal and/or ethical obligations for granting priority access for teaching purposes to medical students from medical schools in their service area communities and, if so, advocate for the development of appropriate regulations at the state level. 4. Our AMA opposes any arrangements of US medical schools or their affiliated hospitals that allow the presence of

visiting students to disadvantage their own students educationally or financially. CME Rep. 2, I-08 Modified: CME Rep. 4, I-09 Reaffirmed: CME Rep. 1, I-13

Competition for Clinical Training Sites D-295.937 - Our AMA will, through the Council of Medical Education, conduct an analysis of the adequacy of clinical training sites to accommodate the increasing number of medical students in the US accredited medical schools and study the impact of growing pressure, including political and financial, to accommodate clinical training in US hospitals for US citizen international medical students. Res. 324, A-08

AMA Principles on International Medical Graduates H-255.988 - Our AMA supports: 1. Current U.S. visa and immigration requirements applicable to foreign national physicians who are graduates of medical schools other than those in the United States and Canada. 2. Current regulations governing the issuance of exchange visitor visas to foreign national IMGs, including the requirements for successful completion of the USMLE. 3. The AMA reaffirms its policy that the U.S. and Canada medical schools be accredited by a nongovernmental accrediting body. 4. Cooperation in the collection and analysis of information on medical schools in nations other than the U.S. and Canada. 5. Continued cooperation with the ECFMG and other appropriate organizations to disseminate information to prospective and current students in foreign medical schools. An AMA member, who is an IMG, should be appointed regularly as one of the AMA's representatives to the ECFMG Board of Trustees. 6. The core clinical curriculum of a foreign medical school should be provided by that school; U.S. hospitals should not provide substitute core clinical experience for students attending a foreign medical school. 7. Working with the Accreditation Council for Graduate Medical Education (ACGME) and the Federation of State Medical Boards (FSMB) to assure that institutions offering accredited residencies, residency program directors, and U.S. licensing authorities do not deviate from established standards when evaluating graduates of foreign medical schools. 8. In cooperation with the ACGME and the FSMB, supports only those modifications in established graduate medical education or licensing standards designed to enhance the quality of medical education and patient care. 9. The AMA continues to support the activities of the ECFMG related to verification of education credentials and testing of IMGs. 10. That special consideration be given to the limited number of IMGs who are refugees from foreign governments that refuse to provide pertinent information usually required to establish eligibility for residency training or licensure. 11. That accreditation standards enhance the quality of patient care and medical education and not be used for purposes of regulating physician manpower. 12. That AMA representatives to the ACGME, residency review committees and to the ECFMG should support AMA policy opposing discrimination. Medical school admissions officers and directors of residency programs should select applicants on the basis of merit, without considering status as an IMG or an ethnic name as a negative factor. 13. The requirement that all medical school graduates complete at least one year of graduate medical education in an accredited U.S. program in order to qualify for full and unrestricted licensure. 14. Publicizing existing policy concerning the granting of staff and clinical privileges in hospitals and other health facilities. 15. The participation of all physicians, including graduates of foreign as well as U.S. and Canadian medical schools, in organized medicine. The AMA offers encouragement and assistance to state, county, and specialty medical societies in fostering greater membership among IMGs and their participation in leadership positions at all levels of organized medicine, including AMA committees and councils and state boards of medicine, by providing guidelines and non-financial incentives, such as recognition for outstanding achievements by either individuals or organizations in promoting leadership among IMGs. 16. Support studying the feasibility of conducting peer-to-peer membership recruitment efforts aimed at IMGs who are not AMA members. 17. AMA membership outreach to IMGs, to include a) using its existing publications to highlight policies and activities of interest to IMGs, stressing the common concerns of all physicians; b) publicizing its many relevant resources to all physicians, especially to nonmember IMGs; c)

identifying and publicizing AMA resources to respond to inquiries from IMGs; and d) expansion of its efforts to prepare and disseminate information about requirements for admission to accredited residency programs, the availability of positions, and the problems of becoming licensed and entering full and unrestricted medical practice in the U.S. that face IMGs. This information should be addressed to college students, high school and college advisors, and students in foreign medical schools. 18. Recognition of the common aims and goals of all physicians, particularly those practicing in the U.S., and support for including all physicians who are permanent residents of the U.S. in the mainstream of American medicine. 19. Its leadership role to promote the international exchange of medical knowledge as well as cultural understanding between the U.S. and other nations. 20. Institutions that sponsor exchange visitor programs in medical education, clinical medicine and public health to tailor programs for the individual visiting scholar that will meet the needs of the scholar, the institution, and the nation to which he will return. 21. Informing foreign national IMGs that the availability of training and practice opportunities in the U.S. is limited by the availability of fiscal and human resources to maintain the quality of medical education and patient care in the U.S., and that those IMGs who plan to return to their country of origin have the opportunity to obtain GME in the United States. 22. U.S. medical schools offering admission with advanced standing, within the capabilities determined by each institution, to international medical students who satisfy the requirements of the institution for matriculation. 23. Providing U.S. students who are considering attendance at an international medical school with information enabling them to assess the difficulties and consequences associated with matriculation in a foreign medical school. 24. The Federation of State Medical Boards, its member boards, and the ECFMG in their willingness to adjust their administrative procedures in processing IMG applications so that original documents do not have to be recertified in home countries when physicians apply for licenses in a second state. BOT Rep. Z, A-86 Reaffirmed: Res. 312, I-93 Modified: CME Rep. 2, A-03 Reaffirmation I-11 Reaffirmed: CME Rep. 1, I-13 Modified: BOT Rep. 25, A-15 Modified: CME Rep. 01, A-16

Foreign Medical Graduates H-255.987 - 1. Our AMA supports continued efforts to protect the rights and privileges of all physicians duly licensed in the US regardless of ethnic or educational background and opposes any legislative efforts to discriminate against duly licensed physicians on the basis of ethnic or educational background. 2. Our AMA will: (a) continuously study challenges and issues pertinent to IMGs as they affect our country's health care system and our physician workforce; and (b) lobby members of the US Congress to fund studies through appropriate agencies, such as the Department of Health and Human Services, to examine issues and experiences of IMGs and make recommendations for improvements. Res. 56, A-86 Reaffirmed: Sunset Report, I-96 Reaffirmation A-00 Reaffirmed: CME Rep. 2, A-10 Reaffirmed: CME Rep. 11, A-10 Appended: Res. 303, A-10 Reaffirmation A-11 Reaffirmation A-12

Foreign Medical Graduates H-255.998 - Our AMA supports the following principles, based on recommendations of the Ad Hoc Committee on Foreign Medical Graduates (FMGs): Our AMA supports the practice of U.S. teaching hospitals and foreign medical educational institutions entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities which lack educational resources and experience for supervised teaching of clinical medicine. CME Rep. F, A-81 Reaffirmed: CLRPD Rep. F, I-91 Modified: Sunset Report, I-01 Reaffirmed: CME Rep. 2, A-11

Graduates of Foreign Health Professional Schools H-255.985 - (1) Any United States or alien graduate of a foreign health professional education program must, as a requirement for entry into graduate education and/or practice in the United States, demonstrate entry-level competence equivalent to that required of graduates of United States' programs. Agencies recognized to license or certify health professionals in the United States should have mechanisms to evaluate the entry-level competence of graduates of foreign health professional programs. The level of competence and the means used to assess it should be the same or equivalent to those required of graduates of U.S. accredited programs. (2) All health care facilities, including governmental facilities, should adhere to the same or equivalent licensing and credentialing requirements in their employment practices. BOT Rep. NN, A-87 Reaffirmed: Sunset Report, I-97 Reaffirmed: Res. 320 and Res. 305, A-03 Reaffirmed: CME Rep. 1, I-03 Reaffirmed: CME Rep. 2, A-13

Preservation of Opportunities for US Graduates and International Medical Graduates Already Legally Present in the US H-255.974 - In the event of reductions in the resident workforce, the AMA will advocate for a mechanism of resident selection which promotes the maintenance of resident physician training opportunities for all qualified graduates of United States Liaison Committee on Medical Education and American Osteopathic Association accredited institutions; and the AMA adopts the position that it will be an advocate for IMGs already legally present in this country. Res. 324, A-97 Reaffirmed: CME Rep. 10, A-99 Reaffirmed: CME Rep. 2, A-09

Demonstration of Clinical Competence H-275.956

It is the policy of the AMA to (1) support continued efforts to develop and validate methods for assessment of clinical skills; (2) continue its participation in the development and testing of methods for clinical skills assessment; and (3) recognize that clinical skills assessment is best performed using a rigorous and consistent examination administered by medical schools and should not be used for licensure of graduates of Liaison Committee on Medical Education (LCME)- and American Osteopathic Association (AOA)-accredited medical schools or of Educational Commission for Foreign Medical Graduates (ECFMG)-certified physicians. CME Rep. E, A-90 Reaffirmed: CME Rep. 5, A-99 Modified: Sub. Res. 821, I-02 Modified: CME Rep. 1, I-03 Reaffirmed: CME Rep. 16, A-09 Reaffirmed in lieu of Res. 313, A-12

Advance Tuition Payment Requirements for International Students Enrolled in US Medical Schools H-255.968 - Our AMA: 1. Supports the autonomy of medical schools to determine optimal tuition requirements for international students; 2. Encourages medical schools and undergraduate institutions to fully inform international students interested in medical education in the US of the limited options available to them for tuition assistance; 3. Supports the Association of American Medical Colleges (AAMC) in its efforts to increase transparency in the medical school application process for international students by including school policy on tuition requirements in the Medical School Admission Requirements (MSAR?); and 4. Encourages medical schools to explore alternative means of prepayment, such as a letter of credit, for four years of medical school. CME Rep. 5, A-12

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 309
(I-16)

Introduced by: Michigan

Subject: Development of Alternative Competency Assessment Models

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

1 Whereas, Hospitals, medical offices, skilled nursing facilities, and third party payers have used
2 board certification, board recertification, and maintenance of certification (MOC) as one tool for
3 assessing initial and ongoing clinical competency; and
4

5 Whereas, MOC and board recertification have not been shown to provide proof of a higher level
6 of clinical competency; and
7

8 Whereas, MOC is being challenged because of this lack of evidence; and
9

10 Whereas, Various organizations are looking for other methods to determine ongoing clinical
11 competency; therefore be it
12

13 RESOLVED, That our American Medical Association amend AMA Policy H-275.936,
14 Mechanisms to Measure Physician Competency, by addition and deletion to read as follows:
15

16 Our AMA (1) works with the American College of Graduate Medical Education,
17 American Board of Medical Specialties, and other relevant organizations to develop
18 alternative and more accurate methods to determine ongoing clinical competency; (2)
19 reviews and proposes improvements for assuring continued physician competence,
20 including but not limited to performance indicators, board certification and
21 recertification, professional experience, continuing medical education, and teaching
22 experience; and (2)(3) opposes the development and/or use of "Medical Competency
23 Examination" and establishment of oversight boards for current state medical boards
24 as proposed in the fall 1998 Report on Professional Licensure of the Pew Health
25 Professions Commission, as an additional measure of physician competency. (Modify
26 Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

The topic of this resolution is currently under study by the Council on Medical Education.

RELEVANT AMA POLICY

Mechanisms to Measure Physician Competency H-275.936

Our AMA (1) reviews and proposes improvements for assuring continued physician competence, including but not limited to performance indicators, board certification and recertification, professional experience, continuing medical education, and teaching experience; and (2) opposes the development and/or use of "Medical Competency Examination" and establishment of oversight boards for current state medical boards as proposed in the fall 1998 Report on Professional Licensure of the Pew Health Professions Commission, as an additional measure of physician competency.

Res. 320, I-98 Amended: Res. 817, A-99 Reaffirmed: CME Rep. 7, A-02 Reaffirmed: CME Rep. 7, A-07 Reaffirmed: CME Rep. 16, A-09 Reaffirmed in lieu of Res. 313, A-12

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 310
(I-16)

Introduced by: Michigan

Subject: Maintenance of Certification and Insurance Plan Participation

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

1 Whereas, Board certification has been accepted by insurance companies as a measure of
2 expertise; and
3

4 Whereas, Board certification has often been required for insurance program participation; and
5

6 Whereas, Maintenance of certification (MOC) is a new concept; and
7

8 Whereas, MOC has never been proven to demonstrate more expertise or better patient care
9 than board certification; and
10

11 Whereas, Insurance companies may begin to require MOC as a criterion for participation with
12 insurance plan panels; therefore be it
13

14 RESOLVED, That our American Medical Association increase its efforts to work with the
15 insurance industry to ensure that maintenance of certification does not become a requirement
16 for insurance panel participation. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 09/30/16

The topic of this resolution is currently under study by the Council on Medical Education.

RELEVANT AMA POLICY

Maintenance of Certification H-275.924

AMA Principles on Maintenance of Certification (MOC)

1. Changes in specialty-board certification requirements for MOC programs should be longitudinally stable in structure, although flexible in content.
2. Implementation of changes in MOC must be reasonable and take into consideration the time needed to develop the proper MOC structures as well as to educate physician diplomates about the requirements for participation.
3. Any changes to the MOC process for a given medical specialty board should occur no more frequently than the intervals used by that specialty board for MOC.
4. Any changes in the MOC process should not result in significantly increased cost or burden to physician participants (such as systems that mandate continuous documentation or require annual milestones).
5. MOC requirements should not reduce the capacity of the overall physician workforce. It is important to retain a structure of MOC programs that permits physicians to complete modules with temporal flexibility, compatible with their practice responsibilities.

6. Patient satisfaction programs such as The Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient survey are neither appropriate nor effective survey tools to assess physician competence in many specialties.
7. Careful consideration should be given to the importance of retaining flexibility in pathways for MOC for physicians with careers that combine clinical patient care with significant leadership, administrative, research and teaching responsibilities.
8. Legal ramifications must be examined, and conflicts resolved, prior to data collection and/or displaying any information collected in the process of MOC. Specifically, careful consideration must be given to the types and format of physician-specific data to be publicly released in conjunction with MOC participation.
9. Our AMA affirms the current language regarding continuing medical education (CME): "Each Member Board will document that diplomates are meeting the CME and Self-Assessment requirements for MOC Part II. The content of CME and self-assessment programs receiving credit for MOC will be relevant to advances within the diplomate's scope of practice, and free of commercial bias and direct support from pharmaceutical and device industries. Each diplomate will be required to complete CME credits (AMA PRA Category 1 Credit™, American Academy of Family Physicians Prescribed, American College of Obstetricians and Gynecologists, and/or American Osteopathic Association Category 1A)."
10. In relation to MOC Part II, our AMA continues to support and promote the AMA Physician's Recognition Award (PRA) Credit system as one of the three major credit systems that comprise the foundation for continuing medical education in the U.S., including the Performance Improvement CME (PICME) format; and continues to develop relationships and agreements that may lead to standards accepted by all U.S. licensing boards, specialty boards, hospital credentialing bodies and other entities requiring evidence of physician CME.
11. MOC is but one component to promote patient safety and quality. Health care is a team effort, and changes to MOC should not create an unrealistic expectation that lapses in patient safety are primarily failures of individual physicians.
12. MOC should be based on evidence and designed to identify performance gaps and unmet needs, providing direction and guidance for improvement in physician performance and delivery of care.
13. The MOC process should be evaluated periodically to measure physician satisfaction, knowledge uptake and intent to maintain or change practice.
14. MOC should be used as a tool for continuous improvement.
15. The MOC program should not be a mandated requirement for licensure, credentialing, reimbursement, network participation or employment.
16. Actively practicing physicians should be well-represented on specialty boards developing MOC.
17. Our AMA will include early career physicians when nominating individuals to the Boards of Directors for ABMS member boards.
18. MOC activities and measurement should be relevant to clinical practice.
19. The MOC process should not be cost prohibitive or present barriers to patient care.
20. Any assessment should be used to guide physicians' self-directed study.
21. Specific content-based feedback after any assessment tests should be provided to physicians in a timely manner.
22. There should be multiple options for how an assessment could be structured to accommodate different learning styles.
23. Physicians with lifetime board certification should not be required to seek recertification.
24. No qualifiers or restrictions should be placed on diplomates with lifetime board certification recognized by the ABMS related to their participation in MOC.
25. Members of our House of Delegates are encouraged to increase their awareness of and participation in the proposed changes to physician self-regulation through their specialty organizations and other professional membership groups.

Citation: CME Rep. 16, A-09; Reaffirmed: CME Rep. 11, A-12; Reaffirmed: CME Rep. 10, A-12; Reaffirmed in lieu of Res. 313, A-12; Reaffirmed: CME Rep. 4, A-13; Reaffirmed in lieu of Res. 919, I-13; Appended: Sub. Res. 920, I-14; Reaffirmed: CME Rep. 2, A-15; Appended: Res. 314, A-15; Modified: CME Rep. 2, I-15; Reaffirmation A-16; Reaffirmed: Res. 309, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 311
(I-16)

Introduced by: Michigan

Subject: Prevent Maintenance of Certification Licensure and Hospital Privileging Requirements

Referred to: Reference Committee C
(Martin D. Trichtinger, MD, Chair)

1 Whereas, Board certification is a vigorous and arduous process; and
2
3 Whereas, Board certification has been long accepted as a measure of tested expertise; and
4
5 Whereas, Continuing medical education (CME) has been required to insure continuing
6 expertise and as a condition for license renewal; and
7
8 Whereas, Maintenance of certification (MOC) is a fairly new process with unproven benefit
9 that is a separate process from board certification and CME; and
10
11 Whereas, The American Board of Medical Specialties has been trying to link MOC with state
12 licensure requirements; and
13
14 Whereas, Some hospitals are now requiring MOC for privileging; and
15
16 Whereas, There are no evidence-based studies that the newly required MOC enhances
17 physician performance or patient care; and
18
19 Whereas, The MOC process is expensive and disruptive in physicians' lives and practices;
20 and
21
22 Whereas, The MOC process decreases a physician's time available for patient care; and
23
24 Whereas, There have been numerous resolutions attempting to point out the problems of
25 MOC; and
26
27 Whereas, Despite these resolutions, MOC abuses persist; therefore be it
28
29 RESOLVED, That our American Medical Association, consistent with Policy H-275.924,
30 vigorously advocate by legislation, regulation, or other appropriate activity to prevent the use
31 of maintenance of certification as a licensing requirement in any state; (Directive to Take
32 Action) and be it further

1 RESOLVED, That our AMA amend Policy H-275.924, "Maintenance of Certification," Bullet
2 No. 15, by addition to read as follows:

3

4 15. The MOC program should not be a mandated requirement for licensure,
5 credentialing, hospital privileging, reimbursement, network participation or employment.
6 (Modify Current HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

The topic of this resolution is currently under study by the Council on Medical Education.

RELEVANT AMA POLICY

Maintenance of Certification H-275.924

AMA Principles on Maintenance of Certification (MOC)

1. Changes in specialty-board certification requirements for MOC programs should be longitudinally stable in structure, although flexible in content.
2. Implementation of changes in MOC must be reasonable and take into consideration the time needed to develop the proper MOC structures as well as to educate physician diplomates about the requirements for participation.
3. Any changes to the MOC process for a given medical specialty board should occur no more frequently than the intervals used by that specialty board for MOC.
4. Any changes in the MOC process should not result in significantly increased cost or burden to physician participants (such as systems that mandate continuous documentation or require annual milestones).
5. MOC requirements should not reduce the capacity of the overall physician workforce. It is important to retain a structure of MOC programs that permits physicians to complete modules with temporal flexibility, compatible with their practice responsibilities.
6. Patient satisfaction programs such as The Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient survey are neither appropriate nor effective survey tools to assess physician competence in many specialties.
7. Careful consideration should be given to the importance of retaining flexibility in pathways for MOC for physicians with careers that combine clinical patient care with significant leadership, administrative, research and teaching responsibilities.
8. Legal ramifications must be examined, and conflicts resolved, prior to data collection and/or displaying any information collected in the process of MOC. Specifically, careful consideration must be given to the types and format of physician-specific data to be publicly released in conjunction with MOC participation.
9. Our AMA affirms the current language regarding continuing medical education (CME): "Each Member Board will document that diplomates are meeting the CME and Self-Assessment requirements for MOC Part II. The content of CME and self-assessment programs receiving credit for MOC will be relevant to advances within the diplomate's scope of practice, and free of commercial bias and direct support from pharmaceutical and device industries. Each diplomate will be required to complete CME credits (AMA PRA Category 1 Credit™, American Academy of Family Physicians Prescribed, American College of Obstetricians and Gynecologists, and/or American Osteopathic Association Category 1A)."
10. In relation to MOC Part II, our AMA continues to support and promote the AMA Physician's Recognition Award (PRA) Credit system as one of the three major credit systems that comprise the foundation for continuing medical education in the U.S., including the Performance Improvement CME (PICME) format; and continues to develop relationships and agreements that may lead to standards accepted by all U.S. licensing boards, specialty boards, hospital credentialing bodies and other entities requiring evidence of physician CME.

11. MOC is but one component to promote patient safety and quality. Health care is a team effort, and changes to MOC should not create an unrealistic expectation that lapses in patient safety are primarily failures of individual physicians.
 12. MOC should be based on evidence and designed to identify performance gaps and unmet needs, providing direction and guidance for improvement in physician performance and delivery of care.
 13. The MOC process should be evaluated periodically to measure physician satisfaction, knowledge uptake and intent to maintain or change practice.
 14. MOC should be used as a tool for continuous improvement.
 15. The MOC program should not be a mandated requirement for licensure, credentialing, reimbursement, network participation or employment.
 16. Actively practicing physicians should be well-represented on specialty boards developing MOC.
 17. Our AMA will include early career physicians when nominating individuals to the Boards of Directors for ABMS member boards.
 18. MOC activities and measurement should be relevant to clinical practice.
 19. The MOC process should not be cost prohibitive or present barriers to patient care.
 20. Any assessment should be used to guide physicians' self-directed study.
 21. Specific content-based feedback after any assessment tests should be provided to physicians in a timely manner.
 22. There should be multiple options for how an assessment could be structured to accommodate different learning styles.
 23. Physicians with lifetime board certification should not be required to seek recertification.
 24. No qualifiers or restrictions should be placed on diplomates with lifetime board certification recognized by the ABMS related to their participation in MOC.
 25. Members of our House of Delegates are encouraged to increase their awareness of and participation in the proposed changes to physician self-regulation through their specialty organizations and other professional membership groups.
- Citation: CME Rep. 16, A-09; Reaffirmed: CME Rep. 11, A-12; Reaffirmed: CME Rep. 10, A-12; Reaffirmed in lieu of Res. 313, A-12; Reaffirmed: CME Rep. 4, A-13; Reaffirmed in lieu of Res. 919, I-13; Appended: Sub. Res. 920, I-14; Reaffirmed: CME Rep. 2, A-15; Appended: Res. 314, A-15; Modified: CME Rep. 2, I-15; Reaffirmation A-16; Reaffirmed: Res. 309, A-16

An Update on Maintenance of Licensure D-275.957

- Our American Medical Association will:
1. Continue to monitor the evolution of Maintenance of Licensure (MOL), continue its active engagement in discussions regarding MOL implementation, and report back to the House of Delegates on this issue.
 2. Continue to review, through its Council on Medical Education, published literature and emerging data as part of the Council's ongoing efforts to critically review MOL issues.
 3. Work with the Federation of State Medical Boards (FSMB) to study whether the principles of MOL are important factors in a physician's decision to retire or have a direct impact on the U.S. physician workforce.
 4. Work with interested state medical societies and support collaboration with state specialty medical societies and state medical boards on establishing criteria and regulations for the implementation of MOL that reflect AMA guidelines for implementation of state MOL programs and the FSMB's Guiding Principles for MOL.
 5. Explore the feasibility of developing, in collaboration with other stakeholders, AMA products and services that may help shape and support MOL for physicians.
 6. Encourage the FSMB to continue to work with state medical boards to accept physician participation in the American Board of Medical Specialties maintenance of certification (MOC) and the American Osteopathic Association Bureau of Osteopathic Specialists (AOA-BOS) osteopathic continuous certification (OCC) as meeting the requirements for MOL and to develop alternatives for physicians who are not certified/recertified, and advocate that MOC or OCC not be the only pathway to MOL for physicians.
 7. Continue to work with the FSMB to establish and assess MOL principles, with the AMA to assess the impact of MOL on the practicing physician and the FSMB to study its impact on state medical boards.
 8. Encourage rigorous evaluation of the impact on physicians of any future proposed changes to MOL processes, including cost, staffing, and time.
- Citation: (CME Rep. 3, A-15; Modified: CME Rep. 2, I-15)

MOC Provisions of Interstate Medical Licensure Compact D-275.955

Our American Medical Association will, in collaboration with the Federation of State Medical Boards and interested state medical boards, request a clarifying statement from the Interstate Medical Licensure Compact Commission that the intent of the language in the model legislation requiring that a physician "holds" specialty certification refers only to initial specialty certification recognized by the American Board of Medical Specialties or the American Osteopathic Association's (AOA's) Bureau of Osteopathic Specialists and that there is no requirement for participation in ABMS's Maintenance of Certification or AOA's Osteopathic Continuous Certification (OCC) program in order to receive initial or continued licensure under the Interstate Medical Licensure Compact.

Citation: (Res. 235, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 312
(I-16)

Introduced by: Maryland

Subject: Eliminating the Tax Liability for Payment of Student Loans

Referred to: Reference Committee C
(Martin J. Trichtinger, MD, Chair)

Whereas, It may be difficult to recruit physicians to underserved areas where there are physician shortages; and

Whereas, Private employers offering student loan repayment to physicians that agree to work in underserved areas could help to alleviate physician shortages in these areas; and

Whereas, The current tax code requires funds given by the private employers to physicians to repay student loans to be considered ordinary income and a tax liability; and

Whereas, The private employers would need to provide additional funds to the physicians to cover the tax liability which significantly increases the cost of repayment of student loans; therefore be it

RESOLVED, That our American Medical Association work with the Internal Revenue Service to eliminate the tax liability when private employers provide the funds to repay student loans for physicians who agree to work in an underserved area. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/11/16

RELEVANT AMA POLICY

Effectiveness of Strategies to Promote Physician Practice in Underserved Areas D-200.980

1. Our AMA, in collaboration with relevant medical specialty societies, will continue to advocate for the following: (a) Continued federal and state support for scholarship and loan repayment programs, including the National Health Service Corps, designed to encourage physician practice in underserved areas and with underserved populations. (b) Permanent reauthorization and expansion of the Conrad State 30 J-1 visa waiver program. (c) Adequate funding (up to at least FY 2005 levels) for programs under Title VII of the Health Professions Education Assistance Act that support educational experiences for medical students and resident physicians in underserved areas.

2. Our AMA encourages medical schools and their associated teaching hospitals, as well as state medical societies and other private sector groups, to develop or enhance loan repayment or scholarship programs for medical students or physicians who agree to practice in underserved areas or with underserved populations.

3. Our AMA will advocate to states in support of the introduction or expansion of tax credits and other practice-related financial incentive programs aimed at encouraging physician practice in underserved areas.

4. Our AMA will advocate for the creation of a national repository of innovations and experiments, both successful and unsuccessful, in improving access to and distribution of physician services to government-insured patients (National Access Toolbox).

CME Rep. 1, I-08 Modified: CME Rep. 4, A-10 Reaffirmation I-11 Appended: Res. 110, A-12 Reaffirmation A-13 Reaffirmation A-14

Reference Committee F

CLRPD Report(s)

01 Minority Affairs Section and Integrated Physician Practice Section, Five-Year Reviews

HOD Comm on Compensation of the Officers

* Report of the House of Delegates Committee on Compensation of the Officers

Resolution(s)

602 Equality

603 Support a Study on the Minimum Competencies and Scope of Medical Scribe Utilization

604* Oppose Physician Gun Gag Rule Policy by Taking our AMA Business Elsewhere

* contained in Handbook Addendum

REPORT OF THE COUNCIL ON LONG RANGE PLANNING AND DEVELOPMENT

CLRPD Report 1-I-16

Subject: Minority Affairs Section and Integrated Physician Practice Section, Five-Year Reviews

Presented by: Mary T. Herald, MD, Chair

Referred to: Reference Committee F
(Gary R. Katz, MD, MBA, Chair)

1 AMA Bylaw 7.0.9 states, “A delineated section must reconfirm its qualifications for continued
2 delineated section status and associated representation in the House of Delegates by demonstrating
3 at least every 5 years that it continues to meet the criteria adopted by the House of Delegates.”
4 AMA Bylaw 6.6.1.5 states that one function of the Council on Long Range Planning and
5 Development (CLRPD) is “to evaluate and make recommendations to the House of Delegates,
6 through the Board of Trustees, only with respect to the formation and/or change in status of any
7 section. The Council will apply criteria adopted by the House of Delegates.”
8

9 The Council analyzed information from letters of application submitted by the Minority Affairs
10 Section (MAS) and the Integrated Physician Practice Section (IPPS) for renewal of delineated
11 section status.
12

13 APPLICATION OF CRITERIA TO THE MINORITY AFFAIRS SECTION

14

15 Criterion 1: Issue of Concern - Focus will relate to concerns that are distinctive to the subset within
16 the broader, general issues that face medicine. A demonstrated need exists to deal with these
17 matters, as they are not currently being addressed through an existing AMA group.
18

19 Initially established in 1992 as a Board of Trustees advisory committee, the House of Delegates
20 (HOD) adopted the MAS as a delineated section in 2011. The MAS facilitates the development of
21 information and policies for underrepresented minority (URM) physicians and medical students,
22 and provides a national platform to advocate for minority health issues. URM represent only nine
23 percent of the U.S. physician workforce. In the medical profession certain racial and ethnic groups,
24 such as African Americans, Hispanics/Latinos, and American Indians/Alaska Natives lag
25 significantly behind their numbers in the general population. Studies have documented that
26 physicians from diverse backgrounds increase patient satisfaction, provide culturally competent
27 care, and decrease racial and ethnic health care disparities.
28

29 CLRPD assessment: The MAS provides the only formal structure for minority physicians to
30 participate directly in the deliberations of the HOD and activities of the AMA.
31

32 Criterion 2: Consistency - Objectives and activities of the group are consistent with those of the
33 AMA. Activities make good use of available resources and are not duplicative.
34

35 The primary objectives of the MAS are to influence and contribute to AMA policy and program
36 development on issues of importance to minority physicians and the AMA. The section works to

1 eliminate racial and ethnic disparities in health care and improve the health status of minority
2 patients; promote diversity in the profession and increase the number of URM in medicine; assist
3 physicians in delivering culturally effective health care; and increase membership, participation,
4 and leadership of minority physicians in the AMA.

5
6 The MAS collaborates with other sections on policy development and reports, and planning
7 educational sessions and outreach programs. The section developed the Doctors Back to School™
8 program as a diversity pipeline initiative to inspire the next generation of URM physicians. The
9 MAS collaborates with the Medical Student Section as well as external partners by connecting
10 members with minority youth in classrooms and school assemblies around the nation. Since its
11 launch in 2002, tens of thousands of children have been engaged through this educational program.
12 The MAS collaborated with the Accelerating Change in Medical Education (ACE) strategic focus
13 area by participating with ACE grant recipients in efforts to identify best practices and common
14 barriers to increasing diversity at their institutions.

15
16 CLRPD Assessment: The MAS serves its constituents by bringing professional issues unique to
17 them to the forefront of organized medicine and by providing targeted educational and policy
18 resources.

19
20 Criterion 3: Appropriateness - The structure of the group will be consistent with its objectives and
21 activities.

22
23 The MAS convenes a nine-member governing council (GC) to direct the section's agenda and
24 strategies. Only current MAS members with an active AMA membership are eligible to be
25 nominated to the designated positions on the GC. Prior leadership experience and an interest or
26 expertise in minority health issues are recommended for anyone wishing to run for the GC. Three
27 minority physician organizations (National Medical Association, Association of American Indian
28 Physicians, and National Hispanic Medical Association) nominate representatives to be elected to
29 designated positions on the GC. Each of the three AMA fixed sections (Medical Student Section,
30 Resident Fellow Section, and Young Physicians Section) also nominates their respective
31 representatives, whom the MAS membership elects via electronic ballot. The GC elects its chair
32 and vice-chair in a closed session at each Annual Meeting of the HOD. To facilitate section
33 business and policy development, the section's GC meets in-person three times each year.
34 Additional GC meetings are held monthly via teleconference.

35
36 CLRPD Assessment: The MAS convenes a GC from its members. The section has established
37 business meetings that are open to its members and provides venues for sharing concerns and
38 identifying opportunities for URM physicians and medical students, which is consistent with the
39 objectives of this section.

40
41 Criterion 4: Representation Threshold - Members of the formal group would be based on
42 identifiable segments of the physician population and AMA membership. The formal group would
43 be a clearly identifiable segment of AMA membership and the general physician population. A
44 substantial number of members would be represented by this formal group. At minimum, this
45 group would be able to represent 1,000 AMA members.

46
47 Over 4,400 medical students and physicians have joined the MAS via an online registration form.
48 Approximately 300 members are active participants in MAS programs, events, and meetings. The
49 AMA has approximately 24,000 URM members and all of these physicians are eligible members of
50 the MAS. The section undertakes regular communications and recruitment efforts to attract new

members. When the AMA attends ethnic medical association meetings, the primary goal is to recruit new AMA and MAS members.

CLRPD Assessment: The MAS is comprised of members from an identifiable segment of AMA membership and the general physician population. This group is able to represent a minimum of 1,000 AMA members.

Criterion 5: Stability - The group has a demonstrated history of continuity. This segment can demonstrate an ongoing and viable group of physicians will be represented by this section and both the segment and the AMA will benefit from an increased voice within the policymaking body.

Approximately, 100 members attend each of the two MAS meetings held in conjunction with HOD meetings. A typical agenda for a MAS meeting includes a networking reception, a report from the chair on current MAS activities, the MAS delegate's report on resolutions, a keynote presentation on a critical minority health issue, and a discussion of new business. Physicians have benefited from participation in the MAS in the following ways: members vote and comment on MAS resolutions before they are submitted to the HOD, propose strategies to increase diversity in the recruitment and selection of nominees (e.g., proposed revisions to the AMA Nominations Form), identify gaps in policy, and propose research projects that may improve minority health. Examples of issues brought forth by the MAS to the HOD include the need for expanded immunization promotion in minority communities; broader awareness of sexual violence against Native American/Alaska Native women; and inclusion of cultural competency, medical translators, patient navigators, and diversity in the physician work force to address racial and ethnic disparities in patient outcomes.

CLRPD Assessment: The MAS has a long history with the AMA, which benefits from having a distinct voice of the MAS in the HOD. Since its inception, the MAS has taken numerous steps to align its structure with the policymaking activities of the AMA.

Criterion 6: Accessibility - Provides opportunity for members of the constituency who are otherwise underrepresented to introduce issues of concern and to be able to participate in the policymaking process within the AMA HOD.

The MAS represents the interests of its members in the HOD through the actions of its elected delegate. Individual members with an active AMA membership may submit resolutions for consideration, which the GC either approves for adoption as written or works with the author(s) on refining language and/or researching citations. To develop a consensus on MAS resolutions, section members meet virtually and offer votes supporting or opposing a resolution. Members also may submit comments or testimony, which suggest revisions to the original resolution. The GC considers all comments, votes, and testimony before editing the resolution for a final ratification vote. A majority vote of those present (via electronic vote) directs the action of the GC and delegate to submit (or not submit) a resolution to the HOD. Additionally, the MAS holds business meetings in conjunction with HOD meetings to solicit additional ideas and identify gaps in current policies to submit at future HOD meetings. The section contributes to the advocacy agenda by participating in the Grassroots Advocacy Network on issues such as repealing the sustainable growth rate (SGR) and the Save GME initiative.

CLRPD Assessment: The MAS provides numerous opportunities for members of the constituency who are otherwise underrepresented to introduce issues of concern and to be able to participate in the HOD policymaking process.

1 CONCLUSION

2
3 The CLRPD has determined that the MAS meets all criteria; therefore, it is appropriate to renew
4 the delineated section status of the section.
5

6
7 APPLICATION OF CRITERIA TO THE INTEGRATED PHYSICIAN PRACTICE SECTION
8

9 Criterion 1: Issue of Concern - Focus will relate to concerns that are distinctive to the subset within
10 the broader, general issues that face medicine. A demonstrated need exists to deal with these
11 matters, as they are not currently being addressed through an existing AMA group.
12

13 The HOD adopted the Integrated Physician Practice Section (IPPS) as a delineated section in 2011
14 and the section held its inaugural meeting at the 2013 Annual Meeting. The precursor to the IPPS
15 was the Advisory Committee on Group Practice Physicians, a Board-appointed committee founded
16 in the early 1990s. The characteristic that distinguishes IPPS from other AMA component groups is
17 that the section focuses on the continuum of care through an integrated delivery system. The IPPS
18 works to advance the interests of multi-specialty, physician-led, integrated health care delivery
19 systems, and medical groups actively working toward systems of coordinated care. Since the
20 founding of the IPPS, key factors have moved health care delivery in the direction of integrated,
21 accountable care, including implementation of the Affordable Care Act and its requirement that
22 Medicare create an Accountable Care Organization (ACO) program, and the passage of the
23 Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).
24

25 CLRPD assessment: The IPPS provides the only formal structure for physicians in or actively
26 working toward multi-specialty, physician-led, integrated health care delivery groups or systems to
27 participate in the deliberations of the HOD and impact policy.
28

29 Criterion 2: Consistency - Objectives and activities of the group are consistent with those of the
30 AMA. Activities make good use of available resources and are not duplicative.
31

32 The IPPS collaborates with other sections, most frequently with the Organized Medical Staff
33 Section, on topics of common interest. Both sections participate in biannual meetings with the
34 AMA-appointed Commissioners to the Joint Commission. AMA councils have sought IPPS's input
35 on a variety of reports. The Council on Ethical and Judicial Affairs (CEJA) met with the IPPS
36 seeking early input on its report on free pharmaceutical samples, and the Council on Medical
37 Service (CMS) sought IPPS input on reports related to physician-led team-based care. Further, the
38 IPPS contributes to efforts of the Physician Satisfaction and Practice Sustainability focus area by
39 providing input on alternative payment models, contributing to surveys of physician leaders, and
40 participating in a multi-stakeholder work group to develop the AMA/AHA integrated physician
41 leadership model, which resulted in the Integrated Leadership for Hospitals and Health Systems:
42 Guiding Principles.
43

44 CLRPD Assessment: The IPPS works with a variety of groups to help support the vital work of the
45 AMA related to health system reform and physician-led integrated care. Additionally, participation
46 in the IPPS serves as a key member benefit for physician groups considering AMA group
47 membership.

1 Criterion 3: Appropriateness - The structure of the group will be consistent with its objectives and
2 activities.

3
4 Candidates for the IPPS governing council (GC), including the delegate and alternate delegate,
5 must be from physician-led, integrated groups or health systems and meet the criteria for Associate
6 membership in the IPPS. Voting members of the IPPS select GC members. Following the
7 completion of its first cycle of meetings, the GC proposed and the Board adopted changes to the
8 IPPS Internal Operating Procedures to refine its governance structure and election procedure. To
9 ensure balanced representation from groups of varying size, the IPPS added slotted seats for
10 representation from a small-medium sized group (50 physicians or less) and a large group (more
11 than 51). The "officer track" was eliminated, and a chair and vice chair are now elected separately.
12 Intra-council elections were eliminated and replaced with direct elections for all positions.

13
14 CLRPD Assessment: The IPPS convenes a GC from its members. The section has established
15 business meetings that are open to its members and provides venues for sharing concerns and
16 identifying opportunities for physicians from various-sized group practices, which is consistent
17 with the objectives of this section.

18
19 Criterion 4: Representation Threshold - Members of the formal group would be based on
20 identifiable segments of the physician population and AMA membership. The formal group would
21 be a clearly identifiable segment of AMA membership and the general physician population. A
22 substantial number of members would be represented by this formal group. At minimum, this
23 group would be able to represent 1,000 AMA members.

24
25 Regarding potential IPPS membership, no existing data clearly identify eligible members.
26 Additionally, potential members of IPPS span a broad spectrum. Members could be from
27 physician-led, integrated, multi-specialty groups of all sizes and types, or from small independent
28 practices of any specialty aligned through one of a variety of models such as IPAs, PHOs, ACOs,
29 etc. Since there is no way to know if a physician is from an organization that fits these descriptors,
30 the IPPS casts a wide net in seeking to attract members and welcomes any physician who either
31 meets the IPPS member criteria or is simply interested in learning more about physician-led
32 integrated care.

33
34 Currently, 46 organizations have completed the IPPS certification form. The number of physicians
35 practicing within those organizations is approximately 41,000. Assuming an AMA market share of
36 14 percent of practicing physicians, there are approximately 5,800 physician members in those
37 groups. Meeting registration varies from 80-120 attendees, and the number of IPPS-certified
38 physicians at any given meeting is 25-35.

39
40 CLRPD Assessment: A substantial number of AMA members would be represented by IPPS. This
41 group is able to represent a minimum of 1,000 AMA members.

42
43 Criterion 5: Stability - The group has a demonstrated history of continuity. This segment can
44 demonstrate an ongoing and viable group of physicians will be represented by this section and both
45 the segment and the AMA will benefit from an increased voice within the policymaking body.

46
47 The IPPS has been fully functioning as a section for 2.5 years and has sponsored five meetings;
48 thus, the amount of data indicating stability is limited compared to other sections. Before each
49 meeting, the IPPS uses the AMA database to identify group practice physicians in surrounding
50 states and sends an email inviting them to the IPPS meeting. Further, the IPPS has developed a
51 database that includes mailing addresses for over 600 physician leaders from mostly large multi-

1 specialty groups and Medicare ACOs. While the IPPS is still developing its policymaking process
2 and capacity, the section's voice has benefited the AMA's policy development process on a
3 number of occasions resulting in the adoption of new AMA policy, such as the importance of
4 physician leadership in all modes of practice, and quality reporting for physician-led, team-based
5 care. These policy positions bring the section's unique perspective to bear on AMA policy.

6
7 CLRPD Assessment: As a relatively new section, the IPPS has not yet had the opportunity to
8 demonstrate the same level of stability as other sections. However, since its inception, the IPPS has
9 taken numerous steps to align its structure with the policymaking activities of the AMA and grow
10 its membership. The AMA and physicians from physician-led integrated practices benefit from
11 having a distinct voice of the IPPS in the HOD.

12
13 Criterion 6: Accessibility - Provides opportunity for members of the constituency who are
14 otherwise underrepresented to introduce issues of concern and to be able to participate in the
15 policymaking process within the HOD.

16
17 At each meeting, the IPPS GC presents a report identifying select items from the HOD Handbook
18 that may be of particular interest to members of the IPPS, as well as all IPPS resolutions. The IPPS
19 Policy Development Committee is open to all members, who are invited to comment on the items,
20 as well as raise items of interest from the HOD that have not been included. During the discussion,
21 if it is unclear where the attendees stand on an issue, the Chair calls for a vote. It is through this
22 discussion and voting process that the IPPS develops consensus on HOD business. The IPPS has
23 actively sought to include physicians from smaller and independent practices, a minority within the
24 section, with the creation of a slotted seat on the GC for a physician from a smaller integrated
25 practice. Frequently, breakout sessions during the meetings are organized by group size, thereby
26 affording smaller groups greater opportunity to be involved. At the I-15 meeting, IPPS reached out
27 to members of the HOD by offering an education program, "How to integrate and remain
28 independent."

29
30 CLRPD Assessment: The IPPS provides numerous opportunities for members of the constituency
31 who are otherwise underrepresented to introduce issues of concern and to be able to participate in
32 the HOD policymaking process.

33 34 CONCLUSION

35
36 The CLRPD has determined that the IPPS meets all criteria; therefore, it is appropriate to renew the
37 delineated section status of this section.

38 39 RECOMMENDATION

40
41 The Council on Long Range Planning and Development recommends that our American Medical
42 Association renew delineated section status for the Minority Affairs Section and the Integrated
43 Physician Practice Section through 2021 with the next review no later than the 2021 Interim
44 Meeting and that the remainder of this report be filed. (Directive to Take Action)

Fiscal Note: Less than \$500

REPORT OF THE HOUSE OF DELEGATES COMMITTEE
ON THE COMPENSATION OF THE OFFICERS

Report I-16

Subject: Report of the House of Delegates Committee on Compensation of the Officers

Presented by: Anthony M. Padula, MD, Chair

Referred to: Reference Committee F
(Jane C. Fitch, MD, Chair)

1 This report by the Committee at the 2016 Interim Meeting presents five recommendations. It also
2 documents the compensation paid to Officers for the period July 1, 2015 thru June 30, 2016 and
3 includes the 2015 calendar year IRS reported taxable value of benefits, perquisites, services, and
4 in-kind payments for all Officers.

5
6 BACKGROUND

7
8 At the 1998 Interim Meeting, the House of Delegates (HOD) established a House Committee on
9 Trustee Compensation, currently named the Committee on Compensation of the Officers, (the
10 “Committee”). The Officers are defined in the American Medical Association’s (AMA)
11 Constitution and Bylaws. (Note: under changes to the Constitution previously approved by the
12 HOD, Article V refers simply to “Officer,” which includes all 21 members of the Board among
13 whom are President, President-Elect, Immediate Past President, Secretary, Speaker of the HOD and
14 Vice Speaker of the HOD, collectively referred to in this report as Officers). The composition,
15 appointment, tenure, vacancy process and reporting requirements for the Committee are covered
16 under the AMA Bylaws. Bylaws 2.645 provides:

17
18 The Committee shall present an annual report to the House of Delegates recommending the
19 level of total compensation for the Officers for the following year. The recommendations of the
20 report may be adopted, not adopted or referred back to the Committee, and may be amended
21 for clarification only with the concurrence of the Committee.

22
23 At A-00, the Committee and the Board jointly adopted the American Compensation Association’s
24 definition of total compensation which was added to the Glossary of the AMA Constitution and
25 Bylaws. Total compensation is defined as the complete reward/recognition package awarded to an
26 individual for work performance including: (a) all forms of money or cash compensation; (b)
27 benefits; (c) perquisites; (d) services; and (e) in-kind payments.

28
29 Since the inception of this Committee, its reports document the process the Committee follows to
30 ensure that current or recommended Officer compensation is based on sound, fair, cost-effective
31 compensation practices as derived from research and use of independent external consultants,
32 expert in Board compensation. Reports beginning in December 2002 documented the principles the
33 Committee followed in creating its recommendations for Officer compensation.

1 At A-08, the HOD approved changes that simplified compensation practices with increased
2 transparency and consistency. At A-10, Reference Committee F requested that this Committee
3 recommend that the HOD affirm a codification of the current compensation principle, which
4 occurred at I-10. At that time, the HOD affirmed that this Committee has and will continue to base
5 its recommendations for Officer compensation on the principle of the value of the work performed,
6 consistent with IRS guidance and best practices as recommended by the Committee's external
7 independent consultant, who is expert in Board compensation.

8
9 At A-11, the HOD approved the alignment of Medical Student and Resident Officer compensation
10 with that of all other Officers (excluding Presidents and Chair) because these positions perform
11 comparable work.

12
13 Immediately following A-11, the Committee retained Mr. Don Delves, founder of the Delves
14 Group, to update his 2007 research by providing the Committee with comprehensive advice and
15 counsel on Officer compensation. The Committee asked for this update because it had been four
16 years since the last comprehensive review and because the Committee wanted to continue refining
17 its compensation practices to improve simplification and transparency. The updated compensation
18 structure was presented and approved by the HOD at I-11 with an effective date of July 1, 2012.

19
20 At I-11, Reference Committee F requested that the Committee list the specific benefits, perquisites
21 and in-kind payments provided to the Officers and to document annually the taxable value of these
22 benefits. The Committee first reported this information, as reported to the IRS, in its A-12 report.

23
24 The Committee's I-12 report referenced discussion and research concerning Presidents' travel on
25 regional airlines. The A-13 report expanded the travel discussion to include travel on airlines
26 without preferred status. The HOD approved the Committee's recommendation to provide a travel
27 allowance for each President to be used for upgrades, primarily on non-preferred status airlines,
28 because of the significant volume of travel by the Presidents in representing our AMA.

29 30 CASH COMPENSATION SUMMARY

31
32 The cash compensation of the Officers shown in the following table will not be the same as
33 compensation reported annually on the AMA's IRS Form 990 because Form 990s are based on a
34 calendar year. The total cash compensation in the summary is compensation for the days these
35 Officers spend away from home on AMA business approved by the Board Chair. The total cash
36 compensation in the summary includes work as defined by the Governance Honorarium and Per
37 Diem for Representation including conference calls with groups outside of the AMA, totaling 2
38 hours or more per calendar day as approved by the Board Chair. Detailed definitions are located in
39 the Appendix.

1 The summary covers July 1, 2015 to June 30, 2016:

2

AMA Officers	Position	Total Compensation	Total Days
Maya A Babu, MD, MBA	Resident Officer	\$ 72,900	62
Susan R Bailey, MD	Speaker, House of Delegates	\$ 74,700	52
David O Barbe, MD, MHA	Officer	\$ 92,700	78
Willarda V Edwards, MD, MBA	Officer	-	2.5
Jesse M Ehrenfeld, MD, MPH	Young Physician Officer	\$ 87,900	64
Julie K Goonewardene	Public Board Member Officer	\$ 61,500	37
Andrew W Gurman, MD	President-Elect	\$ 274,000	128
Gerald E Harmon, MD	Secretary	\$ 65,700	57
Patrice A Harris, MD, MA	Chair-Elect	\$ 205,500	94
William E Kobler, MD	Officer	\$ 92,700	71
Russell WH Kridel, MD	Officer	\$ 73,500	54.5
Omar Z Maniya, MBA	Medical Student Officer	-	1.5
Barbara L McAneny, MD	Immediate Past Chair	\$ 87,300	75.5
Mary Anne McCaffree, MD	Officer	\$ 89,700	69.5
William A McDade, MD, PhD	Officer	-	1
Albert J Osbahr, III, MD	Officer	\$ 87,300	59
Stephen R Permut, MD, JD	Chair	\$ 269,500	106
Dina Marie Pitta, MPP	Medical Student Officer	\$ 61,500	31.5
Jack Resneck, Jr, MD	Officer	\$ 77,100	59
Bruce A Scott, MD	Vice Speaker, House of Delegates	\$ 61,500	44
Carl A Sirio, MD	Officer	\$ 106,500	80
Steven J Stack, MD	President	\$ 279,000	169
Georgia A Tuttle, MD	Officer	\$ 77,700	56
Robert M Wah, MD	Immediate Past President	\$ 274,000	129
Kevin W Williams	Public Board Member Officer	-	2

3

4 President, President-Elect, Immediate Past President and Chair

5 In 2015-2016, each of these positions received an annual Governance Honorarium which was paid
6 in monthly increments. These four positions spent a total of 532 days on approved Assignment and
7 Travel, or 133 days each on average.

8

9 Chair-Elect

10 This position received a Governance Honorarium of approximately 75% of the Governance
11 Honorarium provided to the Chair.

12

13 All other Officers

14 All other Officers received cash compensation, which included a Governance Honorarium of
15 \$61,500 paid in monthly installments. The remaining cash compensation is for Assignment and
16 Travel Days that are approved by the Board Chair to externally represent the AMA. These days are
17 compensated at a per diem rate of \$1,200.

18

19 Assignment and Travel Days

20 The total Assignment and Travel Days for all Officers (excluding the President, President-Elect,
21 Immediate Past President and Chair) were 1051; this includes reimbursement for telephonic
22 representation meetings for external organizations that are 30 minutes or longer during a calendar
23 day and total 2 or more hours. These are reimbursed at ½ of the current per diem rate. During this
24 reporting period, there were 30 reimbursed calls, representing 15 per diem days.

1 EXPENSES

2
3 Total expenses paid for the period, July 1, 2015 – June 30, 2016, were \$881,137 compared to
4 \$832,337 for the previous period, representing a 5.9% increase. This includes \$1,040 in upgrades
5 for Presidents’ travel per the approved Presidential Upgrade Allowance of \$2,500 per position per
6 term.

7
8 BENEFITS, PERQUISITES, SERVICES AND IN-KIND PAYMENTS

9
10 Officers are able to request benefits, perquisites, services and in-kind payments, as defined in the
11 “AMA Board of Trustees Standing Rules on Travel and Expenses.” These non-taxable business
12 expense items are provided to assist the Officers in performing their duties:

- 13
14
 - AMA Standard laptop computer or iPad
 - 15 • iPhone
 - 16 • American Express card (for AMA business use)
 - 17 • Combination fax/printer/scanner
 - 18 • An annual membership to the airline club of choice offered each year during the Board
 - 19 member’s tenure
 - 20 • Personalized AMA stationery, business cards and biographical data for official use.

21

22 Additionally, all Officers are eligible for \$300,000 term life insurance and are covered under the
23 AMA’s \$500,000 travel accident policy and \$10,000 individual policy for medical costs arising out
24 of any accident while traveling on official business for the AMA. Life insurance premiums paid by
25 the AMA are reported as taxable income.

26
27 Secretarial support, other than that provided by AMA’s Board office, is available up to defined
28 annual limits as follows: President, during the Presidential year, \$15,000; \$5,000 each for the
29 President-Elect, Chair, Chair-Elect and Immediate Past president per year. Secretarial expenses
30 incurred by other Officers in connection with their official duties are paid up to \$750 per year per
31 Officer. This is reported as taxable income.

32
33 Travel expenses incurred by family members are not reimbursable, with the exception of the family
34 of the incoming President at the Annual Meeting of the HOD.

35
36 Calendar year taxable life insurance and taxable secretarial fees reported to the IRS totaled \$25,755
37 and \$20,375 respectively for 2015. An additional \$16,500 was paid to third parties for secretarial
38 services during 2015.

39
40 METHODOLOGY

41
42 As noted in its A-16 report, the Committee commissioned a comprehensive compensation review
43 with an outside consultant expert in Board compensation to refresh the Committee’s knowledge of
44 market conditions related to Board compensation because it has been five years since the last
45 compensation review. The purpose of the review is to ensure the Officers are compensated
46 appropriately for the work performed on behalf of the AMA. The Committee also continues to be
47 interested in reviewing and refining its compensation practices for increased simplification and
48 transparency. The Committee also asked the consultant to review the structure of Officer
49 compensation to ensure continued alignment with current trends in for-profit Board compensation
50 which had been to move away from paying for each individual Board or Board committee meeting
51 to one annual fee.

The Committee's review and subsequent recommendations for Officer compensation are based on the principle of the value of the work performed, as affirmed by the HOD. In addition, the following additional guidelines were followed:

- Compensation should be based on the value expected by the AMA from its Officers.
- Compensation should take into account that the AMA is a complex organization when comparing compensation provided to Board members by for-profit organizations and by complex not-for-profit organizations of similar size and activities.
- Compensation should be aligned with the long-term interests of AMA members and the fulfillment of the fiduciary responsibilities of the Officers.
- Officers should be adequately compensated for their value, time, and effort.
- Compensation should reinforce choices and behaviors that enhance effectiveness.
- Compensation should be approached on a comprehensive basis, rather than as an array of separate elements.

It is important to note that the process the Committee followed along with the aforementioned principles are consistent with the guidelines recommended by the IRS for determining reasonable and competitive levels of Officer compensation.

To complete the compensation review, the Committee retained a new consultant, Becky Glantz Huddleston, of Willis Towers Watson. Ms. Huddleston is an expert in Board compensation and works with both for-profit and not-for profit organizations. The firm she works for, Willis Towers Watson, is one of the largest, most prestigious and well-respected compensation consulting firms.

To develop her recommendations with the Committee, Ms. Huddleston:

- Met with internal AMA staff assigned to support this Committee to review and understand the current compensation structure.
- Interviewed certain Board members to gain an understanding of their thoughts and insights related to the current Officer compensation program.
- Discussed her interview results with the Committee.
- Reviewed and analyzed Officer compensation data for the past three terms.
- Analyzed and researched pay practices for Board of directors at for-profit and not-for-profit organizations similar to the AMA who pay their Board members.
- Prepared a final report to the Committee following a collaborative, deliberative and objective process to arrive at the recommendations as documented in this report to the House of Delegates.

FINDINGS

The Committee notes that Officers continue to make significant time commitments in supporting our AMA in governance and representation functions. Given the amount of time required of Board members, it is important that individuals seeking a position on the Board be aware of the scope of the commitment and the related compensation.

The Committee further notes that external data indicates for-profit organizations are continuing the trend of eliminating meeting fees while increasing the annual retainer in an effort to simplify the program and to recognize that Board work has become more fluid in nature and is increasingly completed outside of formal meetings; this is also a trend at the AMA based on Officer feedback.

1 In 2011, the HOD approved this Committee's recommendation to refine the AMA's compensation
2 structure for non-leadership Officers by expanding the Governance definition to include Chair-
3 assigned internal representation and increasing the amount of the annual Governance Honorarium.
4 Chair-assigned External Representation continued to be paid by a Per Diem. The \$61,500 annual
5 Governance Honorarium has been in effect since July 1, 2012 and the \$1200 Per Diem has been the
6 same amount since 2008.

7
8 The Committee and its consultant reviewed and considered feedback from the interviews with
9 Officers. The overall consensus from the Officers interviewed was that the Board compensation
10 program is generally working and while there were not any major issues, modest adjustments to the
11 compensation levels may be appropriate. However, Officer interviews included concerns that the
12 current structure resulted in an unequal internal time commitment among Officers because some
13 internal representation assignments result in greater time commitments which, by definition, are
14 included as part of the Governance Honorarium unlike external assignments compensated by per
15 diem.

16
17 Review of AMA data for the past three terms showed that the time commitment for Board-related
18 work was generally consistent among the Officers. Internal representation had more variability than
19 Board-related work and External Representation was the most variable. The Governance
20 Honorarium does not address the variability of internal representation. The wide variance in
21 External Representation reflects the unique skillset and expertise of each Officer and the
22 responsibility of the Board Chair to make assignments that optimize the Officers' expertise. The
23 current use of the Per Diem for External Representation addresses the wide variance in time
24 commitment of the Officers.

25
26 Compensation data from both for-profit and not-for-profit organizations was reviewed. For-profit
27 Board compensation data was sourced from the National Association of Corporate Directors
28 (NACD) 2015-2016 survey of organizations with revenue between \$50M - \$500M. This data
29 indicated for-profit Board compensation consisted of both a pay and stock component. The
30 Committee's external consultant noted that not-for-profit organizations do not have the ability to
31 grant stock awards and therefore do not necessarily intend to be competitive with the for-profit
32 sector from the perspective of total compensation. While AMA's Governance Honorarium was
33 close to the median cash compensation, it was well below the total Board compensation due to
34 absence of stock awards.

35
36 The consultant collected and analyzed data from not-for-profit organizations determined to be of
37 similar size and complexity as the AMA; AMA's not-for-profit peer group. This information was
38 collected from Form 990 filings, generally for 2014. This data showed that AMA non-leadership
39 Officers spend significantly more time on internal Board and representation when compared to the
40 peer group. Further analysis, to adjust for the variance in time commitments, showed that AMA's
41 Governance Honorarium was significantly lower than the peer group.

42
43 In determining the Governance Honorarium recommendation for non-leadership Officers, the
44 Committee balanced simplicity, transparency and comparability versus pay for internal
45 representation days as a compensation structure, Board feedback and the total cost of governance to
46 the AMA. There is no good external comparison for Per Diem pay for External Representation for
47 non-leadership Officers given the unique nature of this function at the AMA. However, the Per
48 Diem amount has not changed since 2008 and the Committee used the data from the not-for-profit
49 peer group Governance Honorarium comparison to directionally inform them.

Officers in leadership, the Board Chair, Chair-elect, President, President-elect and Immediate Past President have a significant level of responsibility, representing a time commitment well above that required by other non-profit Board leadership. This led to further analysis by the consultant to adjust for the variance in time commitment. This analysis showed that compensation for AMA Officers in leadership roles for the past three terms ranged near the median, resulting in the recommendation that leadership compensation continues to be appropriate and no change is necessary.

RECOMMENDATIONS

The Committee on Compensation of the Officers recommends the following recommendations be adopted and the remainder of this report be filed:

1. That there be no change to the current Definitions effective July 1, 2012 as they appear in the Travel and Expenses Standing Rules for AMA Officers for the Governance Honorarium, Per Diem for External Representation and Telephonic Per Diem for External Representation except for the Governance Honorarium and Per Diem amounts as recommended in 2, 3 and 4 below.
 - Definition of Governance Honorarium effective July 1, 2012:
The purpose of this payment is to compensate Officers for all Chair-assigned internal AMA work and related travel. This payment is intended to cover all currently scheduled Board meetings, special Board or Board committee meetings, task forces, subcommittees, Board orientation, development and media training, Board calls, sections, councils or other internal representation meetings or calls, and any associated review or preparatory work, and all travel days related to all meetings as noted above.
 - Definition of Per Diem for Representation effective July 1, 2012:
The purpose of this payment is to compensate for Board Chair-assigned representation day(s) and related travel for Officers, excluding Board Chairs and Presidents. Representation is either external to the AMA, or for participation in a group or organization with which the AMA has a key role in creating/partnering/facilitating achievement of the respective organization goals such as the AMA Foundation, PCPI, etc. The Board Chair may also approve a per diem for special circumstances that cannot be anticipated such as weather related travel delays.
 - Definition of Telephonic Per Diem for External Representation effective July 1, 2011:
Officers, excluding the Board Chairs and the Presidents, who are assigned as the AMA representative to outside groups as one of their specific Board assignments, receive a per diem rate for teleconference meetings when the total of all teleconference meetings of 30 minutes or longer during a calendar day equal 2 or more hours. Payment for these meetings would require approval of the Chair of the Board.
2. That the Governance Honorarium for all Board members excluding leadership, Board Chair, Board Chair-elect, President, President-elect, and Immediate Past President Board Chairs be increased effective July 1, 2017 to \$65,000. (Directive to Take Action)
3. That the Per Diem for Chair-assigned representation external to the AMA or for participation in a group or organization with which the AMA has a key role in creating/partnering/facilitating achievement of the respective organization goals such as the AMA Foundation, PCPI, etc., and related travel be increased effective July 1, 2017 to \$1,300 per day. (Directive to Take Action)

- 1 4. That the Per Diem for Chair-assigned Telephonic Per Diem for External Representation be
2 increased effective July 1, 2017 to \$650 as defined. (Directive to Take Action)
3
- 4 5. Except as noted above, there be no other changes to the Officers compensation for the period
5 beginning July 1, 2017. (Directive to Take Action)

Fiscal Note: Estimated annual cost of Recommendations 2, 3 and 4 is \$80,350 based on data reported for July 1, 2015 through June 30, 2016. This cost represents the impact of the Governance Honorarium increase (\$3,500 for each of the 16 non-leadership Officers), the Per Diem increase (\$100 per External Representation day as defined), and the Telephonic Per Diem increase (\$50 per teleconference meeting as defined).

APPENDIX

Current Leadership Compensation Summary

Officer compensation and definitions initially approved at I-11 and effective July 1, 2012.

POSITION	GOVERNANCE HONORARIUM
President	\$279,000
Immediate Past President & President-Elect	\$274,000
Chair	\$269,500
Chair-Elect	\$199,500
Other Officers	\$61,500

Definition of Governance Honorarium Effective July 1, 2012:

The purpose of this payment is to compensate Officers for all Chair-assigned internal AMA work and related travel. This payment is intended to cover all currently scheduled Board meetings, special Board or Board Committee meetings, task forces, subcommittees, Board orientation, development and media training, Board calls, sections, councils or other internal representation meetings or calls, and any associated review or preparatory work, and all travel days related to all meetings as noted above.

Definition of Per Diem for Representation effective July 1, 2012:

The purpose of this payment is to compensate for Board Chair-assigned representation day(s) and related travel. Representation is either external to the AMA, or for participation in a group or organization with which the AMA has a key role in creating/partnering/facilitating achievement of the respective organization goals such as the AMA Foundation, PCPI, etc. The Board Chair may also approve a per diem for special circumstances that cannot be anticipated such as weather related travel delays. Per Diem for Chair-assigned representation and related travel is \$1,200 per day.

Definition of Telephonic Per Diem for External Representation effective July 1, 2011:

Officers, excluding the Board Chair and the Presidents, who are assigned as the AMA representative to outside groups as one of their specific Board assignments, receive a per diem rate for teleconference meetings when the total of all teleconference meetings of 30 minutes or longer during a calendar day equal 2 or more hours. Payment for these meetings would require approval of the Chair of the Board. The amount of the Telephonic Per Diem will be ½ of the full Per Diem or \$600.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 602
(I-16)

Introduced by: Young Physicians Section

Subject: Equality

Referred to: Reference Committee F
(Gary R. Katz, MD, Chair)

1 Whereas, In its Code of Medical Ethics, the American Medical Association (AMA) states,
2 “Physicians must also uphold ethical responsibilities not to discriminate against a prospective
3 patient on the basis of race, gender, sexual orientation or gender identity, or other personal or
4 social characteristics that are not clinically relevant to the individual’s care. Nor may physicians
5 decline a patient based solely on the individual’s infectious disease status”; and
6

7 Whereas, Physicians have a professional obligation, and a specific ethical duty and policies that
8 prohibit discrimination, and physicians are expected to adhere to it; and
9

10 Whereas, When discrimination based on race, color, religion, national origin, language, creed,
11 sexual orientation and gender identity and gender expression continues, it leads to lower
12 productivity of individuals, worse health outcomes and increased suicide rates in the affected
13 populations; therefore be it
14

15 RESOLVED, That all future meetings and conferences organized and/or sponsored by our
16 American Medical Association, not yet contracted, only be held in towns, cities, counties, and
17 states that do not have discriminatory policies based on race, color, religion, ethnic origin,
18 national origin, language, creed, sex, sexual orientation, gender, gender identity and gender
19 expression, disability, or age. (New HOD Policy)

Fiscal Note: No fiscal impact.

Received: 09/26/16

RELEVANT AMA POLICY

E-1.1.2 Prospective Patients

As professionals dedicated to protecting the well-being of patients, physicians have an ethical obligation to provide care in cases of medical emergency. Physicians must also uphold ethical responsibilities not to discriminate against a prospective patient on the basis of race, gender, sexual orientation or gender identity, or other personal or social characteristics that are not clinically relevant to the individual's care. Nor may physicians decline a patient based solely on the individual's infectious disease status. Physicians should not decline patients for whom they have accepted a contractual obligation to provide care.

However, physicians are not ethically required to accept all prospective patients. Physicians should be thoughtful in exercising their right to choose whom to serve.

A physician may decline to establish a patient-physician relationship with a prospective patient, or provide specific care to an existing patient, in certain limited circumstances:

- (a) The patient requests care that is beyond the physician's competence or scope of practice; is known to be scientifically invalid, has no medical indication, or cannot reasonably be expected to achieve the intended clinical benefit; or is incompatible with the physician's deeply held personal, religious, or moral beliefs in keeping with ethical guidelines on exercise of conscience.
- (b) The physician lacks the resources needed to provide safe, competent, respectful care for the individual. Physicians may not decline to accept a patient for reasons that would constitute discrimination against a class or category of patients
- (c) Meeting the medical needs of the prospective patient could seriously compromise the physician's ability to provide the care needed by his or her other patients. The greater the prospective patient's medical need, however, the stronger is the physician's obligation to provide care, in keeping with the professional obligation to promote access to care.
- (d) The individual is abusive or threatens the physician, staff, or other patients, unless the physician is legally required to provide emergency medical care. Physicians should be aware of the possibility that an underlying medical condition may contribute to this behavior.

AMA Principles of Medical Ethics: I,VI,VIII,X

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 603
(I-16)

Introduced by: Medical Student Section

Subject: Support a Study on the Minimum Competencies and Scope of Medical Scribe Utilization

Referred to: Reference Committee F
(Gary R. Katz, MD, Chair)

Whereas, There will be an estimated 100,000 medical scribes in 2020 with no national standardization of training in place;¹ and

Whereas, Because medical scribes have no patient care responsibilities, they are not currently required to undergo specific training or meet any background requirements prior to starting their positions;² and

Whereas, Federal law inhibits medical scribes from entering certain patient information including but not limited to prescription medication and lab and imaging orders, but there is no enforcement mechanism to ensure adherence;³ and

Whereas, Nearly 1 in 5 physicians currently employ medical scribes who are unlicensed workers hired to enter patient history and physical exam findings into the electronic health record (EHR) at the direction of a physician or practitioner;⁴ and

Whereas, Several studies suggest that medical scribes improve clinician satisfaction, productivity, time-related efficiencies, revenue, and patient-clinician interactions since EHR-use can be cumbersome and time-consuming;⁵ and

Whereas, ScribeAmerica, the largest professional medical scribe training and management company in the United States, provides only two weeks of training for new medical scribes;¹ and

Whereas, Health information technology experts, health informaticists, and the American College of Medical Scribe Specialists would be useful partners in establishing standardized training for medical scribes; therefore be it

RESOLVED, That our American Medical Association partner with The Joint Commission and other stakeholders to study the minimum skills and competencies required of a medical scribe regarding documentation performance and clinical boundaries of medical scribe utilization.
(Directive to Take Action)

¹ Conn J. Medical scribes lack consensus on training, certification. Modern Healthcare 2013. Available at: <http://www.modernhealthcare.com/article/20130905/news/309059952>. Accessed April 20, 2016.

² ACEP. Scribe FAQ // 2015. Available at: <https://www.acep.org/physician-resources/practice-resources/administration/financial-issues/-reimbursement/scribe-faq/>. Accessed April 19, 2016.

³ Use of Unlicensed Persons Acting as Scribes. The Joint Commission- Standards FAQ Details. Available at: http://www.jointcommission.org/mobile/standards_information/jcfaqdetails.aspx. Accessed February 8, 2016.

⁴ Gillespie L. The Unregulated Rise of the Medical Scribe. The Atlantic 2015. Available at: http://www.theatlantic.com/health/archive/2015/12/why-so-many-doctors-are-hiring-scribes/419838/?utm_source=sffb. Accessed February 8, 2016.

⁵ Shultz CG, Holmstrom HL. The Use of Medical Scribes in Health Care Settings: A Systematic Review and Future Directions. The Journal of the American Board of Family Medicine 2015;28(3):371–381. doi:10.3122/jabfm.2015.03.140224.

Fiscal Note: Moderate - between \$5,000 - \$10,000.

Received: 09/29/16

Innovation to Improve Usability and Decrease Costs of Electronic Health Record Systems for Physicians D-478.976

1. Our AMA will: (A) advocate for CMS and the Office of the National Coordinator (ONC) to support collaboration between and among proprietary and open-source EHR developers to help drive innovation in the marketplace; (B) continue to advocate for research and physician education on EHR adoption and design best practices specifically concerning key features that can improve the quality, safety, and efficiency of health care regardless of proprietary or open-source status; and (C) through its partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs--open source and proprietary--to create more transparency and support more informed decision making in the selection of EHRs. 2. Our AMA will, through partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs--open source and proprietary--to create more transparency and formulate more formal decision making in the selection of EHRs. 3. Our AMA will work with AmericanEHR Partners to modify the current survey to better address the economics of EHR use by physicians including the impact of scribes. 4. Our AMA will make available the findings of the AmericanEHR Partners' survey and report back to the House of Delegates.

BOT Rep. 23, A-13; BOT Rep. 24, A-13; Reaffirmed: BOT Rep. 17, A-15

Status and Utilization of New or Expanding Health Professionals in Hospitals H-35.996

(1) The services of certain new health professionals, as well as those professionals assuming an expanded medical service role, may be made available for patient care within the limits of their skills and the scope of their authorized practice. The occupations concerned are those whose patient care activities involve medical diagnosis and treatment to such an extent that they meet the three criteria specified below: (a) As authorized by the medical staff, they function in a newly expanded medical support role to the physician in the provision of patient care. (b) They participate in the management of patients under the direct supervision or direction of a member of the medical staff who is responsible for the patient's care. (c) They make entries on patients' records, including progress notes, only to the extent established by the medical staff. Thus this statement covers regulation of such categories as the new physician-support occupations generically termed physician assistants, nurse practitioners, and those allied health professionals functioning in an expanded medical support role. (2) The hospital governing authority should depend primarily on the medical staff to recommend the extent of functions which may be delegated to, and services which may be provided by, members of these emerging or expanding health professions. To carry out this obligation, the following procedures should be established in medical staff bylaws: (a) Application for use of such professionals by medical staff members must be processed through the credentials committee or other medical staff channels in the same manner as applications for medical staff membership and privileges. (b) The functions delegated to and the services provided by such personnel should be considered and specified by the medical staff in each instance, and should be based upon the individual's professional training, experience, and demonstrated competency, and upon the physician's capability and competence to supervise such an assistant. (c) In those cases involving use by the physician of established health professionals functioning in an expanded medical support role, the organized medical staff should work closely with members of the appropriate discipline now employed in an administrative capacity by the hospital (for example, the director of nursing services) in delineating such functions.

BOT Rep. G, A-73; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00;
Modified: CMS Rep. 6, A-10; Reaffirmation A-12

Health Workforce H-200.994 - The AMA endorses the following principle on health manpower: Both physicians and allied health professionals have legal and ethical responsibilities for patient care, even though ultimate responsibility for the individual patient's medical care rests with the physician. To assure quality patient care, the medical profession and allied health professionals should have continuing dialogue on patient care functions that may be delegated to allied health professionals consistent with their education, experience and competency.

BOT Rep. C, I-81 Reaffirmed: Sunset Report, I-98 Modified: CME Rep. 2, I-03; Reaffirmed: CME Rep. 2, A-13

Protecting Physician Led Health Care H-35.966 - Our American Medical Association will continue to work with state and specialty medical associations and other organizations to collect, analyze and disseminate data on the expanded use of allied health professionals, and of the impact of this practice on healthcare access (including in poor, underserved, and rural communities), quality, and cost in those states that permit independent practice of allied health professionals as compared to those that do not. This analysis should include consideration of practitioner settings and patient risk-adjustment.
Res. 238, A-15

Council on Medical Education. B-6.2

6.2.1 Functions.

6.2.1.1 To study and evaluate all aspects of medical education continuum, including the development of programs approved by the House of Delegates, to ensure an adequate continuing supply of well-qualified physicians to meet the needs of the public;

6.2.1.2 To review and recommend policies for medical and allied health education, whereby the AMA may provide the highest education service to both the public and the profession;

6.2.1.3 To consider and recommend means by which the AMA may, on behalf of the public and the medical profession at-large, continue to provide information, leadership, and direction to the existing inter-organizational bodies dealing with medical and allied health education; and

6.2.1.4 To consider and recommend the means and methods whereby physicians may be assisted in maintaining their professional competence and the development of means and criteria for recognition of such achievement.

6.2.2 Membership.

6.2.2.1 Twelve active members of the AMA, one of whom shall be a resident/fellow physician, and one of whom shall be a medical student.

AMA Support for States in Their Development of Legislation to Support Physician-Led, Team Based Care D-35.982 - 1. Our AMA will continue to assist states in opposing legislation that would allow for the independent practice of certified registered nurse practitioners. 2. Our AMA will assist state medical societies and specialty organizations that seek to enact legislation that would define the valued role of mid-level and other health care professionals within a physician-led team based model structured to efficiently deliver optimal quality patient care and to assure patient safety. 3. Our AMA will actively oppose health care teams that are not physician-led.
Res. 240, A-13; Reaffirmation A-15

Education Programs Offered to, for or by Allied Health Professionals Associated with a Hospital H-35.978 - The AMA encourages hospital medical staffs to have a process whereby physicians will have input to and provide review of education programs provided by their hospital for the benefit of allied health professionals working in that hospital, for the education of

patients served by that hospital, and for outpatient educational programs provided by that hospital.

BOT Rep. B, A-93; Adopts Res. 317, A-92; Reaffirmed: CME Rep. 2, A-03; Reaffirmed: CME Rep. 2, A-13

Patient Protection and Clinical Privileges H-230.989 - Concerning the granting of staff and clinical privileges in hospitals and other health care facilities, the AMA believes: (1) the best interests of patients should be the predominant consideration; (2) the accordance and delineation of privileges should be determined on an individual basis, commensurate with an applicant's education, training, experience, and demonstrated current competence. In implementing these criteria, each facility should formulate and apply reasonable, nondiscriminatory standards for the evaluation of an applicant's credentials, free of anti-competitive intent or purpose; (3) differences among health care practitioners in their clinical privileges are acceptable to the extent that each has a scientific basis. However, the same standards of performance should be applied to limited practitioners who offer the kinds of services that can be performed by limited licensed health care practitioners or physicians; and (4) health care facilities that grant privileges to limited licensed practitioners should provide that patients admitted by limited licensed practitioners undergo a prompt medical evaluation by a qualified physician; that patients admitted for inpatient care have a history taken and a comprehensive physical examination performed by a physician who has such privileges; and that each patient's general medical condition is the responsibility of a qualified physician member of the medical staff.

Sub. Res. 36, A-84; Reaffirmed: CME Rep.8, I-93; Reaffirmed: Res. 802, I-99; Reaffirmed: CME Rep. 2, A-09

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 604
(I-16)

Introduced by: American Thoracic Society

Subject: Oppose Physician Gun Gag Rule Policy by Taking our AMA Business
Elsewhere

Referred to: Reference Committee F
(Gary R. Katz, MD, Chair)

1 Whereas, Our AMA encourages our members to reduce firearm morbidity and mortality by
2 asking their patients about household firearms and educating their patients about the dangers
3 such firearms may pose. The AMA opposes laws that restrict physicians from discussing
4 firearms safety with their patients; and
5

6 Whereas, The state of Florida enacted the Firearms Owner's Privacy Law (FOPL), which
7 prohibits health care providers from;
8 (i) intentionally recording information concerning firearm ownership in a patient's medical record
9 if the information is not relevant to the patient's medical care or safety or the safety of others;
10 (ii) asking a patient whether he or she owns a firearm unless the information is relevant to the
11 patient's medical care or safety or the safety of others:
12 (iii) discriminating against a patient based solely on firearms ownership; and
13 (iv) unnecessarily harassing a patient about firearm ownership. Violation of the law constitutes
14 grounds for discipline under the Florida licensure statutes; and
15

16 Whereas, Our sister organizations, American Academy of Pediatrics, the American Academy of
17 Family Physicians, and the American College of Physicians have challenged the Florida
18 Firearms Owners Privacy law in court; and
19

20 Whereas, Our AMA has filed an amicus brief in support of our sister organizations seeking to
21 overturn the Firearms Owner Privacy Law; and
22

23 Whereas, Our AMA is holding our 2016 Interim House of Delegates meeting in Orlando, Florida;
24 and
25

26 Whereas, Orlando, Florida joins a long list of U.S. cities who have suffered directly from mass
27 shootings; therefore be it
28

29 RESOLVED, That our American Medical Association adopt policy that bars our AMA from
30 holding House of Delegates meetings in states that enact physician gun gag rule laws (New
31 HOD Policy); and be it further
32

33 RESOLVED, That our AMA contact governors and convention bureaus of states that have
34 enacted physician gun gag rules and inform them that our AMA will no longer hold House of
35 Delegates meetings in their state, until the restrictive physician gun gag rule is repealed or
36 struck down by the courts. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.
Received: 10/11/16

Reference Committee J

CMS Report(s)

- 01 Infertility Benefits for Veterans
- 02 Health Care While Incarcerated
- 03 Providers and the Annual Wellness Visit
- 04 Concurrent Hospice and Curative Care
- 05 Incorporating Value into Pharmaceutical Pricing
- 06 Integration of Mobile Health Applications and Devices into Practice
- 07 Hospital Discharge Communications

Resolution(s)

- 801 Increasing Access to Medical Devices for Insulin-Dependent Diabetics
- 802 Eliminate "Fail First" Policy in Addiction Treatment
- 803 Reducing Perioperative Opioid Consumption
- 804 Parity in Reproductive Health Insurance Coverage for Same-Sex Couples
- 805 Health Insurance Companies Should Collect Deductible from Patients After Full Payments to Physicians
- 806 Pharmaceutical Industry Drug Pricing is a Public Health Emergency
- 807 Pharmacy Use of Medication Discontinuation Messaging Function
- 808 A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities
- 809 Addressing the Exploitation of Restricted Distribution Systems by Pharmaceutical Manufacturers
- 810 Medical Necessity of Breast Reconstruction and Reduction Surgeries
- 811 Opposition to CMS Mandating Treatment Expectations and Practicing Medicine
- 812 Enact Rules and Payment Mechanisms to Encourage Appropriate Hospice and Palliative Care Usage
- 813 Physician Payment for Information Technology Costs
- 814* Addressing Discriminatory Health Plan Exclusions or Problematic Benefit Substitutions for Essential Health Benefits Under the Affordable Care Act
- 815* Preservation of Physician-Patient Relationships and Promotion of Continuity of Patient Care
- 816* Support for Seamless Physician Continuity of Patient Care

* contained in Handbook Addendum

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-16

Subject: Infertility Benefits for Veterans
(Resolution 223-I-15)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

At the American Medical Association's (AMA) 2015 Interim Meeting, the House of Delegates referred Resolution 223, "Infertility Benefits for Wounded Warriors," submitted by the Young Physicians Section (YPS). The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House of Delegates at the 2016 Interim Meeting. Resolution 223-I-15 asked that our AMA:

(1) support lifting the congressional ban on the Department of Veterans Affairs (VA) from covering in vitro fertilization (IVF) costs and (2) work with the American Society for Reproductive Medicine (ASRM) and other interested organizations to encourage lifting the congressional ban on the VA from covering IVF costs.

This report summarizes the increase in combat-related injuries that cause infertility; outlines coverage of IVF benefits through the Department of Defense (DOD), the Veterans Health Administration (VHA) and private health insurers; highlights the medical community's efforts to provide IVF to veterans; summarizes AMA policy; discusses strategies to eliminate barriers to accessing IVF for veterans; and presents policy recommendations.

BACKGROUND

Testimony on Resolution 223-I-15 expressed concern that there may be inconsistency in health care coverage of IVF between TRICARE, the health care program through the DOD for active duty service members, and the VHA, the health care program through the US Department of Veterans Affairs for veterans. Testimony urged the AMA to address the lack of access to IVF for veterans, review the categories of veterans who are entitled to IVF, consider advocating for parity between private and VA health insurance coverage of IVF, and take into account the cost of such services.

The majority of active duty service members are of childbearing age. Approximately 65 percent of enlisted personnel are younger than 30 years old and about 50 percent of all military officers are between the ages of 26 and 35. About 50 percent of enlisted military members and 70 percent of all officers are married. An estimated 84,000 marriages are unions between two members of the military. Many service members and their partners make family planning decisions to accommodate their military service duties.

COMBAT-RELATED INFERTILITY

Service members may be exposed to job-related risks that can result in injuries impacting their fertility. In recent years, there has been an increased use of improvised explosive devices (IEDs), which are homemade bombs that can be hidden on roads and walkways. A blast from an IED can cause severe damage to the genitourinary system, which includes the kidneys, and reproductive and urinary tract organs. Because of increased ground patrol in the Afghanistan War, the incidence of service members sustaining genitourinary injuries is 350 percent higher than for those who served in the Iraq War. Since 2001, IEDs have caused more US military casualties than traditional weapons.

Gunshot wounds and exposure to hazardous materials are also common causes of infertility. Approximately 1,400 service members returned from Iraq and Afghanistan with severe injuries to their reproductive organs. It is estimated that thousands more sustained paralysis, brain injuries or other conditions that make IVF their best option to conceive a child. Results from the National Health Study for a New Generation of US Veterans indicated that about 16 percent of female veterans and 14 percent of male veterans reported experiencing infertility.¹ According to the most recent Centers for Disease Control and Prevention surveys, approximately 11 percent of female and male civilians aged 15-44 experience infertility.^{2, 3}

ACCESS TO IN VITRO FERTILIZATION

TRICARE

Communication with the DOD's Defense Health Agency clarified that IVF is not included as a TRICARE covered benefit for all active duty service members. By law TRICARE covers medically necessary treatments and procedures that include infertility testing and correction of physical causes of infertility. Assisted Reproductive Technologies (ART), such as IVF, are not covered because they are not considered medically necessary treatments. However, section 1633 of the National Defense Authorization Act for FY 2008 (HR 4986) allows for the provision of ART, including IVF, for certain active duty service members. The limited IVF benefit was implemented in 2012.

If health care providers who specialize in urogenital trauma and ART determine that a service member and their spouse are good candidates for IVF they can request this benefit for their patients who have sustained a serious or severe illness or injury while on active duty that led to the loss of their natural procreative ability. To qualify as seriously ill or injured a service member must meet the following criteria: (1) have a serious injury or illness; (2) be unlikely to return to duty within a time specified by his or her military department; and (3) may be medically separated or retired from the military. To qualify as severely ill or injured a service member must meet the following criteria: (1) have a severe or catastrophic injury or illness; (2) be highly unlikely to return to duty; and (3) will most likely be medically separated or retired from the military. By law, no other TRICARE beneficiaries are eligible for this benefit.

Communication with the DOD's Defense Health Agency indicated that military providers are aware of the DOD policy and make every effort to request the IVF benefit for those who qualify. The most recent data available from the Office of the Secretary of Defense indicates that from 2012–2015, a total of 20 active duty service members met the criteria to receive the IVF benefit. The DOD paid an average of \$5,000 for each IVF cycle.⁴ To date, a total of 26 service members have qualified for the IVF benefit.

1 As part of the “Force of the Future” initiative, the DOD recently announced plans to implement a
2 two-year fertility preservation pilot program to provide sperm banking and egg freezing to active
3 duty service members.⁵ While the program is not available to current veterans, it is a proactive
4 approach to address potential infertility issues for active duty service members and future veterans.
5 The program will only cover fertility preservation, not the cost of IVF, which may pose a
6 significant financial barrier to the use of the benefit.

7 *Veterans Affairs*

9
10 The VA covers fertility assessments, counseling and some treatment, such as surgeries,
11 medications and intrauterine insemination, but has not been able to provide IVF benefits as
12 stipulated by the Veterans Health Care Act of 1992 (PL 102-585).⁶ When the law was enacted, IVF
13 was considered to be experimental, which is no longer the case. Providing IVF health care benefits
14 to veterans has been and still is controversial. Some individuals who are in the position to advocate
15 for changing the VA’s coverage policy on IVF are opposed to the treatment based on religious
16 grounds. However, in October 2016, the Military Construction, Veterans Affairs, and Related
17 Agencies Appropriations Bill for FY 2017 was signed into law, which allows the VA to cover IVF
18 costs for the next two years. While this is a step in the right direction, the legislation is temporary
19 and does not lift the ban on the VA from covering IVF.

20
21 Service members who complete a length of service in any branch of the armed forces are classified
22 as veterans as long as they were not dishonorably discharged. Retired veterans are service members
23 who remain on active duty or have served in the Army National Guard, Army Reserve, Navy
24 Reserve, Marine Corps Reserve, Air National Guard, Air Force Reserve or the Coast Guard
25 Reserve for a sufficient period of time, which is usually a minimum of 20 years. Veterans who are
26 not retired do not qualify for the TRICARE program, whereas retired veterans do qualify with the
27 stipulation that they are no longer eligible for the IVF benefit. Service members who become
28 disabled while on duty may be medically retired and receive a disability retirement before serving
29 20 years in the military. Most of the seriously or severely ill or injured service members are
30 medically retired before serving 20 years, receive the same benefits as other retirees, are eligible to
31 enroll in TRICARE and may qualify for IVF.

32 *Private Insurance*

33
34
35 The Affordable Care Act does not mandate coverage for infertility treatments as one of the 10
36 essential health benefits that must be included in all health plans sold through state health insurance
37 marketplaces. Most health insurance plans provide limited, if any, coverage for infertility
38 treatments according to the National Conference of State Legislatures. However, about a dozen
39 states have laws that require private insurers to cover infertility treatment, with eight of these states
40 having insurance mandates requiring qualified employers to include IVF coverage in the plans they
41 offer to their employees (AR, CT, HI, IL, MD, MA, NJ and RI).⁷ The infertility benefits these
42 states require from health insurers vary. Massachusetts requires insurance policies that provide
43 pregnancy-related benefits to also provide coverage for the diagnosis and treatment of infertility,
44 including IVF. Hawaii requires a one-time benefit for outpatient expenses related to IVF
45 procedures when a couple has a history of infertility for at least five years.^{8, 9} In addition, the
46 federal government does not require coverage of infertility treatment for federally sponsored plans
47 through the Federal Employee Health Benefits Program.

1 MEDICAL ASSISTANCE FOR IN VITRO FERTILIZATION

2
3 In November 2015, the American Society for Reproductive Medicine (ASRM), along with the
4 Society for Assisted Reproductive Technology (SART), announced the “Serving Our Veterans”
5 program.¹⁰ Through the program, participating ASRM and SART members provide discounted IVF
6 treatments to veterans with service-related injuries that have caused infertility. The discount
7 amount is determined by each individual participating clinic, although ASRM and SART
8 recommend that each clinic follow the eligibility criteria established for active duty service
9 members by the DOD, which is a discount of at least 50 percent. In order to provide IVF treatments
10 to as many veterans as possible, the program allows for each clinic to cap the number of discounted
11 treatments it offers each individual. The program will expire when the ban on IVF is lifted or at the
12 end of the 2016 congressional calendar year.

13
14 RELEVANT AMA POLICY

15
16 AMA Policy H-185.990 encourages health insurers to provide benefits for the diagnosis and
17 treatment of male and female infertility; however, AMA Policy H-165.856 cautions that benefit
18 mandates should be minimized to allow markets to determine benefit packages and permit a wide
19 choice of coverage options. Consistent with the ASRM and SART “Serving Our Veterans”
20 program, AMA Policy H-510.986 urges all physicians to participate, when needed, in providing
21 health care to veterans. Policy further encourages state and local medical societies to create a
22 registry of physicians who are willing to provide health care to veterans in their community. The
23 AMA supports improved access to health care for veterans, including in the civilian sector, for
24 returning military personnel when their needs are not being met by locally available resources
25 through the DOD or the VA (Policies H-510.985, H-510.990, H-510.991 and D-510.994).

26
27 DISCUSSION

28
29 Proponents of lifting the congressional ban on the VA from covering IVF costs emphasize that the
30 VA provides comprehensive health care services for injuries sustained in the line of duty so that
31 veterans can live as normal of a life as possible. Veterans who have become infertile due to a
32 service-related injury may view access to IVF treatments as their only opportunity to conceive a
33 child, start a family and live a “normal life.”

34
35 The Council notes that most private insurers do not offer IVF and state laws vary on whether
36 private health insurance companies must provide such coverage. Accordingly, due to the variation
37 in coverage of IVF among private health insurers, parity of IVF treatments between private and VA
38 health insurance is not recommended.

39
40 The Council believes that advocating for the VA to have the option to offer IVF is consistent with
41 AMA policy supporting access to health care for veterans while limiting benefit mandates. As
42 such, the Council suggests that our AMA support lifting the congressional ban on the VA from
43 covering IVF costs for veterans who have become infertile due to service-related injuries and
44 encourage interested stakeholders to collaborate in lifting the ban.

45
46 The potential for active duty service members to sustain injuries impacting their fertility has
47 increased in recent years and should be proactively addressed. The Council believes that service
48 members should be offered pre-deployment fertility counseling and information on the relevant
49 health care benefits provided through TRICARE and the VA before they are deployed and that the
50 same information be provided during the medical discharge process.

1 The DOD's new pilot program offering sperm freezing and egg harvesting to active duty service
2 members has been applauded by stakeholders as a step in the right direction to assist service
3 members with a fertility preservation option. The program was announced earlier this year, has yet
4 to be implemented and may have limited impact because it does not cover the cost of IVF.
5 Accordingly, the Council believes that the AMA should support efforts by the DOD and VA to
6 offer service members comprehensive health care services to preserve their ability to conceive a
7 child and offer treatment to address infertility due to service-related injuries.

8
9 RECOMMENDATIONS

10
11 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
12 223-I-15 and that the remainder of the report be filed:

- 13
14 1. That our American Medical Association (AMA) support lifting the congressional ban on the
15 Department of Veterans Affairs (VA) from covering in vitro fertilization (IVF) costs for
16 veterans who have become infertile due to service-related injuries. (New HOD Policy)
17
18 2. That our AMA encourage interested stakeholders to collaborate in lifting the congressional ban
19 on the VA from covering IVF costs for veterans who have become infertile due to service-
20 related injuries. (New HOD Policy)
21
22 3. That our AMA encourage the Department of Defense (DOD) to offer service members fertility
23 counseling and information on relevant health care benefits provided through TRICARE and
24 the VA at pre-deployment and during the medical discharge process. (New HOD Policy)
25
26 4. That our AMA support efforts by the DOD and VA to offer service members comprehensive
27 health care services to preserve their ability to conceive a child and provide treatment within
28 the standard of care to address infertility due to service-related injuries. (New HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-16

Subject: Health Care while Incarcerated
(Resolution 118-A-16)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

At the 2015 Interim Meeting, the House of Delegates adopted as amended Resolution 801 (Policy D-430.994), which asked that the American Medical Association (AMA) study mental health and health care for incarcerated juvenile and adult individuals and identify the best mental health and health care models for local, state and federal facilities.

At the 2016 Annual Meeting, the House of Delegates referred Resolution 118, “Addressing the Health and Health Care Access Issues of Incarcerated Individuals,” submitted by the Minority Affairs Section. Resolution 118-A-16 asked that our AMA advocate for:

(1) an adequate number of health care providers to address the medical and mental health needs of incarcerated individuals; and (2) an adequate number of primary care and mental health personnel to provide adequate health care treatment to civilly committed (designated to correctional institutions), incarcerated, or detained individuals; and (3) the reversal of the “inmate exclusion clause” such that detainees and inmates who are eligible for state and federally funded insurance programs in the community maintain their eligibility when they are pre-trial, detained up to one year, and within one year of release to improve health outcomes in this vulnerable population and decrease its burden of racial and ethnic health care disparities.

The Board of Trustees referred these items to the Council on Medical Service for a report back to the House of Delegates at the 2016 Interim Meeting. This report provides background on the criminal justice population; explains the role of the Affordable Care Act (ACA) Medicaid expansion in accessing health care for the criminal justice population; highlights quality health care and behavioral health care delivery models in the correctional system; summarizes AMA policy and activity; discusses avenues to provide quality health care to the incarcerated population; and presents policy recommendations.

BACKGROUND

Testimony on Resolution 118-A-16 urged the AMA to address barriers to health care access for the incarcerated population and suggested that the requested study review the provision of behavioral and physical health care throughout the full continuum of incarceration from intake to re-entry into the community. Testimony also requested that the study address the training of correctional facility staff on providing behavioral health care; the training of correctional facility staff on providing prenatal care, delivery support and postpartum care; and the use and interoperability of electronic health records (EHRs) in correctional facilities.

1 Approximately 2.3 million individuals are currently incarcerated, including 34,000 juveniles in the
 2 juvenile justice system and 5,200 juveniles in adult prisons or jails.^{1, 2} An additional 4.7 million
 3 individuals are on probation.³ The incarcerated population disproportionately consists of low-
 4 income, uninsured, adult men of color.^{4, 5, 6} It is widely acknowledged that the incarcerated
 5 population has a higher rate of chronic diseases, mental health conditions, substance use disorders
 6 and contagious diseases than the general population.⁷ Juveniles may also have additional issues
 7 impacting their health, such as more recent histories of physical abuse or assault, sexual abuse or
 8 assault, victimization by sex trafficking, emotional abuse, neglect, domestic violence, traumatic
 9 loss, community violence and school violence.⁸

10
 11 In a 1976 landmark case, *Estelle v. Gamble*, the US Supreme Court established that the standard of
 12 pleading required for a prisoner to assert a denial of access to health care constitutes “cruel and
 13 unusual punishment,” which is in violation of the US Constitution.⁹ Nevertheless, not all
 14 correctional systems comply with providing timely, comprehensive or high quality health care to
 15 their inmates. Many studies analyzing health care provided in correctional institutions are limited
 16 and outdated.

17 18 AFFORDABLE CARE ACT MEDICAID EXPANSION

19
 20 Section 1905 of the Social Security Act prohibits the use of Medicaid funds for the cost of any
 21 services provided to an “inmate of a public institution,” except when the individual is a “patient in
 22 a medical institution.”^{10, 11} This policy is referred to as the “Medicaid Inmate Payment Exclusion.”
 23 Given the historically low number of incarcerated individuals who qualified for Medicaid, some
 24 states have not enrolled their inmates in the program.

25
 26 The ACA has provided states with the opportunity to expand Medicaid eligibility to low-income
 27 childless adults, which characterizes the majority of the incarcerated population. States that have
 28 expanded Medicaid may now have the opportunity to enroll many of their inmates in Medicaid,
 29 which pays for inpatient care if needed and may facilitate continuity of care upon release. Given
 30 the increased number of inmates who could benefit from Medicaid coverage, many expansion
 31 states are eager to enroll their detainees. However, some state laws prohibit the submission of
 32 Medicaid applications during incarceration; whereas others permit submission, but no earlier than
 33 30 days before release from custody.

34
 35 An Illinois state law (HB 1046) was enacted in 2014 allowing individuals to apply for Medicaid
 36 while incarcerated with coverage taking effect upon release. Cook County Jail in Chicago has
 37 enrolled at least 11,000 inmates since the law went into effect. The state of New York has
 38 submitted a waiver request to the Centers for Medicare & Medicaid Services (CMS) asking to use
 39 Medicaid funding to pay for coordination of care services during the 30 days prior to an inmate’s
 40 release. The status of the waiver is pending.

41
 42 CMS has advised states to consider Medicaid as a valuable resource for their incarcerated
 43 populations. In May 2004, CMS issued guidance to state Medicaid agencies to suspend, rather than
 44 terminate, Medicaid enrollment when individuals become incarcerated in order to facilitate re-entry
 45 into the community.¹² Not every state has followed this guidance, as the majority of states currently
 46 terminate instead of suspend Medicaid eligibility upon intake into a correctional system.¹³

47
 48 In April 2016, CMS issued a letter to state health officials providing guidance on facilitating
 49 successful re-entry for individuals transitioning from incarceration into their communities.¹⁴ The
 50 guidance specified that individuals on probation, parole or community release pending trial are

eligible for Medicaid as are individuals residing in corrections-related, supervised community residential facilities.

HEALTH CARE MODELS

Policy D-430.994 requested that the AMA identify the best mental health and health care models for local, state and federal correctional facilities. The National Commission on Correctional Health Care (NCCHC) has developed standards for how health care services should be delivered in jails, prisons, and juvenile facilities as well as for mental health services and opioid treatment programs. Implementing the standards and becoming accredited ensures that systems, policies and procedures are in place to provide quality delivery models for jails, prisons, and juvenile facilities as well as for mental health services and opioid treatment programs. Following are examples of NCCHC accredited health care delivery models on the local and federal levels.

Local: Maricopa County Jail System, Phoenix, AZ

Maricopa County Jail System received the NCCHC's "Facility of the Year" award in 2015 for its efficiency, coordination, information-sharing and provision of quality team-based health care. Inmates are considered patients and receive a comprehensive health screening during the intake process to allow staff to provide continuity of care and make necessary referrals for mental health, substance use or acute care services. Each of the six NCCHC accredited jails in the system include an outpatient clinic staffed by board-certified physicians, psychiatrists and mental health professionals providing medical care and mental health services. An EHR system facilitates coordination of health care services. The correctional system provides classes for inmates on substance use, mental health coping strategies, health care, education, parenting and transitioning into the community.¹⁵ Assistance is provided with enrolling in health care coverage through Medicaid or the federal marketplace.^{16, 17, 18}

Federal: Federal Bureau of Prisons

The Federal Bureau of Prisons (FBP) is the nation's largest correctional system with 121 institutions housing approximately 200,000 inmates. The FBP is overseen by a national health care governing board and mental health clinical care committee and uses a primary care team-based model to ensure continuity of health care. Comprehensive clinical practice guidelines have been developed that define the scope of health care services for federal inmates, which the FBP has published for other correctional systems to emulate.¹⁹ The FBP includes centers of excellence, a system-wide infection control program, inmate access to organ transplants, a preventive health care program, an EHR system, telehealth and telepsychiatry.²⁰

BEHAVIORAL HEALTH CARE

In the vast majority (44) of states, more seriously mentally ill individuals are incarcerated than are receiving treatment in psychiatric hospitals.^{21, 22} The health care professionals and services necessary to address these inmates' behavioral health care needs are often lacking with many inmates not receiving adequate care. Cook County Jail in Chicago has developed a program to provide quality behavioral health care to its inmates.

Cook County Jail, Chicago, IL

Chicago's Cook County Jail is often referred to as the nation's largest mental health facility with approximately 30 percent of the 9,000 daily detainees having a serious mental health diagnosis.

The executive director of the jail is a clinical psychologist. The correctional facility includes a mental health transition center that provides mental health care, psychoeducation, peer support and re-entry services. Ongoing treatment at the center is available once an inmate is released.²³ The Cook County Circuit Court has a countywide network of specialty courts that includes mental health and drug treatment courts to assist individuals who have committed non-violent, nonsexual felonies, and are more in need of health care treatment than incarceration. A team of professionals coordinate efforts between members of the court system and outside organizations to guarantee that participants receive intensive treatment, interventions and supervision. The program has succeeded in significantly reducing its participants' recidivism rates.

RELEVANT AMA POLICY

Notably, Council on Science and Public Health Report 8-A-16, "Juvenile Justice System Reform," established Policy H-60.919, which comprehensively outlines ways to transform the juvenile justice system to focus on preventing delinquency, rehabilitating justice-involved youth, providing access to health care, ensuring a safe environment and prohibiting discrimination. Of note, Policy H-60.919[7] encourages states to suspend rather than terminate Medicaid coverage following arrest and detention.

AMA policy supports access to mental health services, including an adequate supply of psychiatrists, appropriate payment for all services provided and adequate funding levels for public sector mental health services (Policies H-345.981, D-345.997, D-345.998, H-345.976 and H-345.980). AMA Policy H-345.981 further advocates that the diagnosis and treatment of mental illnesses should be tailored to age, gender, race, culture and other characteristics that shape a person's identity. The AMA encourages physicians to become more involved in pre-crisis intervention, treatment and integration of chronic mentally ill patients into the community in order to prevent unnecessary jail confinement (Policies H-345.995 and H-95.931).

The AMA urges state and local health departments to foster closer working relations between the criminal justice, medical, and public health systems to ensure continuity of health care services (Policies H-430.989 and H-60.919). The AMA believes that correctional and detention facilities should provide medical, psychiatric and substance use treatment that meets prevailing community standards, including appropriate referrals for ongoing care upon release from the correctional facility in order to prevent recidivism (Policies H-430.997, H-430.987, H-430.988, H-440.931 and H-430.994). The AMA advocates for the maintenance of essential mental health services at the state level to identify and refer individuals with significant mental illnesses for treatment in order to avoid repeated interactions with the law primarily as a result of untreated mental health conditions (Policy H-345.975). The AMA supports the accreditation standards developed by the National Commission on Correctional Health Care (NCCHC) to improve the quality of physical and behavioral health care services to the incarcerated population and encourages all correctional systems to support NCCHC accreditation (Policy D-430.997).

As outlined in Policy H-60.986, the AMA encourages state and county medical societies to become involved in the provision of adolescent health care within correctional facilities and to work to ensure that these facilities meet minimum national accreditation standards for health care as established by the NCCHC. The AMA opposes the use of solitary confinement in juvenile correctional facilities (Policy H-60.922), advocates that juveniles receive comprehensive screening and treatment for sexually transmitted infections and sexual abuse (Policy D-60.994), and that safeguards be in place to protect prisoners from sexual misconduct and assault (Policy D-430.999).

1 A correctional facility should use the least restrictive restraints necessary for pregnant inmates. No
2 restraints of any kind should be used when an inmate is in labor, delivering her baby or
3 recuperating from the delivery unless the inmate poses a serious threat of harm to herself or others
4 and cannot be reasonably contained by other means (Policy H-420.957).

5 6 AMA ACTIVITY

7
8 The AMA, as a supporting organization of the NCCHC, has a physician member as a liaison to the
9 NCCHC. The NCCHC maintains standards on how to manage the delivery of behavioral and
10 physical health care in correctional systems. The standards are the foundation of NCCHC's
11 voluntary accreditation program for correctional facilities to demonstrate a commitment to
12 delivering high quality health care. The NCCHC also offers a correctional health professional
13 program, which certifies individuals working in the correctional system who demonstrate mastery
14 of national standards. Advanced certifications can be obtained by behavioral health practitioners,
15 physicians and registered nurses. In addition, the AMA has developed model state legislation
16 advocating for states to study the physical and mental health care needs of detained and
17 incarcerated youth, and prohibiting the shackling of pregnant prisoners.

18 19 DISCUSSION

20
21 The Council has highlighted local and federal examples of correctional systems that have been
22 accredited by the NCCHC to serve as models for other systems to emulate. The Council
23 recommends the reaffirmation of Policy D-430.997, which supports the accreditation standards
24 developed by the NCCHC to improve the quality of physical and behavioral health care services to
25 incarcerated individuals and encourages all correctional systems to support NCCHC accreditation.

26
27 The majority of individuals in the correctional system are low-income, uninsured and have multiple
28 health conditions. The Council believes that access to and continuity of care is a priority for this
29 population and recommends that our AMA advocate for adequate payment to health care providers,
30 including primary care and mental health professionals, to encourage improved access to
31 comprehensive physical and behavioral health care services to juveniles and adults throughout the
32 incarceration process from intake to re-entry into the community.

33
34 In order to facilitate continuity of care for individuals transitioning between the correctional system
35 and the community, the Council suggests that the AMA support partnerships and information
36 sharing between correctional systems, community health systems and state insurance programs to
37 provide access to a continuum of health care services for individuals in the correctional system. An
38 avenue to share information could be the implementation of EHRs in correctional facilities.

39
40 The majority of inmates struggle with mental health conditions and substance use disorders.^{24, 25}
41 Some may be incarcerated due to crimes committed because of their illnesses and are in need of
42 consistent health care rather than time in correctional facilities. Some may never have had health
43 care except for while they were incarcerated. The Council suggests that the AMA encourage state
44 Medicaid agencies to accept and process Medicaid applications from individuals who are
45 incarcerated. State Medicaid agencies should work with their local departments of corrections,
46 prisons, and jails to assist incarcerated individuals who may not have been enrolled in Medicaid at
47 the time of their incarceration to apply and receive an eligibility determination for Medicaid.

48
49 Resolution 118-A-16 requested that our AMA advocate for the reversal of the "Medicaid Inmate
50 Payment Exclusion" so that detainees can retain their Medicaid eligibility throughout the
51 incarceration process. The Council cautions that advocating for the elimination of the exclusion

1 necessitates the redistribution of Medicaid funding and could have unintended consequences
2 regarding the provision of care and payment to physicians. AMA Policy H-60.919[7] addresses
3 continuity of Medicaid eligibility by encouraging states to suspend rather than terminate Medicaid
4 coverage for juveniles following arrest and detention. Consistent with Policy H-60.919[7], which
5 was adopted at the 2016 Annual Meeting, the Council believes that Medicaid eligibility for both
6 juveniles and adults should be suspended rather than terminated during the entire incarceration
7 process and that coverage should be reinstated when the individual transitions back into the
8 community.

9
10 The Council recommends that Policy D-430.994 be rescinded, which requested the study that this
11 report has accomplished.

12 13 RECOMMENDATIONS

14
15 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
16 118-A-16 and that the remainder of the report be filed:

- 17
18 1. That our American Medical Association (AMA) reaffirm Policy D-430.997, which supports
19 the accreditation standards developed by the National Commission on Correctional Health Care
20 (NCCHC) to improve the quality of physical and behavioral health care services to
21 incarcerated individuals and encourages all correctional systems to support NCCHC
22 accreditation. (Reaffirm HOD Policy)
23
- 24 2. That our AMA advocate for adequate payment to health care providers, including primary care
25 and mental health professionals, to encourage improved access to comprehensive physical and
26 behavioral health care services to juveniles and adults throughout the incarceration process
27 from intake to re-entry into the community. (New HOD Policy)
28
- 29 3. That our AMA support partnerships and information sharing between correctional systems,
30 community health systems and state insurance programs to provide access to a continuum of
31 health care services for individuals in the correctional system. (New HOD Policy)
32
- 33 4. That our AMA encourage state Medicaid agencies to accept and process Medicaid applications
34 from individuals who are incarcerated. (New HOD Policy)
35
- 36 5. That our AMA encourage state Medicaid agencies to work with their local departments of
37 corrections, prisons, and jails to assist incarcerated individuals who may not have been enrolled
38 in Medicaid at the time of their incarceration to apply and receive an eligibility determination
39 for Medicaid. (New HOD Policy)
40
- 41 6. That our AMA encourage states to suspend rather than terminate an individual's Medicaid
42 eligibility upon intake into the criminal justice system and throughout the incarceration
43 process, and to reinstate coverage when the individual transitions back into the community.
44 (New HOD Policy)
45
- 46 7. That our AMA rescind Policy D-430.994, which requested the study accomplished by this
47 report. (Rescind HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-16

Subject: Providers and the Annual Wellness Visit
(Resolution 824-I-15)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

At the American Medical Association's (AMA) 2015 Interim Meeting, the House of Delegates referred Resolution 824, "Defining the Annual Wellness Visit as Provided by Community-Based Primary Care Physicians." The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2016 Interim Meeting. Introduced by the Pennsylvania Delegation, Resolution 824-I-15 asked:

That our AMA advocate for clear definition of the Centers for Medicare & Medicaid Services' Medicare Annual Wellness Visit as one that is provided only by physicians or members of a community-based, physician-led team that will provide continuity of care to those patients.

This report discusses the history and components of Medicare's Annual Wellness Visit (AWV), including its purpose; explains the role of continuity of care in the AWV; outlines the role of commercial entities; and recommends policy recognizing the importance of the physician-led health care team and the promotion of continuity of care.

BACKGROUND

The Affordable Care Act expanded Medicare preventive services coverage and in particular created the AWV as a new Medicare benefit. The AWV benefit is available to beneficiaries who have had Medicare Part B for longer than 12 months and have not had an AWV in the last 12 months.¹

The purpose of the AWV is to develop or update a personalized prevention plan based on current health and risk factors. It aims to keep Medicare beneficiaries healthy by promoting positive health habits.² The AWV may include the following elements: review of medical and family history; a list of current providers and prescriptions; height, weight, blood pressure, and other routine measurements; a screening schedule for appropriate services; and a list of risk factors and treatment options. It is important to note that the AWV was meant to provide more comprehensive preventive services to Medicare beneficiaries but does not replace the annual physical, which is a more extensive examination.³ Further, if a patient is experiencing physical symptoms or complaints, it is suggested that a patient schedule a problem-oriented visit separate from the AWV. In addition, during both the initial AWV and any subsequent visits, the health professional performing the visit is statutorily required to establish and update a list of current providers and suppliers that are regularly involved in providing medical care to the beneficiary.^{4, 5}

There is no deductible or copayment for the AWW.⁶ However, if during the AWW it is discovered that a patient has a particular medical condition that requires further evaluation or treatment, pursuant to Medicare rules, the additional time or treatment would be billed separately with Medicare paying 80 percent of the allowed charges and the patient paying the remaining 20 percent.

The relevant legislation and Centers for Medicare & Medicaid Services (CMS) regulations list who is eligible to provide the AWW. The list of eligible providers includes: a physician; physician assistant, nurse practitioner, or clinical nurse specialist; or a medical professional or a team of medical professionals working under the supervision of a physician.^{7, 8} Neither the legislation nor the regulations expressly define a “medical professional” eligible for providing the AWW working under the supervision of a physician or otherwise address the issue of physician-led team-based care.

CMS does not assign particular AWW tasks or restrictions for particular members of the team because the concept of team-based care should enable the supervising physician to assign the professionals best suited to provide a portion of the AWW based on individual patient needs.⁹ Physicians leading these teams are empowered to determine the coordination of various team members during the AWW.

CONTINUITY OF CARE

Although the AWW is not a thorough preventive visit or examination, the AWW encourages Medicare beneficiaries to engage with their primary care physician or usual source of care on an annual basis for prevention and early detection of illness, the treatment of which that usual source of care could provide or manage. The AWW facilitates an ongoing relationship between the provider of the AWW and the beneficiary. Consistent with the tenets of continuity of care, the patient and physician are cooperatively involved in ongoing health care management toward the goal of high quality and cost effective care. Continuity of care is rooted in a long-term patient-provider partnership in which the provider knows the patient’s history and can integrate new information, such as that obtained during the AWW, and share in medical decision-making from a whole-patient perspective.

NON-PHYSICIAN COMMERCIAL ENTITIES PROVIDING THE ANNUAL WELLNESS VISIT

Non-physician commercial entities such as retail and mobile health clinics have entered the marketplace to provide the AWW and bill the code to CMS, which potentially precludes the patient from the benefits of the AWW with a regular source of care.¹⁰ These commercial entities often have no prior relationship with the patient and have no intention of caring for the patient after the AWW.¹¹ Commercial encounters can therefore lead to fragmented and duplicative care if the information gathered at the AWW is never communicated to the patient’s physician. Because of potentially disjointed care, there is concern that these commercial entities are subverting the intended benefit of the AWW and may be misleading patients. The presence of commercial entities may interfere with both the provider-patient relationship and appropriate continuity of care.

RELEVANT AMA POLICY

Policy H-425.994 supports the premise of the AWW stating that the evaluation of healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors. Policy H-425.994 also states that the testing of individuals should be pursued only when adequate treatment and follow-up can be arranged for the abnormal conditions and risk factors identified.

Policy H-425.997 addresses preventive services and encourages the development of policies and mechanisms to assure the continuity, coordination, and continuous availability of patient care,

including preventive care and early-detection screening services. Policy H-425.997 states further that preventive care should ideally be coordinated by a patient's physician. To promote continuity of care, Policy H-160.921 states that store-based health clinics must establish protocols for ensuring continuity of care with practicing physicians within the local community and should be encouraged to use electronic health records as a means of communicating patient information and facilitating continuity of care. Further, Policy H-160.921 states that store-based health clinics should encourage patients to establish care with a primary care physician to ensure continuity of care.

Policy D-35.985 recognizes non-physician providers as valuable components of the physician-led health care team. With respect to the health care team, Policy H-275.976 states that the health professional who coordinates an individual's health care has an ethical responsibility to ensure that the services rendered are provided by those whose competence and performance are suited to render those services safely and effectively.

AMA ACTIVITY

Consistent with Resolution 824-I-15, the AMA and several medical specialty societies, whose members often provide the AWV, sent a joint letter to Acting Administrator of CMS expressing concern about potential misuse of the AWV by commercial entities on April 30, 2015. The letter noted that provision of the AWV from a source other than the patient's primary care physician or other usual source of care inhibits the provision of preventive services through the patient's usual source of care and disrupts the continuity of care important for both the physician-patient relationship and the patient's health. The AMA also met with senior CMS officials following the agency's receipt of the letter, and CMS staff expressed appreciation to the physician community for bringing this issue to their attention. CMS indicated that it shares these concerns, particularly for Medicare patients who have regular sources of care that also provide their annual visits.

DISCUSSION

Continuity of care is a bedrock principle of the physician-patient relationship and is a fundamental feature of high-quality health care.^{12, 13} It is the process by which the patient and the physician-led health care team are cooperatively involved in ongoing health care management with the shared goal of high quality, cost-effective care. The Council recognizes continuity of care as a hallmark and primary objective of medicine and believes it is consistent with quality patient care provided through a patient-centered medical home. Continuity of care is rooted in the long-term physician-patient relationship in which the physician knows the patient's information from experience and can integrate new information and decisions from a holistic standpoint.

A physician-led, team-based approach to health care facilitates continuity of care which in turn, reduces fragmentation and thus improves patient safety and quality of care. It ensures salient issues and markers are tracked consistently to further the goal of high quality care.¹⁴ To that end, the Council recommends reaffirming Policy H-425.997 encouraging continuity of care and supporting the principle that preventive care should be coordinated by the patient's physician.

Retail clinics and other non-physician facilities may provide a limited scope of services to patients that may seem to be timely and convenient. However, these clinics can ultimately lead to fragmentation if not properly coordinated with the patient's primary physician's office or usual source of care. This fragmentation compromises patient care and health care quality and cost. Using a retail health clinic for the AWV may result in a missed opportunity to address more complex patient needs. Care delivered in retail clinics and other non-physician facilities must work in coordination with the patient's current and regular sources of care to mitigate the effects of fragmentation. Fragmentation

and unaccountable silos of care are in direct opposition to achieving continuous whole-person care with improved health outcomes.¹⁵ Accordingly, while there is no statutory authority to require that one must be physician or member of a physician-led health care team to provide the AWP, it is crucial to note that the AWP is most appropriately provided by a physician or member of a physician-led health care team to promote efficient, quality care that either establishes or continues to provide ongoing continuity of care. Further, the Council recommends reaffirming Policy H-160.921 on protocols for store-based health clinics to ensure and promote continuity of care. Notably, the Council will be preparing an updated report on retail health clinics for the 2017 Annual meeting. Additionally, the Council recommends that any clinic performing the AWP enumerate all relevant findings and make provisions for all appropriate follow-up care. The Council believes this recommendation will more explicitly hold other clinicians to a reasonable reporting and follow-up standard.

Physicians often do not know whether a patient has received the AWP in the past 12 months until after the physician's claim is denied. Therefore, the Council recommends that CMS promote a mechanism to ensure that physicians have a way to determine whether Medicare has already paid for an AWP for a patient in the past 12 months, thereby ensuring that physicians are paid appropriately for the health care services they provide. Additionally, the Council notes the importance of educating patients on the AWP and continuity of care and believes CMS should have the responsibility for educating beneficiaries. Accordingly, the Council recommends that CMS communicate to Medicare enrollees that, in choosing their primary care physician, they are encouraged to make their AWP appointments with this physician in order to facilitate continuity and coordination of care.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 824-I-15 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-425.997 encouraging continuity of care and supporting the principles that preventive care should be coordinated by the patient's physician. (Reaffirm HOD Policy)
2. That our AMA reaffirm Policy H-160.921 on protocols for store-based health clinics to ensure continuity of care. (Reaffirm HOD Policy)
3. That our AMA support that the Medicare Annual Wellness Visit (AWV) is a benefit most appropriately provided by a physician or a member of a physician-led health care team that establishes or continues to provide ongoing continuity of care. (New HOD Policy)
4. That our AMA support that, at a minimum, any clinician performing the AWP must enumerate all relevant findings from the visit and make provisions for all appropriate follow-up care. (New HOD Policy)
5. That our AMA support that the Centers for Medicare & Medicaid Services (CMS) provide a means for physicians to determine whether or not Medicare has already paid for an AWP for a patient in the past 12 months. (New HOD Policy)
6. That our AMA encourage CMS to educate Medicare enrollees, that, in choosing their primary care physician, they are encouraged to make their AWP with their primary care physician in order to facilitate continuity and coordination of their care. (New HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-16

Subject: Concurrent Hospice and Curative Care
(Resolution 804-I-15)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

At the 2015 Interim Meeting, the House of Delegates referred Resolution 804, which was sponsored by the Medical Student Section. Resolution 804-I-15 asked the American Medical Association (AMA) to amend Policy H-85.955, "Hospice Care" to read as follows:

H-85.955, "Hospice Care"

Our AMA: (1) approves of the physician-directed hospice concept to enable the terminally ill to die in a more homelike environment than the usual hospital; and urges that this position be widely publicized in order to encourage extension and third party coverage of this provision for terminal care; (2) encourages physicians to be knowledgeable of patient eligibility criteria for hospice benefits and, realizing that prognostication is inexact, to make referrals based on their best clinical judgment; (3) supports modification of hospice regulations so that it will be reasonable for organizations to qualify as hospice programs under Medicare; (4) believes that each patient admitted to a hospice program should have his or her designated attending physician who, in order to provide continuity and quality patient care, is allowed and encouraged to continue to guide the care of the patient in the hospice program; (5) supports changes in Medicaid regulation and reimbursement of palliative care and hospice services to broaden eligibility criteria concerning the length of expected survival for pediatric patients and others, to allow provision of concurrent life-prolonging and palliative care, and to provide respite care for family care givers; and (6) seeks amendment of the Medicare law to eliminate the six-month prognosis under the Medicare Hospice benefit and support identification of alternative criteria, meanwhile supporting extension of the prognosis requirement from 6 to 12 months as an interim measure; and (7) supports changes in Medicare regulation to allow provision of concurrent curative and hospice care. (Modify AMA Policy)

The Board of Trustees assigned this report to the Council on Medical Service for a report back to the House of Delegates at the 2016 Interim Meeting. This report provides background on hospice, palliative and curative care; describes Medicare's hospice benefit and the Medicare Care Choices Model (MCCM); summarizes relevant AMA policy; and makes policy recommendations.

BACKGROUND

The American Academy of Hospice and Palliative Medicine (AAHPM) defines palliative care as that which relieves suffering and improves quality of life for people with serious illnesses, no matter whether they can be cured. Hospice is a specific type of palliative care for people who likely have six or fewer months to live. Not all palliative care is hospice, although hospice care is always palliative. Hospice is a distinct delivery system for which eligibility is usually defined by public

1 and private insurers offering the benefit. Curative care under the Medicare program refers to health
 2 care practices that treat patients with the intent of curing them or modifying their underlying
 3 disease as opposed to managing symptoms such as pain or stress.

4 5 *Medicare's Hospice Benefit*

6
 7 Medicare is the largest insurer of end-of-life medical care, with spending on patients during their
 8 last year of life making up 25 percent of total Medicare spending on patients 65 years of age and
 9 older.¹ Predictably, Medicare is also the largest payer of hospice care, most frequently in patients'
 10 homes but also at Medicare-certified hospices, hospitals and skilled nursing facilities. In 2014,
 11 more than 1.3 million people received Medicare hospice services from 4,100 certified for-profit
 12 and non-profit providers at a cost of \$15.1 billion. Average length of stay was about 88 days;
 13 however, median length of stay was only 17 days. Spending on Medicare's hospice benefit has
 14 doubled since 2000 but held steady between 2012 and 2014.²

15
 16 The literature on hospice costs to the Medicare program has produced mixed results, with some
 17 studies showing large cost savings among hospice patients and others pointing to higher costs of
 18 care, particularly for long-term enrollees. A recent MedPAC analysis suggests that hospice on
 19 average produces no savings and may modestly increase end-of-life costs.³ Benefits to patients and
 20 their families—which are not taken into account in cost analyses—have been identified in separate
 21 studies. Although there is evidence that early hospice referral reduces hospitalizations and high-
 22 cost procedures, further research is needed.

23
 24 The hospice benefit was introduced to the Medicare program in 1983 to provide interdisciplinary,
 25 team-based services including: nursing care; physicians' services; social worker services;
 26 counseling; short-term inpatient hospice care; medical appliances and supplies; drugs and biologics
 27 for pain relief and symptom control; home health or hospice aid services; physical, occupational
 28 and speech therapy; bereavement support and other services.⁴ To be eligible to elect hospice care
 29 under Medicare, patients must be certified as having a life expectancy of six months or less if the
 30 terminal illness runs its normal course. Eligible Medicare patients can file an election statement
 31 with a particular hospice. The statement must include a number of elements, including the patient's
 32 acknowledgement that he or she: 1) has been given a full understanding of the palliative rather than
 33 curative nature of hospice care; and 2) waives all rights to Medicare payments for services related
 34 to the treatment of the terminal illness and related conditions.⁵ Patients can revoke their election to
 35 hospice care at any time and return to standard Medicare coverage.

36
 37 Medicare pays for hospice care using per diem payment categories encompassing four levels of
 38 care: (1) routine home care, for which Medicare pays \$187 per day for the first 60 days and \$147
 39 per day thereafter; (2) general inpatient care, paid \$720 per day; (3) continuous home care, paid at a
 40 rate of \$39 per hour; and (4) inpatient respite care, for which Medicare pays \$167 per day (payment
 41 rates are for fiscal year 2016).⁶ Service intensity add-on payments are also made when hospice
 42 provides direct patient care by a registered nurse or social worker during patients' last seven days
 43 of life. In keeping with the hospice philosophy, routine home care accounts for the large majority
 44 of hospice payments.

45
 46 Despite growth in hospice utilization, fewer than half of Medicare patients (47.8 percent in 2014)
 47 elect hospice services, and more than a quarter do not enroll until their final week of life.⁷ In
 48 addition to late enrollments, there are concerns about extremely long hospice stays and
 49 disenrollments prior to death.⁸ Utilization of hospice care is lower among racial and ethnic
 50 minorities.⁹

1 The requirement that patients waive Medicare coverage for services related to the treatment of their
2 terminal illness compels Medicare patients to choose between continuing these treatments and
3 enrolling in hospice care. Reluctance among patients to stop expensive treatments, that may either
4 prolong their lives or improve their functional status and quality of life, is believed to contribute to
5 underutilization of the benefit, as is increased availability of palliative care options outside of
6 hospice.¹⁰ It is important to point out that Medicare-certified hospices are not prohibited from
7 providing treatments that may be life-prolonging or curative, and some hospices have done so
8 under “open access” policies. However, it is generally not financially viable for hospices to provide
9 curative treatments since they receive no additional payments for the significantly higher costs they
10 incur.

11
12 Restricted access policies among hospices are far more common than “open access” policies and
13 may also impact hospice utilization. Findings from a national survey of hospice providers suggest
14 wide variation among hospice enrollment policies, but found that 78 percent of the surveyed
15 providers had at least one restrictive enrollment policy. More than 60 percent of the surveyed
16 hospices will not enroll patients receiving chemotherapy; over half will not accept patients
17 receiving parenteral nutrition; and 40 percent will not take patients who receive transfusions.¹¹

18 19 *Palliative Care*

20
21 The philosophies underlying hospice and palliative care are similar; however, care location, timing
22 and eligibility often differ. At its core, palliative care is designed to assess, prevent and manage
23 physical and psychological symptoms, address spiritual concerns, and focus on communications
24 that establish patient goals of care and assist patients with medical decision-making about treatment
25 options. Whereas services provided by hospice are most commonly provided to patients in their
26 homes, non-hospice palliative care is frequently provided in hospitals or community settings such
27 as cancer centers, clinics and nursing homes, although palliative care can also be provided in-home.
28 Patients can receive palliative care while continuing curative treatment at any stage of their
29 illnesses, and many studies have shown that early palliative care interventions improve quality of
30 life and increase patient and family satisfaction.¹² Palliative care providers—either primary
31 physicians who have the skills and competencies to care for the seriously ill, or physicians with
32 specialty training and certification in palliative medicine—may also help patients who wish to
33 discontinue life-prolonging care to transition to hospice or end-of-life care. Since palliative care is
34 most commonly provided by hospitals, palliative specialists or other physicians, many of these
35 services are covered by public and private insurance.

36 37 *Concurrent Curative Care*

38
39 Some stakeholders question whether Medicare’s requirement that patients forego curative care in
40 order to elect the hospice benefit still makes sense in today’s health care environment.
41 Chemotherapy, radiation and blood transfusions are routinely provided to seriously and terminally
42 ill patients, and the distinction between what constitutes life-prolonging and end-of-life treatment is
43 significantly less clear than it once was. For example, chemotherapy or radiation treatment of
44 certain metastases can be provided to alleviate pain and/or prolong life, and may be considered
45 palliative and/or curative, depending on patient circumstances.

46
47 A provision in the Affordable Care Act stipulated that terminally ill children enrolled in hospice
48 under a state’s Medicaid or Children’s Health Insurance Program be permitted to receive
49 concurrent curative care; however, implementation of this change has proven exceedingly
50 challenging and is not working effectively in most states.

1 *Medicare Care Choices Model*

2
3 In January 2016, the Center for Medicare and Medicaid Innovation (CMMI) launched a concurrent
4 care demonstration project called the Medicare Care Choices Model (MCCM). According to the
5 CMMI, this pilot will test the impact of patient access to concurrent hospice and curative care on
6 quality of care and patient and family satisfaction.¹³

7
8 To participate in the model, Medicare patients diagnosed with certain terminal illnesses must meet
9 the program's hospice eligibility requirements; must not have elected hospice within the last 30
10 days; must receive services from one of about 140 Medicare-certified hospices selected by the
11 CMMI to participate in the model; must have been hospitalized twice in the last year; and must live
12 at home. Eligible patients can receive services from a hospice while continuing to receive curative
13 or disease modifying care from other providers. The model will last five years and target 150,000
14 eligible Medicare patients diagnosed with advanced cancers, chronic obstructive pulmonary
15 disease, congestive heart failure or human immunodeficiency virus/acquired immune deficiency
16 syndrome.¹⁴ Phase 1 hospices began delivering services on January 1, 2016, and Phase 2 will begin
17 on January 1, 2018.

18
19 Under the MCCM, the non-hospice treating physician is the referring physician and is responsible
20 for directing patient care. The role of the hospice under the MCCM is to provide supportive care
21 and to integrate that care with that of the treating physician through case management, care
22 coordination, shared decision-making and other specified services. Participating hospices are paid
23 \$400 per month per MCCM enrollee, which is substantially less than daily rates paid under the
24 traditional Medicare hospice benefit.¹⁵ Some have questioned whether hospice payments under the
25 MCCM are sufficient to deliver true hospice services. The AAHPM maintains, and the Council
26 agrees, that a true concurrent care model should include the full scope of hospice care, services and
27 resources to be successful.

28 29 *AMA POLICY*

30
31 The AMA has longstanding policy on hospice and palliative care. Policy H-85.966 maintains that
32 the use of hospice care should provide the patient and family with appropriate support, but not
33 preclude or prevent the use of appropriate palliative therapies to continue to treat the underlying
34 disease. Under Policy D-140.962, the AMA recognizes the benefits of hospice, and reaffirms that
35 physicians: (a) have a responsibility to see that hospice services are authorized in appropriate
36 circumstances and settings, and (b) should be allowed and encouraged to remain actively involved
37 in managing their patients' hospice care. Policy D-140.962 also asks the AMA to call on the
38 Centers for Medicare & Medicaid Services (CMS) to thoroughly study Medicare's hospice benefit.

39
40 Policy H-85.955 supports changes to the Medicaid program to allow provision of concurrent life-
41 prolonging and palliative care, and also broadening eligibility beyond six-month prognoses under
42 Medicaid and Medicare hospice benefits. Policy H-85.955 also encourages physicians to be
43 knowledgeable of patient eligibility for hospice benefits and maintains that designated attending
44 physicians should be allowed to guide the care of hospice patients. Policy H-70.915 supports
45 improved payments for health care practices caring for dying patients, and encourages research into
46 the needs of dying patients and how they could be better served by the health care system.

47 48 *DISCUSSION*

49
50 A 2014 report from the Institute of Medicine (IOM), *Dying in America*, found that "improving the
51 quality and availability of medical and social services for patients and their families could not only

1 enhance quality of life through the end of life, but may also contribute to a more sustainable care
2 system.” The IOM panel further recommended “a major reorientation of payment systems to
3 incentivize the integration of medical and social services, the coordination of care across multiple
4 care settings, and the use of advance care planning and shared decision making to better align the
5 services patients receive with their care goals and preferences.”¹⁶ The Council found these
6 recommendations sensible and worthy of consideration during its discussions. The Council
7 reviewed the literature on hospice and palliative care and will monitor evaluations of the MCCM as
8 they become available, revisiting hospice payment and coverage issues as needed. Valuable
9 feedback was also solicited and received from the AAHPM.

10
11 The Council wishes to clarify that the Medicare program does not require patients to discontinue
12 life-prolonging treatments in order to enroll in hospice, but Medicare will not pay separately for
13 treatments for one’s terminal illness which are considered to be curative. The Council also clarifies
14 that the policy modification requested by Resolution 804-I-15 would require the AMA to support a
15 legislative rather than regulatory change, given that eligibility for election of Medicare’s hospice
16 benefit is defined in the Social Security Act.

17
18 The Council understands that Medicare’s existing eligibility criteria compel most patients to either
19 pursue curative treatments or enroll in hospice care. The Council concurs with the authors of
20 Resolution 804-I-15 that underutilization of Medicare’s hospice benefit is due in part to reluctance
21 among patients to abandon life-prolonging treatments. The Council further agrees that hospice care
22 should not preclude the use of appropriate palliative therapies to treat underlying disease, which is
23 the essence of Policy H-85.966. Accordingly, the Council recommends that Policy H-85.966 be
24 reaffirmed.

25
26 The Council believes that in the future, thoughtfully designed, financially sustainable concurrent
27 hospice/curative care models have tremendous potential to improve the quality of life and
28 satisfaction of some of Medicare’s sickest patients and their families. However, the evidence base
29 does not yet exist to determine the most effective model for providing and paying for concurrent
30 care. The “open access” hospice model is not financially sustainable for most hospices, and there
31 are questions as to whether the MCCM is too limited to deliver its intended value. The Council has
32 similar misgivings about the MCCM and believes that, as designed, the pilot program may not
33 produce meaningful data on true concurrent care. The Council is equally troubled by the low
34 payment rates under the MCCM, which are not adequate to provide true, interdisciplinary,
35 physician-involved hospice care.

36
37 Additionally, the Council feels strongly that implementation issues associated with concurrent
38 hospice/curative care models must be resolved before the AMA can credibly support a major
39 legislative change to the Medicare statute. For example, it is unclear how life expectancy would be
40 quantified under these models given that life-prolonging care could extend patients’ prognoses
41 beyond six months, thereby affecting their eligibility for hospice. Because there is still so much
42 work to be done, the Council believes it is premature to modify Policy H-85.955 as requested by
43 Resolution 804-I-15. Instead, the Council recommends that the AMA support continued study and
44 pilot testing by CMS of a variety of models for providing and paying for concurrent hospice,
45 palliative and curative care.

46
47 Numerous studies have shown that palliative care improves pain and symptom control, increases
48 satisfaction with care among seriously ill patients and reduces costs. The Council underscores the
49 AMA’s support for palliative care services, and recommends that the AMA encourage CMS to
50 identify ways to optimize patient access to palliative care, which relieves suffering and improves

1 quality of life for people with serious illnesses regardless of whether they can be cured, and to
2 provide appropriate coverage and payment for these services.

3
4 Because many seriously and terminally ill patients and their families may be unaware of the
5 benefits of hospice and palliative care, or available resources in their communities, the Council
6 hopes physicians will learn more about local resources. Patients and physicians can search for
7 hospices and palliative care providers at <http://www.nhpco.org/find-hospice>. The Council
8 recommends that the AMA encourage physicians to be familiar with local hospice and palliative
9 care resources and their benefit structures, and to refer seriously ill patients accordingly.

10 11 RECOMMENDATIONS

12
13 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
14 804-I-15 and the remainder of the report be filed:

- 15
16 1. That our American Medical Association (AMA) reaffirm Policy H-85.966, which maintains
17 that hospice care should provide the patient and family with appropriate physical and
18 emotional support, but not preclude the use of appropriate palliative therapies to continue to
19 treat underlying disease. (Reaffirm HOD Policy)
20
- 21 2. That our AMA support continued study and pilot testing by the Centers for Medicare &
22 Medicaid Services (CMS) of a variety of models for providing and paying for concurrent
23 hospice, palliative and curative care. (New HOD Policy)
24
- 25 3. That our AMA encourage CMS to identify ways to optimize patient access to palliative care,
26 which relieves suffering and improves quality of life for people with serious illnesses,
27 regardless of whether they can be cured, and to provide appropriate coverage and payment for
28 these services. (New HOD Policy)
29
- 30 4. That our AMA encourage physicians to be familiar with local hospice and palliative care
31 resources and their benefit structures, and to refer seriously ill patients accordingly. (New HOD
32 Policy)

Fiscal Note: Less than \$500.

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- ⁵ Code of Federal Regulations. The Social Security Act: Title 42, Chapter IV, Subpart B, Part 418 (USC §418.24 Election of Hospice Care)
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REPORT 5 OF THE COUNCIL ON MEDICAL SERVICE (I-16)
Incorporating Value into Pharmaceutical Pricing
(Resolution 712-A-16)
(Reference Committee J)

EXECUTIVE SUMMARY

Following the adoption of the recommendations of Council on Medical Service Report 2-I-15, “Pharmaceutical Costs,” the Council spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing in the context of rising concerns about pharmaceutical spending. The Council concluded that additional AMA policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for value-based pricing of pharmaceuticals. In addition, at the 2016 Annual Meeting, the House of Delegates referred Resolution 712, which asked that our AMA “advocate with Congress and federal agencies, for any necessary combination of legislation, regulation, negotiation with the pharmaceutical industry, and federal subsidies, to lower the cost of treatment for all Americans infected with Hepatitis C virus using highly effective oral medications, to a price level that would make treatment affordable and accessible.”

The integration of value into pharmaceutical pricing builds upon long-standing AMA policy that supports market-driven mechanisms to control pharmaceutical costs, as well as recognizes that improvements need to be made to ensure that the pharmaceutical marketplace operates efficiently and effectively. Importantly, value-based pricing of pharmaceuticals does not require the establishment of price controls or other mandates that may stifle innovation in the pharmaceutical industry. However, pricing pharmaceuticals based on their value should aim to improve affordability for patients and limit system-wide budgetary impact. As policymakers, insurers and other stakeholders move forward with efforts to integrate value into pharmaceutical pricing, the Council has proposed principles to guide AMA advocacy in this arena, which state that initiatives to determine value-based pricing for pharmaceuticals should aim to ensure patient access to necessary prescription drugs, allow for patient variation and physician discretion, limit administrative burdens on physician practices and patients, and be evidence-based, transparent, objective and involve the input of practicing physicians and researchers.

The Council notes that there continues to be a lack of high-quality data on the cost and value of interventions using pharmaceuticals in practice. Increased comparative effectiveness research on pharmaceuticals is imperative so patients, physicians and other stakeholders are aware of differences between the prescription drugs available within the same category or class. However, in order to be truly effective, the cost of alternatives, as well as cost-effectiveness analysis, should be included in comparative effectiveness research endeavors.

The Council believes that pharmaceutical pricing mechanisms need to take into account a drug’s public health value. For pharmaceuticals that are used to treat or cure diseases that pose unique public health threats, including hepatitis C, the Council supports the use of direct purchasing mechanisms to assure patient access to the treatments they need. Direct purchase arrangements will guarantee prices for prescription drugs as well as volume for manufacturers. As such, lower prices can be achieved in exchange for a larger, guaranteed market for a drug.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5-I-16

Subject: Incorporating Value into Pharmaceutical Pricing
(Resolution 712-A-16)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Following the adoption of the recommendations of Council on Medical Service Report 2-I-15, “Pharmaceutical Costs,” the Council spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, and determining whether additional policy was needed to guide future AMA advocacy efforts. In its review, the Council concluded that additional AMA policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for value-based pricing of pharmaceuticals.

At the 2016 Annual Meeting, the House of Delegates referred Resolution 712, “Remove Pricing Barriers to Treatment for Hepatitis C (HCV),” which was introduced by the New Mexico Delegation and assigned to the Council for study. Resolution 712-A-16 asked:

That our American Medical Association advocate with Congress and federal agencies, for any necessary combination of legislation, regulation, negotiation with the pharmaceutical industry, and federal subsidies, to lower the cost of treatment for all Americans infected with Hepatitis C virus using highly effective oral medications, to a price level that would make treatment affordable and accessible.

This report provides background on prescription drug spending and pricing; summarizes relevant AMA policy; highlights potential mechanisms to determine the value of pharmaceuticals; assesses the impact of Medicare drug price negotiation and associated AMA policy; and presents policy recommendations.

BACKGROUND

According to the Assistant Secretary for Planning and Evaluation of the US Department of Health and Human Services (HHS), prescription drug spending was \$457 billion in 2015, accounting for 16.7 percent of spending on personal health care services. Of this amount, \$328 billion (71.9 percent) was for retail drugs (at outlets that directly serve patients), and \$128 billion (28.1 percent) was for non-retail drugs (by medical providers for drugs they provide directly to patients).¹

Prescription drug spending increased by 12.6 percent in 2014, with a higher rate of spending growth also estimated for 2015. From 2013 to 2018, prescription drug spending is projected to increase by an average of 7.3 percent per year.¹ Leading contributors to the growth in prescription drug spending in the US include the prices and uptake of brand-name drugs and biologics new to the market, the prices of protected brands, the lessening impact of major patent expirations, invoice

price increases of brand-name drugs, biologics and generic drugs, and increases in the number of prescriptions per person.^{1,2} The prices of new treatments for multiple sclerosis, HIV, hepatitis C, oncology and autoimmune conditions have contributed to new brand spending growth, as well as specialty drugs making up 36 percent of drug spending in 2015. At the same time, the uptake levels of specialty drugs have contributed to the growth rate in pharmaceutical spending. For example, approximately 250,000 new patients received treatment for hepatitis C in 2015, with over 400,000 patients having been treated with at least one of the six drugs brought to the market in the past two years. In addition, there has been a rapid uptake in the use of PD-1 inhibitors, new immuno-oncology drugs.²

In 2013, the average annual increase in retail prices for 622 brand name and generic versions of traditional and specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, was 9.4 percent.³ Invoice (list) prices for brand-name prescription drugs and biologics already on the market increased 12.4 percent in 2015, while the average net price for the drugs—i.e., adjusted for rebates and other price concessions by pharmaceutical companies—increased by 2.8 percent.² Cumulatively, between 2008 and 2015, the average price for the most commonly used brand-name prescription drugs, as defined by the Express Scripts Prescription Price Index, increased by 164 percent.⁴ Price increases for older generic drugs moderated in 2015 when compared to 2013 and 2014, contributing \$0.5 billion versus more than \$3 billion in spending growth. However, the invoice prices of branded generics notably increased.²

The level at which drugs are priced impacts health plans, payers, pharmacy benefit managers, employers, physicians and patients. Medicare, Medicaid, employer-sponsored health plans and plans offered in health insurance exchanges have had to make adjustments in response to the higher costs of prescription drugs. Prescription drug prices have been frequently cited as a main justification for higher health insurance premiums, higher prescription drug cost-sharing, additional prescription drug tiers and use of utilization management techniques.

Approximately 4.4 billion outpatient prescriptions were dispensed in the US in 2015.² In 2013, the average annual retail cost of drug therapy for a prescription drug, based on 477 widely used prescription drugs by older Americans indicated for treating chronic conditions, which include generic, brand and specialty drug products, was \$11,341. The average annual cost of therapy for widely used generic drugs by older Americans was \$283 in 2013, while the average cost of therapy was \$2,960 for widely used brand-name drugs and \$53,384 for widely used specialty drugs.³ The cost of drug therapies impacts patient cost-sharing responsibilities. In 2015, stand-alone Part D prescription drug plans (PDPs) had median cost sharing of \$38 for preferred brand-name drugs, \$80 for non-preferred brand-name drugs, and \$1 for preferred generic drugs. Median cost-sharing in Medicare Advantage prescription drug plans (MA-PDPs) was \$45 for preferred brand-name drugs, \$95 for non-preferred brand-name drugs and \$3 for preferred generic drugs. In 2015, 48 percent of enrollees in PDPs with a specialty drug tier and approximately three-quarters of MA-PD enrollees in plans with specialty drug tiers were in plans that required 33 percent coinsurance for specialty drugs.⁵ In commercial plans overall, the average patient cost exposure for a brand prescription filled was \$44 in 2015. The percentage of brand prescriptions with patient cost exposure over \$50 increased to 17 percent in 2015, while the percentage with \$0 patient cost exposure increased to 24 percent. The average patient cost exposure for generic drugs was approximately \$8 in 2015.²

AMA POLICY ADDRESSING PHARMACEUTICAL PRICING AND VALUE

Council on Medical Service Report 2-I-15, which established Policy H-110.987, stipulates that our AMA:

- 1 • Encourage Federal Trade Commission (FTC) actions to limit anticompetitive behavior by
- 2 pharmaceutical companies attempting to reduce competition from generic manufacturers
- 3 through manipulation of patent protections and abuse of regulatory exclusivity incentives.
- 4 • Encourage Congress, the FTC and HHS to monitor and evaluate the utilization and impact of
- 5 controlled distribution channels for prescription pharmaceuticals on patient access and market
- 6 competition.
- 7 • Monitor the impact of mergers and acquisitions in the pharmaceutical industry.
- 8 • Continue to monitor and support an appropriate balance between incentives based on
- 9 appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and
- 10 statutory barriers to competition as part of the patent system.
- 11 • Encourage prescription drug price and cost transparency among pharmaceutical companies,
- 12 pharmacy benefit managers and health insurance companies.
- 13 • Support legislation to require generic drug manufacturers to pay an additional rebate to state
- 14 Medicaid programs if the price of a generic drug rises faster than inflation.
- 15 • Support legislation to shorten the exclusivity period for biologics.
- 16 • Convene a task force of appropriate AMA Councils, state medical societies and national
- 17 medical specialty societies to develop principles to guide advocacy and grassroots efforts
- 18 aimed at addressing pharmaceutical costs and improving patient access and adherence to
- 19 medically necessary prescription drug regimens.
- 20 • Generate an advocacy campaign to engage physicians and patients in local and national
- 21 advocacy initiatives that bring attention to the rising price of prescription drugs and help to put
- 22 forward solutions to make prescription drugs more affordable for all patients, and will report
- 23 back to the House of Delegates regarding the progress of the drug pricing advocacy campaign
- 24 at the 2016 Interim Meeting.

25
 26 As outlined in Board of Trustees Report 10-I-16, “AMA Initiatives on Pharmaceutical Costs,” the
 27 AMA convened a Task Force on Pharmaceutical Costs pursuant to Policy H-110.987, which met
 28 four times to develop principles to guide advocacy and grassroots efforts aimed at addressing
 29 pharmaceutical costs. The Task Force reviewed the substantial body of AMA policy addressing
 30 pharmaceutical costs and pricing, and discussed potential issues and issue combinations to feature
 31 in an AMA grassroots campaign, including pharmaceutical cost and price transparency, Medicare
 32 drug price negotiation, banning direct-to-consumer advertising and prescription drug reimportation.
 33 The Task Force agreed that banning direct-to-consumer advertising and prescription drug
 34 reimportation should not be pursued as part of the grassroots campaign at this time, after
 35 considering several factors, including political feasibility, as well as the thresholds for AMA
 36 support for prescription drug reimportation outlined in Policy D-100.983. The Task Force agreed
 37 that increasing transparency among pharmaceutical companies, health plans and PBMs should be
 38 the focus of Phase I of the grassroots campaign (remainder of 2016), with the specifics of Phase II
 39 of the grassroots campaign (2017) to be determined after the 2016 presidential and congressional
 40 elections and after any additional policy is established by the House of Delegates. However, the
 41 Task Force agreed that strong consideration should be given to including Medicare drug price
 42 negotiation in Phase II of the campaign. Resulting from the work of the Task Force, the AMA
 43 launched a grassroots campaign on increasing pharmaceutical cost and price transparency among
 44 pharmaceutical companies, health plans and pharmacy benefit managers.

45
 46 Previously, at the 2015 Annual Meeting, the House of Delegates adopted Policy H-110.988, which
 47 states that the AMA will:

- 48
- 49 • Work collaboratively with relevant federal and state agencies, policymakers and key
- 50 stakeholders (e.g., the US Food and Drug Administration, the FTC, and the Generic

- Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs;
- Advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients;
 - Encourage the development of methods that increase choice and competition in the development and pricing of generic prescription drugs; and
 - Support measures that increase price transparency for generic prescription drugs.

Addressing the integration of value in the health care system, Policy H-460.909 outlines principles for creating a centralized comparative effectiveness research entity, including a principle that states that the comparative effectiveness research entity must not have a role in making or recommending coverage or payment decisions for payers. Of note, the Patient-Centered Outcomes Research Institute (PCORI), which sunsets in 2019, does not fund studies conducting formal cost-effectiveness analyses or directly comparing the costs of care between two or more alternative approaches to providing care due to restrictions outlined in the Affordable Care Act.

Policy H-155.960 advocates that sources of medical research funding give priority to studies that collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well as clinical outcomes; and translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments. The policy also advocates that health information systems be designed to provide physicians and other health care decision-makers with relevant, timely, actionable information, automatically at the point of care, including relative cost-effectiveness of alternative diagnostic services and treatments. This information would help fulfill the intent of Policy H-450.938, which outlines principles to guide physician value-based decision-making. Policy H-155.960 encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. Likewise, Policy H-185.939 supports flexibility in the design and implementation of value-based insurance design programs, consistent with outlined principles. Policy H-185.935 supports the appropriate use of reference pricing as a possible method of providing health insurance coverage of specific procedures, products or services, consistent with outlined principles.

Policy H-450.933 encourages multi-stakeholder efforts to develop and fund clinical data registries for the purpose of facilitating quality improvements and research that result in better health care, improved population health, and lower costs. The policy also encourages national medical specialty societies, state medical associations, and other physician groups to join the National Quality Registry Network and to participate in efforts to advance the development and use of clinical data registries. Finally, the policy supports flexibility in the development and implementation of clinical data registries, and outlines guidelines to help maximize opportunities for clinical data registries to enhance the quality of care provided to patients.

POTENTIAL MECHANISMS TO DETERMINE THE VALUE OF PHARMACEUTICALS

During its review of AMA policy addressing pharmaceutical pricing, as well as responses to address the high costs of pharmaceuticals, the Council determined that policy had a noteworthy gap with respect to value-based pricing—an approach that has the potential to impact the prices of drugs across the health care system. Policy H-460.909 defines value as “the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information.” However, the pricing of prescription drugs, which is market-based

in nature, is often not clearly commensurate with the drug's clinical outcomes, and reductions in morbidity and mortality.

Various public and private payers have moved forward in implementing initiatives to tie drug prices to outcomes. In addition, value frameworks exist to support a transition to basing prescription drug pricing on a balance of value and health outcomes—converting evidence based on patient health outcomes to a price. Two of the value frameworks outlined below provide value-based prices for drugs, while others could be used to measure a drug's value as part of the shared decision-making process between patients and their physicians. The strength and accuracy of any framework to support value-based pricing of prescription drugs depends on the validity, reliability and comprehensiveness of necessary inputs and data, which could come from clinical trials, clinical data registries and comparative effectiveness research, as well as an integrated information infrastructure.

Outcomes-Based Pricing Initiatives

Public and private payers have moved forward with initiatives that would tie how much they pay for drugs to patient health outcomes. Cigna entered into value-based contracts with both Amgen and Sanofi/Regeneron for their PCSK9 inhibitors, Repatha and Praluent, which reduce the amount of harmful LDL cholesterol circulating in the bloodstream. Under the agreement, if Cigna enrollees who take the drugs do not achieve reductions in their LDL-C levels as was experienced in clinical trials, the two pharmaceutical companies would give Cigna discounts on the original negotiated price. If the drugs meet or exceed the expected LDL-C reduction target, the original negotiated price remains in place.⁶ Express Scripts has launched its Oncology Care Value Program, which is aiming to align the cost of cancer treatment with its outcomes. This year, the program is focusing on prostate cancer, lung cancer, and renal cell carcinoma.⁴ In addition, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule that put forward a two-phase drug payment model under Medicare Part B, the second phase of which includes a proposal to allow CMS to enter into voluntary agreements with manufacturers to link health care outcomes to payment. As outlined in the proposed rule, these outcomes-based risk-sharing agreements “tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers agree to provide rebates, refunds, or price adjustments if the product does not meet targeted outcomes.” CMS proposed that value would be measured “through data collection likely, though not necessarily, provided by the prescriber,” intended to address factors such as long-term safety and outcomes, effects on individual patients, patient adherence, or impact on utilization and costs.⁷

Institute for Clinical and Economic Review (ICER)

The Value Assessment Framework developed by ICER includes two components: a drug's long-term care value and the potential short-term budget impact following a drug's introduction to the marketplace. ICER determines care value by evaluating a drug's comparative clinical effectiveness, incremental costs per outcomes achieved, other benefits or disadvantages (e.g., methods of administration, public health benefit) and contextual considerations (e.g., future competition in the marketplace). In measuring incremental costs per outcomes achieved, ICER uses quality-adjusted life years (QALYs) and sets thresholds of reasonable ratios of cost-effectiveness at \$100,000 (high care value) to \$150,000 (intermediate care value) per QALY. ICER measures provisional health system value to assess the short-term budget impact of a drug in comparison with its long-term care value. To measure the short-term budget impact of a drug, ICER estimates the net change in total health care costs during the five years following the launch of a new drug into the marketplace. ICER developed an affordability threshold of a drug's short-term budgetary impact to serve as an

“alarm bell” to indicate whether additional responses may be needed due to a drug’s short-term budgetary impact. The short-term affordability threshold represents the contribution of a new drug to the growth in overall health care spending of no more than the anticipated growth in national gross domestic product plus one percent. Therefore, ICER calculates its value-based price benchmark using long-term cost-effectiveness as well as potential short-term budget impact, developing prices to achieve cost-effectiveness thresholds of \$100,000 per QALY and \$150,000 per QALY, as well as a maximum price using its affordability threshold. For example, in its review of PCSK9 drugs, which have a list price of \$14,350, ICER concluded that the drugs would have to be priced at \$5,404 to achieve a cost-effectiveness ratio of \$100,000 per QALY; \$7,735 to achieve a cost-effectiveness ratio of \$150,000 per QALY; and \$2,177 to meet its affordability threshold. In its review of Entresto, which has a list price of \$4,560, ICER determined that the drug would have to be priced at \$9,480 to achieve a cost-effectiveness ratio of \$100,000 per QALY; \$14,472 to achieve a cost-effectiveness ratio of \$150,000 per QALY; and \$4,168 to meet its affordability threshold.⁸

DrugAbacus, Memorial Sloan Kettering Cancer Center

DrugAbacus is a tool that could potentially be used to help stakeholders determine value-based prices for 52 cancer drugs approved between 2001 and 2015. The DrugAbacus price, which is relevant for a typical treatment period, is calculated using a formula that uses eight domains as inputs: efficacy, tolerability, novelty, research and development costs, rarity, population burden, unmet need, and prognosis. Users of the tool determine the weight (i.e., value) to be given to each domain, which results in a value-based price. Again, the value-based price is dependent on user inputs and determinations of value. Of note, DrugAbacus includes an indication-specific pricing feature, which allows users to compare the actual and DrugAbacus price of different indications for four drugs: Abraxane, Avastin, Nexavar, and Tarceva.⁹

National Comprehensive Cancer Network (NCCN) Evidence Blocks

NCCN Evidence Blocks provide five key value measures of systemic cancer therapy, meant to be used in shared decision-making between patients and their physicians. The five value measures—efficacy, safety, quality of evidence, consistency of evidence, and affordability—are each rated on a scale of one to five. The value measures provide additional information about specific NCCN guideline recommendations, and allow physicians and patients to be able to visually compare the values of available therapies and make their own assessments of value. As of the drafting of this report, NCCN Evidence Blocks are available for breast cancer; breast cancer risk reduction; central nervous system cancers gliomas; chronic myelogenous leukemia; colon cancer; head and neck cancers—very advanced head and neck cancer; hepatobiliary cancers; kidney cancer; malignant pleural mesothelioma; melanoma; multiple myeloma; non-Hodgkin's lymphomas—diffuse large B-cell lymphoma; non-small cell lung cancer; ovarian cancer; penile cancer; prostate cancer; rectal cancer; testicular cancer; and thymomas and thymic carcinomas.¹⁰

American College of Cardiology/American Heart Association (ACC/AHA)

The ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures provides a value framework for practice guideline and performance measurement development that establishes the benefit of diagnostic approaches and treatment compared with risk (COR), assesses the level/quality of evidence, and gives each approach/treatment a level of value. CORs can range from class I (highest) to III (lowest). The level/quality of evidence underlying a diagnostic approach and treatment would be given a value of

A, B or C. In addition, the approach or treatment would be given a value level of high, intermediate, low or uncertain, or value not assessed, based on QALYs gained.¹¹

American Society of Clinical Oncology (ASCO)

In June 2015, ASCO released a conceptual framework to assess the value of cancer treatment options to be used in shared decision-making. Two versions of the framework were developed: one for advanced cancer and one for potentially curative treatment.¹² ASCO then opened up the conceptual value framework to a 60-day public comment period; more than 400 comments were received. Based on the input and feedback received, ASCO released revised versions of the framework for advanced disease and adjuvant settings in May 2016. In both frameworks, points are awarded based on clinical benefit and toxicity, and bonus points can also be applied. Overall, both versions of the framework use points to determine the net health benefit, and have the net health benefit and the cost of the regimen side by side in order to assist physicians and patients to assess value at the point of care. ASCO plans to launch the framework in a software application, which would allow for the modification of the weight attributed to the elements included in the net health benefit based on patient preferences and circumstances.¹³

Public Health Approaches to Drug Pricing

The Council notes that Resolution 712-A-16 was focused on lowering the cost of treatments for hepatitis C, a disease with an incidence rate of 0.7 cases per 100,000 population in 2014 in the US. Approximately 30,500 acute hepatitis C cases occurred in 2014, with an estimated 2.7-3.9 million individuals in the US with chronic hepatitis C.¹⁴ The Council notes that different approaches have been used to directly purchase drugs and vaccines that have been determined to have a high value in terms of protecting public health. Preventing the spread of infectious diseases, such as hepatitis C, as well as the occurrence of vaccine-preventable diseases, impacts the treatment burden of these diseases, in terms of number of individuals affected, and total treatment costs. The Vaccines for Children (VFC) program is used to provide federally purchased vaccines to children who are uninsured, underinsured, Medicaid-eligible or Native Americans at no cost. Purchasing vaccines through VFC ensures access to lower prices for vaccines; the Centers for Disease Control and Prevention purchases vaccines at a discount, and distributes the vaccines to grantees (i.e., state health departments and local public health agencies), which in turn distribute them at no charge to participating public and private VFC providers.¹⁵

In addition, the AIDS Drug Assistance Program (ADAP), authorized under Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009, is a federally funded, but state-administered program that provides FDA-approved HIV medications to uninsured or underinsured low-income individuals living with HIV. ADAPs are required to purchase drugs in the most economic manner feasible, which can either be 340B pricing or otherwise showing that they pay no more than 340B prices for drugs covered under ADAP formularies. In June 2015, 197,117 individuals were enrolled in ADAPs.¹⁶

ANALYZING THE IMPACT OF MEDICARE DRUG PRICE NEGOTIATION

In addition to reviewing and analyzing approaches to value-based pricing of prescription drugs, the Council, based on feedback received from the Task Force on Pharmaceutical Costs, reviewed policy addressing Medicare drug price negotiation, and analyzed whether additional changes should be made to increase the policy's ability to achieve cost savings and political feasibility. Policy D-330.954 states that our AMA will support federal legislation which gives the Secretary of

1 HHS the authority to negotiate contracts with manufacturers of covered Part D drugs, and will
2 work toward eliminating Medicare prohibition on drug price negotiation.

3
4 Policy D-330.954 responds to the “noninterference clause” in the Medicare Modernization Act of
5 2003 (MMA), which states that the Secretary of HHS “may not interfere with the negotiations
6 between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may
7 not require a particular formulary or institute a price structure for the reimbursement of covered
8 part D drugs.” Instead, participating Part D plans compete with each other based on plan premiums,
9 cost-sharing and other features, which provides an incentive to contain prescription drug spending.
10 To contain spending, Part D plans not only establish formularies, implement utilization
11 management measures and encourage beneficiaries to use generic and less-expensive brand-name
12 drugs, but are required under the MMA to provide plan enrollees access to negotiated drug prices.
13 These prices are achieved through direct negotiation with pharmaceutical companies to obtain
14 rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.

15 16 *Lack of Bipartisan Support*

17
18 The scope and approach of federal legislation introduced to date that would grant the Secretary of
19 HHS the authority to negotiate contracts with manufacturers of Part D drugs vary. The Council
20 notes that, at the time this report was written, none of the bills introduced that would allow the
21 Secretary of HHS to negotiate drug prices in Part D included any Republican sponsors or
22 cosponsors. As such, achieving legislative success in this arena considering the current political
23 atmosphere is unlikely.¹⁷ S. 31/H.R. 3061, the Medicare Prescription Drug Price Negotiation Act of
24 2015, and S. 2023/H.R. 3513, the Prescription Drug Affordability Act, include language that
25 authorizes the HHS Secretary to negotiate Part D drug discounts and prohibits the Secretary from
26 imposing a national formulary. H.R. 4207, the Medicare Fair Drug Pricing Act of 2015, contains a
27 provision allowing for an exception to Medicare Part D’s “noninterference clause” for specified
28 covered part D drugs, which are defined as either sole source drugs or biologics and are not
29 manufactured by more than two drug manufacturers, or other covered drugs for which there is a
30 limited ability for Medicare Part D and Medicare Advantage plans to negotiate rebates that have a
31 significant fiscal impact on Medicare Part D. If the Secretary and the applicable drug
32 manufacturers are not able to agree on a negotiated price for these specified drugs, the legislation
33 grants the Secretary the authority to determine the price of the drug based on certain factors,
34 including the VA price of the drug (if applicable) and what price would ensure affordability and
35 accessibility. Part D plans could still negotiate for lower prices than the one determined by the
36 Secretary. The legislation also prohibits the Secretary from establishing or requiring a particular
37 formulary.

38
39 An alternative to simply allowing the Secretary of HHS to negotiate drug prices in Part D is to
40 establish a “public option” in Part D, an approach included in S. 1884/H.R. 3261, the Medicare
41 Prescription Drug Savings and Choice Act. The legislation would establish a Medicare operated
42 Medicare prescription drug plan option – a public option. The legislation would authorize the use
43 of a formulary for this public option, but would not establish a national formulary for all Part D
44 plans. This public Part D plan would operate nationwide, but would not alter the private insurance
45 plan administered Part D program.

46 47 *Limited Ability to Achieve Savings Without Additional Negotiating Leverage*

48
49 In addition, questions have been raised whether HHS could achieve much greater savings than
50 what is currently achieved by health plans and pharmacy benefit managers in Part D. The
51 Congressional Budget Office (CBO), as well as CMS actuaries, have estimated that providing the

Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D.^{18,19} Therefore, it is projected that legislation granting the Secretary of HHS broad authority to negotiate drug prices would likely have a negligible effect on federal spending.

If the Secretary of HHS were granted the authority to negotiate prices for unique covered Part D drugs that lack competitor products or therapeutic alternatives, the CBO has stated that there may be potential savings.¹⁶ However, neither the CBO or the Office of Management and Budget (OMB) has scored any savings associated with providing the Secretary of HHS the authority to negotiate drug prices for biologics and high-cost drugs in Medicare Part D, an option which was included in the Obama administration's fiscal year 2016 and 2017 budget proposals.^{20,21,22,23}

Perhaps of most concern, CBO has acknowledged that, in order for the Secretary to have the ability to obtain significant discounts in negotiations with drug manufacturers, the Secretary would also need the "authority to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions. In the absence of such authority, the Secretary's ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited."¹⁸ CMS actuaries have concurred, stating "the inability to drive market share via the establishment of a formulary or development of a preferred tier significantly undermines the effectiveness of this negotiation. Manufacturers would have little to gain by offering rebates that are not linked to a preferred position of their products, and we assume that they will be unwilling to do so."¹⁹

Any Positive Impact Primarily Limited to Medicare Part D Beneficiaries

The Council notes that, if allowing for Medicare drug price negotiation would achieve any savings, the primary impact would be to reduce the cost-sharing of patients enrolled in Medicare Part D plans, versus patients insured in both private and public plans. At the same time, pharmaceutical companies could potentially shift costs to commercial health plans, as Medicaid programs already have access to lower prescription drug prices resulting from existing rebates and other measures. If Medicare drug price negotiation does indeed cause pharmaceutical manufacturers to shift their costs to commercial health plans, that may cause plans offered in the exchanges and by employers to raise their premiums and cost-sharing, which could negatively impact patient access and adherence.

Unintended Consequences of Amending Policy

Accordingly, the Council believes that amending Policy D-330.954 to increase the likelihood for cost savings associated with allowing the Secretary of HHS to negotiate drug prices in Medicare Part D would entail supporting authority for the Secretary to establish a Part D formulary or develop a preferred tier in Part D. The Council does not support amending the policy in this fashion, due to its expected impact on patient choice of Part D plans, and patient access to the prescription drugs they need. If the Secretary were given the authority to establish a Part D formulary, any drug not on the formulary or at a high tier on the formulary would require an exception request/appeal by the patient. In addition, formularies include prior authorization requirements, quantity limits and step therapy requirements. Importantly, expanding the Secretary's authority in this fashion may further reduce the political feasibility of the policy. Overall, the Council believes that value-based pricing may serve as a more politically viable, cost-saving, choice-saving and fair alternative to the Secretary of HHS negotiating drug prices in Medicare Part D. In addition, value-based pricing has the potential to impact the prescription drug cost-sharing of all patients, not just those enrolled in Medicare Part D plans.

1 DISCUSSION
2

3 The integration of value into pharmaceutical pricing has the potential to build off of long-standing
4 AMA policy that supports market-driven mechanisms to control pharmaceutical costs, as well as
5 recognizes that improvements need to be made to ensure that the pharmaceutical marketplace
6 operates efficiently and effectively. Importantly, value-based pricing of pharmaceuticals does not
7 require the establishment of price controls or other mandates that may stifle innovation in the
8 pharmaceutical industry. However, pricing pharmaceuticals based on their value should aim to
9 improve affordability for patients and limit system-wide budgetary impact. As policymakers,
10 insurers and other stakeholders move forward with efforts to integrate value into pharmaceutical
11 pricing, the Council believes that the establishment of principles are necessary to guide AMA
12 advocacy. Initiatives to determine value-based pricing for pharmaceuticals should aim to ensure
13 patient access to necessary prescription drugs and allow for patient variation and physician
14 discretion. In addition, such initiatives should limit administrative burdens on physician practices
15 and patients. The Council is concerned that some value-based pricing approaches, by being
16 dependent on the tracking and reporting of outcomes, have the potential to impose administrative
17 burdens on physicians and patients.

18
19 Processes that determine value-based prices of pharmaceuticals need to be evidence-based,
20 transparent, and objective, and involve the input of practicing physicians and researchers. The
21 Council notes that the strength and accuracy of any framework to support value-based pricing of
22 pharmaceuticals depends on the validity, reliability and comprehensiveness of necessary inputs and
23 data, which could come from clinical trials, clinical data registries and comparative effectiveness
24 research, as well as an integrated information infrastructure. The Council notes that there continues
25 to be a lack of high-quality data on the cost and value of interventions using pharmaceuticals in
26 practice. Increased comparative effectiveness research in the pharmaceutical arena is imperative so
27 patients, physicians and other stakeholders are aware of differences between the prescription drugs
28 available within the same category or class. The Council believes that the AMA must continue to
29 advocate for adequate investment in comparative effectiveness research, as called for in Policies
30 H-460.909 and D-390.961. However, in order to be truly effective, the cost of alternatives, as well
31 as cost-effectiveness analysis, should be included in comparative effectiveness research endeavors.
32 In addition, your Council recognizes that clinical data registries, as addressed in Policy H-450.933,
33 may be useful in measuring and tracking short- and long-term clinical outcomes of
34 pharmaceuticals.

35
36 Value-based pharmaceutical pricing can also be incorporated into health insurance benefit design,
37 to limit patient cost-sharing for pharmaceuticals that have a high clinical benefit. Policies
38 H-155.960 and H-185.939, which are also relevant to alternative payment models, support the use
39 of value-based insurance design, determining patient cost-sharing requirements based on the
40 clinical value of a health care service or treatment. Policy also states that consideration should be
41 given to further tailoring cost-sharing requirements to patient income and other factors known to
42 impact compliance. Importantly, Policy H-185.939 states that value-based plan designs that include
43 higher cost-sharing or other disincentives to obtaining services designated as low-value must
44 include an appeals process to enable patients to secure care recommended by their physicians,
45 without incurring cost-sharing penalties.

46
47 With respect to Resolution 712-A-16, the Council believes that pharmaceutical pricing mechanisms
48 need to take into account a drug's public health value. For pharmaceuticals that are used to treat or
49 cure diseases that pose unique public health threats, including hepatitis C, the Council supports the
50 use of direct purchasing mechanisms to assure patient access to the treatments they need, which
51 will impact disease transmission rates as well as overall treatment costs. Existing models, including

1 the VFC program and the AIDS Drug Assistance Program, show the potential for using the direct
2 purchasing approach for other drugs. The Council notes that direct purchase arrangements will
3 guarantee prices for prescription drugs as well as volume for manufacturers. As such, lower prices
4 can be achieved in exchange for a larger, guaranteed market for a drug.

5
6 RECOMMENDATIONS

7
8 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
9 712-A-16, and that the remainder of the report be filed.

- 10
11 1. That our American Medical Association (AMA) reaffirm Policies H-155.960 and H-185.939,
12 which support the use of value-based insurance design, determining patient cost-sharing
13 requirements based on the clinical value of a treatment. (Reaffirm HOD Policy)
14
15 2. That our AMA reaffirm Policy H-450.933, which establishes guidelines to help maximize
16 opportunities for clinical data registries to enhance the quality of care provided to patients.
17 (Reaffirm HOD Policy)
18
19 3. That our AMA reaffirm Policies H-460.909 and D-390.961 in support of adequate investments
20 in comparative effectiveness research. (Reaffirm HOD Policy)
21
22 4. That our AMA support value-based pricing programs, initiatives and mechanisms for
23 pharmaceuticals that are guided by the following principles:
24
25 a) Value-based prices of pharmaceuticals should be determined by objective, independent
26 entities;
27 b) Value-based prices of pharmaceuticals should be evidence-based and be the result of valid
28 and reliable inputs and data that incorporate rigorous scientific methods, including clinical
29 trials, clinical data registries, comparative effectiveness research, and robust outcome
30 measures that capture short- and long-term clinical outcomes;
31 c) Processes to determine value-based prices of pharmaceuticals must be transparent, easily
32 accessible to physicians and patients, and provide practicing physicians and researchers a
33 central and significant role;
34 d) Processes to determine value-based prices of pharmaceuticals should limit administrative
35 burdens on physicians and patients;
36 e) Processes to determine value-based prices of pharmaceuticals should incorporate
37 affordability criteria to help assure patient affordability as well as limit system-wide
38 budgetary impact; and
39 f) Value-based pricing of pharmaceuticals should allow for patient variation and physician
40 discretion. (New HOD Policy)
41
42 5. That our AMA support the inclusion of the cost of alternatives and cost-effectiveness analysis
43 in comparative effectiveness research. (New HOD Policy)
44
45 6. That our AMA support direct purchasing of pharmaceuticals used to treat or cure diseases that
46 pose unique public health threats, including hepatitis C, in which lower drug prices are assured
47 in exchange for a guaranteed market size. (New HOD Policy)

Fiscal Note: Less than \$500.

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REPORT 6 OF THE COUNCIL ON MEDICAL SERVICE (I-16)
Integration of Mobile Health Applications and Devices into Practice
(Reference Committee J)

EXECUTIVE SUMMARY

Digital health, including the utilization of mobile health applications (mHealth apps) and devices, has the potential to be integrated into everyday practice in order to promote improved patient health outcomes, support care coordination and improve communication. The Council initiated this report to address the need to balance these innovations with appropriate industry standards for mHealth apps and US Food and Drug Administration (FDA) regulation of mobile medical devices. For those mHealth apps and mobile medical devices that are subject to FDA review and approval, FDA resources need to be sufficient to respond to the number of mHealth products under its jurisdiction.

While some mobile apps and devices are subject to FDA regulation, others are not, and do not undergo rigorous evaluation before deployment for general use, which raises quality and patient safety concerns. However, without ensuring that there is strong and sufficient evidence that provides clinical validation to mHealth apps and associated devices, trackers and sensors, the Council recognizes that physicians will not fully integrate mHealth apps into their practices. More investment is needed in expanding the evidence base necessary to show the accuracy, effectiveness, safety and security of mHealth apps.

The Council proposes principles to guide health plan coverage and payment decisions, employer wellness program inclusions and flexible spending account eligibility determinations concerning mHealth apps and associated devices, in order to protect the patient-physician relationship, support care delivery that is patient-centered, promote care coordination and facilitate team-based communication. Overall, coverage of and payment for mHealth apps and associated devices should be contingent upon a clinical evidence base to support their use in order to ensure app safety and effectiveness. In addition, interoperability between a patient's mobile technology and electronic health records will be an asset, as physicians must be able to meaningfully use the volumes of data mHealth apps and devices create. It is also essential for mHealth apps to follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes. National medical specialty societies have a key role in developing guidelines for the integration of mHealth apps and associated devices into care delivery.

Patient privacy and data security need to be a priority in digital health, because mobile apps and devices can be subject to privacy and data breaches. Patients must also be aware of the level at which their information and data is protected by mHealth apps. Overall, mHealth apps and associated devices, trackers and sensors need to abide by applicable laws addressing the privacy and security of patients' medical information. If physicians are unsure of whether mHealth apps meet Health Insurance Portability and Accountability Act's standards, they should consult with qualified legal counsel and inquire about any applicable state privacy and security laws. Given the lack of regulation of mHealth apps, regardless of whether an mHealth device is encrypted, physicians should alert patients to the potential privacy and security risks of any mHealth apps that he or she prescribes or recommends, and document the patient's understanding of such risks. Questions remain regarding liability risks to physicians who use, recommend or prescribe mHealth apps. Accordingly, the Council believes that the AMA should assess the potential liability risks to physicians for using, recommending, or prescribing mHealth apps, including risk under federal and state medical liability, privacy, and security laws.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6-I-16

Subject: Integration of Mobile Health Applications and Devices into Practice

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

The use of digital and mobile health technologies and tools is increasing among patients and physicians, with the potential to play a significant role in new payment and care delivery models. The evolution of digital and mobile health technologies, including mobile applications (apps) and devices, impacts all three strategic focus areas of the American Medical Association (AMA): improving health outcomes, creating the medical school of the future, and creating thriving physician practices. This Council-initiated report provides background on the number, use, effectiveness and safety of mobile health applications (mHealth apps) and medical devices; outlines relevant regulatory and legislative activity; provides a snapshot of the current coverage and payment environment for mobile health apps and devices; summarizes relevant AMA policy and advocacy; and presents policy recommendations.

BACKGROUND

Mobile health apps and medical devices are continuously being introduced into the marketplace to assist patients in managing their health and wellness, with some having the capacity to support the ability of physicians to monitor the health status and indicators of patients. Mobile health apps that facilitate chronic disease management and patient engagement have the potential to serve as tools to manage the care of patients with comorbidities, as well as patients who incur high health care costs. There are distinct definitions that can be applied to the range of mobile apps and devices available for use by patients and physicians:

- Mobile applications (mobile apps): A software application that can be run on a mobile product such as a mobile phone, smartphone, or tablet (with or without wireless connectivity) or a web-based software application run on a server, but meant to be used through a mobile product (such as a smartphone).
- Mobile health applications (also referred to as mobile health or mHealth apps): A mobile app that delivers health-related services using a mobile phone, smartphone or tablet. These apps cover a wide spectrum of functions to support health and fitness, as well as disease management.
- Mobile medical device applications: A mobile app that meets the definition of a device in the Federal Food, Drug, and Cosmetic Act is considered by the US Food and Drug Administration (FDA) to be a medical device, subject to risk-based oversight and regulation. A mobile medical device app could be considered a regulated subset of mHealth apps.

1 Approximately two-thirds of Americans own smartphones, including 27 percent of individuals 65
2 and older and half of those with incomes under \$30,000 per year¹—populations that may be key
3 targets for mobile health interventions. In addition, an increasing number of patients are taking
4 advantage of mHealth apps, as well as wearable sensor technologies to allow for real-time
5 monitoring and tracking of important health information.

6
7 There are more than 165,000 mHealth apps available to consumers. The number of mHealth apps
8 available in the marketplace has been increasing at a significant rate—from 2013 to 2015, the
9 number of mHealth apps on the iOS platform rose from 43,689 to 90,088—a 106 percent increase.²
10 While patient-facing health apps may track personal fitness and nutrition, provide medication
11 reminders, provide health-related information and display personal health records, physicians and
12 other health care providers can use mobile health apps to track patient vital signs and other health
13 indicators, and as diagnostic tools. Two-thirds of consumer mHealth apps are focused on wellness
14 (e.g., fitness, diet, nutrition and lifestyle), with approximately one-quarter of mHealth apps
15 targeting disease and treatment management.²

16
17 Mobile health apps vary greatly in their functionality, accuracy, safety and effectiveness. Most
18 mHealth apps have limited functionality, with many solely providing information without
19 additional capabilities. In fact, providing information is the most common capability of mHealth
20 apps. On the other hand, most apps lack the ability to communicate or connect with the systems of
21 physicians and other health care providers. While the percentage of mHealth apps with the capacity
22 to output user data increased between 2013 and 2015, the ability of mHealth apps to communicate
23 externally, including with patients' treating physicians, remained the same. Approximately 10
24 percent of mHealth apps have the ability to connect to a device, which not only include fitness
25 apps, but also disease management apps that monitor blood pressure and blood glucose levels.²

26
27 The Commonwealth Fund conducted a search of the iOS and Android app stores for patient-facing
28 health apps for a broad set of medical conditions. Notably, upon evaluating the 1,046 apps related
29 to health care that were patient-facing based on criteria related to patient engagement, quality and
30 safety, 43 percent of iOS apps and 27 percent of Android apps appeared to be useful.³ Although the
31 Commonwealth Fund evaluated the health apps selected for this study for quality and safety, the
32 Council notes that its evaluation process was limited to analyses under its purview, and additional
33 efforts by industry to develop standards addressing the quality and safety of mHealth apps are
34 needed moving forward. Overall, while recent studies show promise in using mHealth apps for
35 patient engagement and treatment adherence, studies have also raised concerns regarding mHealth
36 app content and accuracy, which can pose threats to the health and safety of patients.^{2,4,5,6} The
37 nature of threats to patient safety differ based on what mHealth apps and associated devices
38 measure. For example, while apps that measure steps taken or calories consumed would be
39 considered to be lower-risk in nature, mHealth apps that are inaccurate in their blood pressure and
40 blood sugar readings, miscalculate insulin doses or misdiagnose skin cancer raise significant and
41 serious patient safety concerns.

42 43 REGULATORY AND LEGISLATIVE ACTIVITY

44
45 The Council notes that most mHealth apps available to consumers have not received clearance or
46 approval by the FDA. In 2015, the FDA released guidance on mobile medical applications for
47 industry and FDA staff.⁷ The guidance reiterated that the focus of FDA oversight of mobile health
48 apps is on those meeting the statutory definition of a medical device; either are intended to be used
49 as an accessory to a regulated medical device, or convert a mobile platform into a regulated
50 medical device; and pose a risk to patient safety if they do not function as intended. Accordingly,
51 the FDA regulates mobile health apps that use a mobile platform's built-in features (light,

vibrations, camera, etc.) to perform medical device functions. In addition, the FDA regulates mobile health apps that control the operation or function of an implantable or body worn medical device. Finally, the FDA regulates mobile health apps that are used in active patient monitoring.⁸

The FDA has stated that it intends to exercise enforcement discretion for a subset of mobile health apps that meet the definition of a medical device, but pose a low risk to the consumer. Therefore, for these apps, the FDA's current guidance provides it does not intend to enforce requirements of the Federal Food, Drug, and Cosmetic Act for this subset of mobile health apps that are medical devices at this time. For example, mobile apps that fall into this category include those that assist patients in managing their disease or conditions without providing specific treatment or treatment suggestions, or provide patients with tools to organize and track their health information. In addition, there are mobile health apps that are not considered medical devices, so the FDA does not regulate them.

There is a noteworthy gap in ensuring the quality, safety, accuracy, effectiveness, and security of mHealth apps, in part, due to the FDA's decision to exercise enforcement discretion with regard to a broad category of medical devices apps coupled with the proliferation of mobile health apps that do not meet the definition of medical device and, by law, are not subject to the FDA's jurisdiction. As a result, several entities, including PatientView, Wellocracy and IMS Health's Appscript, are moving forward with efforts to rate, evaluate and/or certify health apps.

In addition, the Federal Trade Commission (FTC), in cooperation with the FDA, the US Department of Health and Human Services' Office for Civil Rights and Office of National Coordinator for Health Information Technology (ONC), has developed the Mobile Health Apps Interactive Tool to assist health app developers in ascertaining which federal laws apply to the health app(s) they are developing, ranging from the Health Insurance Portability and Accountability Act (HIPAA) to the FTC's Health Breach Notification Rule.⁹ In addition, the FTC has offered best practices for mobile health app developers to build privacy and security into their apps, as well as comply with the FTC Act, which prohibits deceptive or unfair acts or practices in or affecting commerce, including those relating to privacy and data security, and those involving false or misleading claims about apps' safety or performance.¹⁰

In addition to supporting health information technology (health IT) policy, ONC is charged with establishing the certification and testing criteria for health IT products required by Centers for Medicare & Medicaid Services (CMS) reporting programs. These programs, including the electronic health records (EHR) incentive, or "Meaningful Use" program, require eligible physicians to adopt and use health IT specifically designed to accommodate CMS objectives and measures. While some base-level EHR functionality requirements can benefit physicians and patients, CMS places additional requirements on the use of those functions – influencing the design of the software. With the release of ONC's 2015 Edition Health IT Certification requirements, by 2018 many physicians participating in CMS reporting programs must use EHRs that include application programming interfaces (API). These APIs will allow an app to access patient information stored in the EHR.

Addressing health information privacy, the HIPAA Privacy, Security and Breach Notification Rules apply only to covered entities, which include health plans, health care clearinghouses, and health care providers, and their business associates. HIPAA generally does not apply to mHealth apps, even if they handle or store an individual's health information. As such, mHealth apps are not required to protect the privacy and security of an individual's health information in the same way that a physician must because mHealth apps are not directly subject to HIPAA regulations.

Although HIPAA does not directly apply to mHealth apps, the HIPAA Security Rule sets out a framework for safeguarding the content of transfers of protected health information. HIPAA requires covered entities to consider encryption as an appropriate method of safeguarding protected health information (PHI) and to encrypt electronic PHI if such a practice is considered a “reasonable and appropriate” method of safeguarding PHI from environmental security threats. Encryption offers the additional benefit of alleviating the physician from breach notification in the event of impermissible use or disclosure. If the covered entity does not deem encryption to be a reasonable and appropriate method of safeguarding PHI, then it must document the reasons for its decision and adopt an equivalent alternative method for protecting PHI as necessary.

Legislation has been introduced in Congress in an effort to modify the FDA’s regulatory authority and role in this space. Representative Marsha Blackburn (R-TX) introduced H.R. 2396, the Sensible Oversight for Technology which Advances Regulatory Efficiency Act or the SOFTWARE Act. An amended version of the legislation was passed by the US House of Representatives as part of the 21st Century Cures Act. The SOFTWARE Act provides new statutory definitions and categories of apps that would exempt health software from FDA regulation, including as a medical device, with the exception of software that provides patient-specific recommendations and poses a significant risk to patient safety. In addition, Senator Michael Bennet (D-CO) has introduced S. 1101, the Medical Electronic Data Technology Enhancement for Consumers’ Health Act or the MEDTECH Act, which would exempt additional medical device software and mobile medical devices from FDA regulation, and provide limitations on the software that would be regulated by the FDA to protect patients.

COVERAGE AND PAYMENT OF MOBILE HEALTH APPS AND MEDICAL DEVICES

As payment models evolve, with payments to physicians and other health care entities being tied to outcomes, digital and mobile health technologies are being increasingly used to manage patient populations, improve patient access and engagement, and potentially control costs. Due to the wide range of mHealth apps in the marketplace, the level of integration of applications into practice is based on several factors, including whether or not the app and/or associated device are FDA-cleared or approved; the demonstrated health benefit of the app and/or associated device; the strength of research and data supporting the use of the health app and/or associated device; the interoperability with EHR systems; outreach to physicians and patients; and patient and physician out-of-pocket costs.

Typically, medical devices are covered by health insurance, conditioned on their FDA clearance and approval, which can limit patient out-of-pocket costs. However, as most mHealth apps currently will not be subject to clearance or approval by the FDA, the Council notes that health insurance coverage of mHealth apps is likely to be an underutilized avenue to limit patient cost exposure in this area in the near term. However, other financial incentives exist to spur patient uptake of mHealth apps and associated devices, including eligibility for flexible spending account (FSA) reimbursement and use in employee wellness programs, which could lead to a reduction in employee health insurance premiums. Without mechanisms to limit patient cost exposure, patient uptake of many mHealth apps and associated devices, trackers and sensors will depend on their prices. This will be especially critical for low-income and elderly individuals, who could potentially benefit from these digital health interventions.

There is a wide variation of how mobile apps are priced; pricing can include the initial purchase price, in-app purchases and annual subscription costs. In addition, the functionality of some mobile apps are dependent upon the purchase of an associated device, sensor or tracker. Increasingly, sensors and trackers are increasingly built into the mobile device itself. One-third of apps studied

1 by IMS Institute for Healthcare Informatics in 2015 required a paid sensor for operation. More than
2 90 percent of mHealth apps are available to consumers at no cost.² The Council notes that mHealth
3 app costs can be hidden due to in-app techniques for purchasing and advertising. For those apps
4 that have a cost, the average price of an mHealth app doubled from \$1 to \$2 between 2013 and
5 2015. In this time period, there was also a four percent decrease in the percentage of mHealth apps
6 costing less than \$3 and an increase in the cost for apps over \$10. A significant proportion of the
7 most expensive mHealth apps available, the cost of which all exceed \$150, target therapeutic areas,
8 including for autism and augmentative and alternative communication.²

9
10 More than a third of US physicians have recommended an mHealth app to patients.² A noteworthy
11 barrier to physician adoption of mHealth apps is the lack of evidence demonstrating the
12 effectiveness, safety, and security of mHealth apps. In addition, within the fee-for-service payment
13 environment, there are insufficient pathways to incentivize physicians and other providers to
14 implement systems that use mobile apps and devices. Notably, the integration of mobile
15 applications and devices into practice is directly related to the ability of physicians to analyze and
16 interpret their data. Overall, payment mechanisms are necessary for physicians to allocate their
17 time to provide services including, but not limited to, the review, analysis and follow-up of
18 synthesized mHealth app data.

19 20 RELEVANT AMA POLICY AND ACTIVITIES

21
22 Policy H-480.946 outlines principles to guide the appropriate coverage of and payment for
23 telemedicine services, encourages additional research to develop a stronger evidence base for
24 telemedicine and supports pilot programs and demonstration projects to enable coverage of
25 telemedicine services and address how telemedicine can be integrated into new payment and
26 delivery models. Policy H-480.974 states that the AMA will work with CMS and other payers to
27 develop and test appropriate payment mechanisms for telemedicine through demonstration projects
28 aimed at evaluating the effect of care delivered by physicians using telemedicine-related
29 technology on costs, quality, and the patient-physician relationship. The policy also encourages
30 development of a code change application for Current Procedural Terminology (CPT) codes or
31 modifiers for telemedical services, to be submitted pursuant to CPT processes.

32
33 Addressing mobile applications and devices specifically, Policy D-480.972 states that our AMA
34 will monitor market developments in mHealth, including the development and uptake of mHealth
35 apps, in order to identify developing consensus that provides opportunities for AMA involvement.
36 The policy also states that our AMA will continue to engage with stakeholders to identify relevant
37 guiding principles to promote a vibrant, useful and trustworthy mHealth market. Important for the
38 integration of mHealth apps in medical practice, the policy states that our AMA will make an effort
39 to educate physicians on mHealth apps that can be used to facilitate patient communication, advice,
40 and clinical decision support, as well as resources that can assist physicians in becoming familiar
41 with mHealth apps that are clinically useful and evidence-based. Finally, the policy states that our
42 AMA will develop and publically disseminate a list of best practices guiding the development and
43 use of mobile medical applications.

44
45 Policy H-450.949 encourages physicians to become familiar with and capitalize on opportunities to
46 use technology to ensure patient safety in prescribing medications and medical devices. Policy
47 H-480.972 stresses that manufacturers are ultimately responsible for conducting the necessary
48 testing, research and clinical investigation to establish the safety and efficacy of medical devices
49 requiring FDA approval.

The AMA has been engaged in legislative and regulatory advocacy concerning mHealth apps and coverage of telemedicine services, including remote patient monitoring. Federal and state advocacy efforts have been focused on streamlining and updating regulatory oversight and expanding private and public payer coverage. In addition, the AMA submitted comments for the record to the Subcommittee on Commerce, Manufacturing and Trade of the House Energy and Commerce Committee addressing health care apps.

The AMA also has hosted regular meetings with national medical specialty societies to encourage the development of objectives and initiatives to support digital medicine adoption, including the use of telemedicine and mobile medical apps. The AMA is a member of Health Level Seven International (HL7), a not-for-profit, standards developing organization accredited by the American National Standards Institute (ANSI), with its current Fast Healthcare Interoperability Resources (FHIR) standard being recognized as having the capacity to facilitate interoperability in the mHealth space. The AMA is working with others to develop an industry collaborative representing diverse stakeholder perspectives whose objective is to develop guidance for the mHealth community that focuses on issues of importance to physicians and their patients, to be used in the development and evaluation of digital health tools. This activity and forthcoming guidance will fulfill the intent of Policy D-480.972, which calls for the AMA to develop and publically disseminate a list of best practices guiding the development and use of mobile medical applications.

The AMA is a founding partner of Health2047, an integrated health care innovation company that is working to develop and make available system-level solutions that enhance care delivery and practice of medicine. One of the purposes of Health2047 is to catalyze collaboration across a network of partners including technology firms, product companies, physicians and payers to drive rapid and responsive change that makes new solutions possible. Health2047 incorporates physician perspectives to inform every step – from the design process, to testing prototypes, early access to solutions, and the ability to submit ideas of their own – so that health technology solutions work well in the practice setting and benefit physicians and patients.

Another partnership includes the AMA at MATTER, an effort to support ideation and collaboration with hundreds of entrepreneurs to ensure the physician perspective is included in the development of new tools and innovative solutions from the outset, and includes an interaction studio so entrepreneurs are able to test their solutions in a simulated clinical and non-clinical environment and collaborate with physicians virtually. Since the partnership was established in 2015, hundreds of physicians have visited MATTER or offered insight and feedback to entrepreneurs working on early stage technologies and solutions. Additionally, the AMA at MATTER partnership has brought physicians and entrepreneurs together for a variety of educational workshops, interactive simulations, and collaboration events focused on optimizing health care.

Furthermore, since 2014, the AMA has been an active participant and board member of the Substitutable Medical Applications & Reusable Technology Platforms project. This initiative with Boston Children's Hospital and Harvard University's Medical School is working to use a mobile app infrastructure to improve existing EHR technology and enhance interoperability. The project also promotes the development and use of mobile health apps with the goal of making such applications widely available to practicing physicians and patients.

The AMA conducted a survey of 1,300 physicians during the summer of 2016, which focused on physicians' understanding digital health and their attitudes regarding adoption. The survey covered a broad range of digital health tools, including telemedicine and telehealth, mobile health apps, wearables and remote patient monitoring technologies. The purpose of the survey was to obtain a

summary view of physicians' thoughts regarding digital health, to understand what motivates them to want to use various emerging digital tools, and what their requirements are for successfully integrating them into patient care and their practices. The survey results and report were released at the end of September, and can be accessed at ama-assn.org/ama/pub/news/news/2016/2016-09-26-digital-health-innovation.page. Survey results show that in order to spur physician adoption of digital health technologies, including mobile health apps, physicians require such tools to fit within their existing systems and practices, including being linked to and working within their EHRs. The survey found that physicians need experts to ensure the data privacy and security of such tools. Results also indicated that physicians need digital health tools to be covered by liability insurance and linked to appropriate physician payment. In addition, as part of its work to bridge and increase interactions between physicians and digital health stakeholders, the AMA has plans to pilot the AMA Physician Innovation Network, which will connect physicians and health technology entrepreneurs and industry for interaction and feedback. The AMA continues to monitor the evolution of the digital health sector.

DISCUSSION

The Council believes that digital health, including the utilization of mobile health apps and devices, has the potential to be integrated into everyday practice in order to promote improved patient health outcomes, support care coordination and improve communication. The Council believes that, moving forward, there needs to be a balance between innovation and appropriate industry standards for mHealth apps and FDA regulation of mobile medical devices. For those mHealth apps and mobile medical devices that are subject to FDA review and approval, FDA resources need to be sufficient to respond to the number of mHealth products under its jurisdiction. Policy H-100.980 supports a strong and adequately funded FDA to ensure that safe and effective medical products are made available to the American public as efficiently as possible.

While some mobile apps and devices are subject to FDA regulation, others are not, and do not undergo rigorous evaluation before deployment for general use, which raises quality and patient safety concerns. However, without ensuring that there is strong and sufficient evidence that provides clinical validation to mHealth apps and associated devices, trackers and sensors, the Council recognizes that physicians will not fully integrate mHealth apps into their practices. In addition, health insurers will not be as likely to consider payment for interventions stemming from mHealth apps, and employers will not be as likely to incorporate mHealth apps in their wellness programs. As such, the Council believes more investment is needed in expanding the evidence base necessary to show the accuracy, effectiveness, safety and security of mHealth apps, and believes that research should also focus on showing the impact of mHealth apps on costs, practice efficiencies and improvement in outcomes to facilitate mHealth app uptake and integration in alternative payment models. Overall, coverage of and payment for mHealth apps and associated devices should be contingent upon a clinical evidence base to support their use in order to ensure app safety and effectiveness.

It is also essential for mHealth apps to follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes. The Council believes that national medical specialty societies have a key role in developing guidelines for the integration of mHealth apps and associated devices into care delivery.

Other obstacles to the acceptance and widespread utilization of mHealth technologies include the current drivers of physician payment, as well as health insurance coverage and other mechanisms to limit patient cost exposure or provide financial incentives to patients. While the shift to alternative payment models is propelling the increased use of digital and mobile health tools, the

1 lack of insurance payment for related services remains an obstacle. Health insurance payment for
2 mobile apps and associated devices has the potential to serve as a pathway to assist patients and
3 physicians in monitoring patient health indicators, as well as improve medication and treatment
4 adherence. For any mHealth app or device that facilitates the delivery of any telemedicine service,
5 the Council stresses that Policy H-480.946, which guides the appropriate coverage of and payment
6 for telemedicine services, must be followed. In addition, the Council believes that additional
7 principles are necessary to guide health plan coverage and payment decisions, employer wellness
8 program inclusions and FSA eligibility determinations concerning mHealth apps and associated
9 devices, in order to protect the patient-physician relationship, support care delivery that is patient-
10 centered, promote care coordination and facilitate team-based communication.

11
12 The Council believes that prescriptive requirements on the use of EHRs have negatively affected
13 the usability of these tools. Many health information technology (health IT) developers are forced
14 to prioritize the design of their products to meet ONC and CMS demands, contributing to physician
15 dissatisfaction and burnout. The Council is concerned that, while new certification requirements
16 can improve data access for physicians and patients through the use of APIs and apps, many
17 developers will limit software functionality to that of federal requirements. This, coupled with
18 continued interoperability issues, may detract from app uptake, and could taint the rapidly maturing
19 mHealth industry. The Council believes that CMS, ONC, and other federal agencies must
20 acknowledge the history of EHR development, the unintended consequences of the Meaningful
21 Use program, and allow new payment models and user demand to shape health IT functionality
22 going forward. Furthermore, mHealth app developers should strive to incorporate physician and
23 patient input early in the development of their products and allocate resources to ensure design
24 reflects user needs.

25
26 The Council recognizes that physicians can contribute to increases in patient retention rates for
27 mHealth apps. Before prescribing any mHealth app or associated device, the usability of data from
28 mobile apps and devices will remain a priority for physicians and their patients, as the success of
29 mHealth apps in the long term will depend on the level and quality of connectivity between
30 patients, apps and devices, and physicians and other health care providers. Overall, interoperability
31 between a patient's mobile technology and EHRs will be an asset, as physicians must be able to
32 meaningfully use the volumes of data mHealth apps and devices create. As such, EHRs must have
33 the capacity to download and synthesize data from such mobile technologies. In addition, there
34 must be mechanisms for physician payment to allow for the review, analysis and follow-up of
35 synthesized mHealth app data.

36
37 Patient privacy and data security need to be a priority in the digital health space, as mobile apps
38 and devices can be subject to privacy and data breaches. Accordingly, the Council recommends
39 that mHealth apps and associated devices, trackers and sensors must abide by applicable laws
40 addressing the privacy and security of patients' medical information. In addition, physicians should
41 consider whether the mHealth apps they wish to use offer encryption, and whether the level of
42 encryption satisfies HIPAA's standards. Mobile health app developers may not readily disclose
43 whether their apps are encrypted, and the level of encryption may be unclear. If the physician is
44 unsure of whether the mHealth app meets HIPAA's standards, he or she should consult with
45 qualified legal counsel; the physician should also inquire about any applicable state privacy and
46 security laws. Given the lack of regulation of mHealth apps, regardless of whether an mHealth
47 device is encrypted, physicians should alert patients to the potential privacy and security risks of
48 any mHealth apps that he or she prescribes or recommends, and document the patient's
49 understanding of such risks. The Council recognizes that questions remain regarding liability risks
50 to physicians who use, recommend or prescribe mHealth apps. As such, the Council believes that
51 the AMA should assess the potential liability risks to physicians for using, recommending, or

prescribing mHealth apps, including risk under federal and state medical liability, privacy, and security laws.

Patients must also be aware of the level at which their information and data are protected by mHealth apps. For apps that collect, store and/or transmit protected health information, the Council believes that a standard privacy notice should be provided to patients. To the extent a physician, as a HIPAA-covered entity, incorporates an app into his or her practice, HIPAA is implicated and physicians should revisit their HIPAA Notice of Privacy Practices to ensure apps are appropriately addressed and secured. Overall, there is a need for the mobile app industry and other relevant stakeholders to conduct industry-wide outreach and provide necessary educational materials to patients to promote increased awareness of the varying levels of privacy and security of their data in mHealth apps, and how their information and data can potentially be collected and used.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-480.946, which outlines principles to guide the appropriate coverage of and payment for telemedicine services. (Reaffirm HOD Policy)
2. That our AMA reaffirm Policy H-100.980, which supports a strong and adequately funded US Food and Drug Administration to ensure that safe and effective medical products are made available to the American public as efficiently as possible. (Reaffirm HOD Policy)
3. That our AMA support the establishment of coverage, payment and financial incentive mechanisms to support the use of mobile health applications (mHealth apps) and associated devices, trackers and sensors by patients, physicians and other providers that:
 - a) support the establishment or continuation of a valid patient-physician relationship;
 - b) have a clinical evidence base to support their use in order to ensure mHealth app safety and effectiveness;
 - c) follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes;
 - d) support care delivery that is patient-centered, promotes care coordination and facilitates team-based communication;
 - e) support data portability and interoperability in order to promote care coordination through medical home and accountable care models;
 - f) abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services facilitated by the app;
 - g) require that physicians and other health practitioners delivering services through the app be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board; and
 - h) ensure that the delivery of any services via the app be consistent with state scope of practice laws. (New HOD Policy)
4. That our AMA support that mHealth apps and associated devices, trackers and sensors must abide by applicable laws addressing the privacy and security of patients' medical information. (New HOD Policy)

- 1 5. That our AMA encourage the mobile app industry and other relevant stakeholders to conduct
2 industry-wide outreach and provide necessary educational materials to patients to promote
3 increased awareness of the varying levels of privacy and security of their information and data
4 afforded by mHealth apps, and how their information and data can potentially be collected and
5 used. (New HOD Policy)
6
- 7 6. That our AMA encourage the mHealth app community to work with the AMA, national
8 medical specialty societies, and other interested physician groups to develop app transparency
9 principles, including the provision of a standard privacy notice to patients if apps collect, store
10 and/or transmit protected health information. (New HOD Policy)
11
- 12 7. That our AMA encourage physicians to consult with qualified legal counsel if unsure of
13 whether an mHealth app meets Health Insurance Portability and Accountability Act standards
14 and also inquire about any applicable state privacy and security laws. (New HOD Policy)
15
- 16 8. That our AMA encourage physicians to alert patients to the potential privacy and security risks
17 of any mHealth apps that he or she prescribes or recommends, and document the patient's
18 understanding of such risks. (New HOD Policy)
19
- 20 9. That our AMA assess the potential liability risks to physicians for using, recommending, or
21 prescribing mHealth apps, including risk under federal and state medical liability, privacy, and
22 security laws. (Directive to Take Action)
23
- 24 10. That our AMA support further development of research and evidence regarding the impact that
25 mHealth apps have on quality, costs, patient safety and patient privacy. (New HOD Policy)
26
- 27 11. That our AMA encourage national medical specialty societies to develop guidelines for the
28 integration of mHealth apps and associated devices into care delivery. (New HOD Policy)

Fiscal Note: Less than \$5,000.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 7-I-16

Subject: Hospital Discharge Communications

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

At the 2016 Annual Meeting, the House of Delegates adopted the recommendations of Council on Medical Service Report 6, which addressed communication and care coordination between hospital physicians and their community counterparts during patient hospitalizations (see Policy H-225.946). While developing that report, the Council agreed that communications during the hospital discharge process, which can be a confusing and potentially dangerous time for patients, should be examined in a separate report.

This report, initiated by the Council, provides background on communications during the hospital discharge process, summarizes relevant AMA policy and principles, and makes recommendations for new policy to help safeguard patients as they transition home from hospitals or to continuing care facilities.

BACKGROUND

Suboptimal or delayed communication between hospital and community physicians, and between physicians and patients, can lead to serious and costly post-discharge problems, including adverse events and hospital readmissions. Conversely, effective communication during the discharge period results in more seamless and safe care during this critical transition. An estimated 19 to 23 percent of patients experience an adverse event in the period following hospital discharge,¹ costing the health care system an estimated \$12 - \$44 billion per year.² Twenty percent of Medicare patients are readmitted to hospitals within 30 days of discharge, and approximately one-third of these readmissions could be avoided with improved transitional care.³ Notably, more than one-third of post-discharge follow-up testing is never completed.⁴ Hospitals are penalized financially for excess readmissions associated with certain conditions and, this year, Medicare's readmission penalties have reached a new high.

At the time of discharge, hospital-based physicians—generally hospitalists or proceduralists—hand over clinical responsibility for patients to primary care or other community physicians, or post-acute care facilities. The discharge summary is typically used during discharge transitions to document diagnostic findings and plans for post-discharge follow-up care. The Joint Commission stipulates that discharge summaries include the following elements: the reason for the hospitalization; significant findings; procedures and treatments provided; the patient's condition at discharge; instructions for patients and families, including necessary follow-up, medication changes and dietary needs; and the attending physician's signature. Notwithstanding these standards, hospital discharge summaries vary in terms of content, quality and relevancy. Discharge summaries may be incomplete or lack salient patient information such as pending diagnostic or laboratory tests. Transmittal of discharge summaries to outpatient physicians may be delayed or

never reach the appropriate treating physicians. Patients and/or their families may not fully understand discharge instructions and the importance of follow-up appointments and treatment.

Evidence in the literature has identified widespread deficits in communication at the time of discharge⁵ between physicians overseeing hospital care and community physicians. Many errors and adverse patient events during this time period are the result of communication failures,⁶ with the majority of post-discharge problems related to medications. A recent meta-analysis of interventions to improve care transitions for adults with chronic illnesses suggests that high intensity interventions may be needed to prevent hospital readmissions in the early time period following hospitalization.⁷ This study found an association between reduced 30-day hospital readmission rates and interventions consisting of communication between the hospital and primary care provider, care coordination by a nurse, and a home visit by a nurse within three days of discharge.

Quality improvement projects that have demonstrated reductions in hospital readmissions by improving hospital discharge processes are numerous and varied. Examples of effective, multifaceted interventions include the SafeMed care transitions model, Project BOOST (Better Outcomes for Older Adults through Safe Transitions), and Project RED (Re-Engineered Discharge). SafeMed uses intensive medication reconciliation, home visits and telephone follow-up to manage high-risk/high needs patients as they transition from the hospital to outpatient setting. As part of its *STEPS Forward*TM initiative, the AMA developed a module for implementing the SafeMed model within primary care practices. Project BOOST is the Society of Hospital Medicine's signature mentoring program for improving the care of patients as they transition home from the hospital or to other care facilities. Project RED, developed by Boston University Medical Center, is a multilayered intervention that includes dedicated discharge advocates, improved medication reconciliation and enhanced discharge instructions.

Patient/Family Engagement

Communication between physicians and patients and those persons who will be caring for patients post-discharge is an important component of successful care transitions, and a review of the literature has found deficits in this area as well.⁸ Failure to adequately educate patients about health care decisions and follow-up care; lower levels of health literacy among some patients; and time constraints have been found to contribute to suboptimal care transitions.⁹ Patients with limited education and non-English speakers are less likely to have adequate discharge understanding and more likely to be re-hospitalized. Shared decision-making and patient-centered discharge planning are two factors identified as countering barriers to patient engagement.

A proposed rule by the Centers for Medicare & Medicaid Services (CMS), in the fall of 2015 highlighted the importance of focusing on patients' goals and preferences during the hospital discharge process, and also better preparing patients and their families/caregivers to be active partners in post-discharge care. The proposed rule implements the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. It proposed modifying hospital Conditions of Participation by requiring all hospital inpatients, as well as many outpatients—including those receiving observation care or undergoing same-day procedures that require sedation—to be evaluated for their discharge needs and have a written plan developed. Discharge plans would need to be developed within 24 hours of admission, completed before the patient is discharged, and sent to the physician responsible for follow-up care within 48 hours of discharge. The proposed rule would also require a medication reconciliation process and a post-discharge follow-up process. Hospitals would be required to provide detailed discharge instructions to

patients going home and to continuing care facilities for patients being discharged to these settings. A post-discharge follow-up process to check on patients who return home would also be required.¹⁰

Physician Payment

Current Procedural Terminology (CPT) Codes 99238 and 99239 can be used by hospital-based physicians to bill for a hospital discharge day management service if there is a face-to-face encounter between the patient and attending physician. Medicare also pays for transitional care management (TCM), or services delivered during the 30 days after hospital discharge. TCM services must be furnished to patients who have medical and/or psychosocial problems that require moderate or high complexity medical decision-making.¹¹ Providers are required to contact patients within two business days by telephone or e-mail, or meet them face-to-face. Face-to-face visits are required within seven to 14 days, depending on whether the moderate complexity code (CPT 99494) or the high complexity code (CPT 99496) is used.

AMA POLICY

The AMA has extensive policy on care transitions, including hospital discharge. Policy H-160.942 established comprehensive, evidence-based principles addressing discharge criteria, teamwork involved in discharge planning, contingency plans for adverse events, and communication. Policy H-160.942 makes clear that responsibility and accountability for patients transitioning care settings rests with attending physicians, who are responsible for ensuring that physicians and facilities providing care in new settings are fully informed about the patient. Policy H-160.942 also maintains that the transfer of all pertinent information about the patient, and the discharge summary, should be completed before or at the time the patient is transferred to another setting. Policy H-160.942 in its entirety is appended to this report.

AMA policy recognizes the importance of effective communication between hospital-based and primary care physicians. Policy D-160.945 directs the AMA to advocate for timely and consistent inpatient and outpatient communications among hospital-based physicians and the patient's primary care referring physician to decrease gaps that may occur in the coordination of care process. Policy D-160.945 directs the AMA to explore new mechanisms to facilitate and incentivize this communication and the transmission of important data. Policy H-155.994 encourages the sharing of patients' diagnostic findings and urges hospitals to return information to attending physicians at patient discharge.

Policy D-120.965 supports medication reconciliation as a means to improve patient safety, and calls for systems to support physicians in medication reconciliation. The AMA has numerous policies on usability and interoperability of electronic health records (EHRs), including Policy D-478.995 on health information technology (health IT).

DISCUSSION

The Council recognizes that the health care landscape is evolving in terms of care delivery models and improvements in health IT, and that implementation of a single hospital discharge standard across diverse clinical practice settings is impractical at this time. Improved EHR capabilities, which will enable more widespread use of direct messaging (e.g., admit/discharge/transfer messaging) and standardized electronic forms (e.g., the Continuity of Care Document), have the potential to enhance communication and the timely exchange of patient information among providers across multiple care settings. The Council recognizes that the AMA continues to engage in extensive advocacy to improve EHRs and address technology barriers that impede the exchange

1 of meaningful patient information during care transitions, and that numerous AMA policies guide
2 this work. The Council recommends reaffirming Policy D-478.995, which directs the AMA to
3 continue its advocacy to expedite interoperability of EHR systems, standardize key EHR elements,
4 and engage the vendor community to promote improvements in EHR usability.

5
6 After reviewing the literature and extensive AMA policy on care transitions, the Council
7 appreciates the need for a more refined discharge process that improves the quality and safety of
8 patient care and reduces the incidence of adverse events and hospital readmissions. Recognizing
9 that multi-component interventions are more likely to reduce readmissions, the Council has
10 identified several critical elements that can be adapted locally.

11
12 The Council further recognizes that consistent physician-to-physician communication across care
13 settings is integral to achieving an efficient, patient-centered discharge process. Because
14 community physicians who are knowledgeable of their patients' hospitalizations are better prepared
15 to provide appropriate discharge follow-up, Council on Medical Service Report 6-A-16
16 recommended prompt notification to community physicians of patient hospitalizations, and also the
17 timely exchange of relevant patient information. Communication between hospital and community
18 physicians at the time of discharge, and the timely transfer of patient information between hospitals
19 and providers responsible for patients' follow-up care, are also addressed in Policies H-160.942
20 and D-160.945. The Council believes that the comprehensive, evidence-based discharge principles
21 and criteria outlined in Policy H-160.942 remain relevant and recommends that this policy be
22 reaffirmed. The Council further recommends reaffirmation of Policy D-160.945, which supports
23 timely and consistent communication between physicians in inpatient and outpatient care settings.
24 AMA policies recommended for reaffirmation are appended to this report.

25
26 The Council discussed timing of discharge planning and completion of discharge summaries and
27 points to existing policy stating that discharge summaries should be completed before or at the time
28 of patient transfer, and discouraging discharge timing requirements by Congress for specific
29 treatments or procedures (Policy H-160.942). The Council believes engagement of patients and
30 their families/caregivers at the time of hospital admission, and before hospitalization for surgical
31 patients, will lead to greater patient self-management and participation in their care, especially
32 during brief hospitalizations. Accordingly, the Council recommends that the AMA encourage the
33 initiation of the discharge planning process, whenever possible, at the time patients are admitted for
34 inpatient or observation services and before patients scheduled for surgery are hospitalized.

35
36 The Council recognizes the frustration with lengthy discharge documents that do not highlight key
37 points, often requiring physicians to sift through numerous pages of patient information.
38 Accordingly, the Council recommends that the AMA encourage the development of discharge
39 summaries that are presented to physicians in a meaningful format that prominently highlights
40 salient patient information, such as the discharging physician's narrative and recommendations for
41 ongoing care.

42
43 The Council discussed the importance of engaging patients and their families/caregivers in the
44 discharge process to increase patient involvement in discharge planning and encourage self-
45 management of care after hospitalizations. Communication with patients, and those persons who
46 will be caring for patients post-discharge, is critical to improving patient outcomes and preventing
47 re-hospitalizations and emergency department visits. The Council believes it is good clinical
48 practice to not only provide detailed discharge instructions and education, but also to confirm
49 understanding of this information by patients and their families/caregivers. Accordingly, the
50 Council recommends new AMA policy that encourages active engagement of patients and their
51 families/caregivers in the discharge process, and offers guidelines to ensure that patient needs,

including communication needs, are taken into account and that discharge instructions are fully understood.

In its review of the literature, the Council found that medication reconciliation is an effective strategy for preventing adverse patient events in the post-discharge period. Medication reconciliation is the process of creating the most accurate list of medications a patient is taking, and comparing that list against the medications included in the physician's discharge summary. The Council recommends that the AMA encourage implementation of medication reconciliation as part of the hospital discharge process, and outlines strategies to help ensure that patients take their medications correctly post-hospitalization.

The Council also found that successful discharge interventions often include protocols for post-discharge follow-up. Communicating with patients post hospitalization—in their homes or continuing care facilities, or by telephone or e-mail—helps ensure adherence to discharge instructions and may also uncover symptoms that need attention. Accordingly, the Council recommends that our AMA encourage follow-up in the early time period after discharge as part of the hospital discharge process, particularly for medically complex patients who are at high risk of re-hospitalization.

Finally, the Council maintains that hospitals should evaluate their discharge processes on a regular basis to ensure that they incorporate patients' post-discharge needs. The Council therefore recommends that the AMA encourage hospitals to review early readmissions and modify their discharge processes accordingly. Taken together, the Council is optimistic that these recommendations will be an impactful addition to existing AMA policy on care transitions, including the discharge period.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy D-478.995, which directs the AMA to continue its extensive advocacy to expedite interoperability of electronic health record (EHR) systems, standardize key EHR elements, and engage the vendor community to promote improvements in EHR usability. (Reaffirm HOD Policy)
2. That our AMA reaffirm Policy H-160.942, which outlines evidence-based discharge criteria and principles regarding discharge planning, teamwork, communication, responsibility/accountability among attending physicians and continuing care providers, as well as the transfer of pertinent patient information and the discharge summary. (Reaffirm HOD Policy)
3. That our AMA reaffirm Policy D-160.945, which directs the AMA to advocate for timely and consistent communication between physicians in inpatient and outpatient care settings to decrease gaps in care coordination and improve quality and patient safety, and to explore new mechanisms to facilitate and incentivize this communication. (Reaffirm HOD Policy)
4. That our AMA encourage the initiation of the discharge planning process, whenever possible, at the time patients are admitted for inpatient or observation services and, for surgical patients, prior to hospitalization. (New HOD Policy)

- 1 5. That our AMA encourage the development of discharge summaries that are presented to
2 physicians in a meaningful format that prominently highlight salient patient information, such
3 as the discharging physician's narrative and recommendations for ongoing care. (New HOD
4 Policy)
5
- 6 6. That our AMA encourage hospital engagement of patients and their families/caregivers in the
7 discharge process, using the following guidelines:
8
 - 9 a. Information from patients and families/caregivers is solicited during discharge
10 planning, so that discharge plans are tailored to each patient's needs, goals of care and
11 treatment preferences.
 - 12 b. Patient language proficiency, literacy levels, cognitive abilities and communication
13 impairments (e.g., hearing loss) are assessed during discharge planning. Particular
14 attention is paid to the abilities and limitations of patients and their families/caregivers.
 - 15 c. Specific discharge instructions are provided to patients and families or others
16 responsible for providing continuing care both verbally and in writing. Instructions are
17 provided to patients in layman's terms, and whenever possible, using the patient's
18 preferred language.
 - 19 d. Key discharge instructions are highlighted for patients to maximize compliance with
20 the most critical orders.
 - 21 e. Understanding of discharge instructions and post-discharge care, including warning
22 signs and symptoms to look for and when to seek follow-up care, is confirmed with
23 patients and their families/caregiver(s) prior to discharge from the hospital. (New HOD
24 Policy)
25
- 26 7. That our AMA support implementation of medication reconciliation as part of the hospital
27 discharge process. The following strategies are suggested to optimize medication reconciliation
28 and help ensure that patients take medications correctly after they are discharged:
29
 - 30 a. All discharge medications, including prescribed and over-the-counter medications,
31 should be reconciled with medications taken pre-hospitalization.
 - 32 b. An accurate list of medications, including those to be discontinued as well as
33 medications to be taken after hospital discharge, and the dosage and duration of each
34 drug, should be communicated to patients.
 - 35 c. Medication instructions should be communicated to patients and their
36 families/caregivers verbally and in writing.
 - 37 d. For patients with complex medication schedules, the involvement of physician-led
38 multidisciplinary teams in medication reconciliation including, where feasible,
39 pharmacists should be encouraged. (New HOD Policy)
40
- 41 8. That our AMA encourage patient follow-up in the early time period after discharge as part of
42 the hospital discharge process, particularly for medically complex patients who are at high-risk
43 of re-hospitalization. (New HOD Policy)
44
- 45 9. That our AMA encourage hospitals to review early readmissions and modify their discharge
46 processes accordingly. (New HOD Policy)

Fiscal Note: Less than \$500.

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- ⁴ Moore C, McGinn T et al. Tying up loose ends: Discharging patients with unresolved medical issues. *Archives of Internal Medicine*. 2007: 167(12):1305.
- ⁵ Kripalani S, LeFevre F et al. Deficits in Communication and Information Transfer Between Hospital-Based and Primary Care Physicians: Implications for Safety and Continuity of Care. *JAMA*. Vol. 297, No. 8. February 28, 2007.
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- ¹⁰ Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies. *Federal Register*: Nov. 3, 2015.
- ¹¹ Centers for Medicare & Medicaid Services. Medicare Learning Network: Transitional Care Management Services. March 2016.

Appendix

H-160.942 Evidence-Based Principles of Discharge and Discharge Criteria

- (1) The AMA defines discharge criteria as organized, evidence-based guidelines that protect patients' interests in the discharge process by following the principle that the needs of patients must be matched to settings with the ability to meet those needs.
- (2) The AMA calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients and that are flexible to meet advances in medical and surgical therapies and adapt to local and regional variations in health care settings and services.
- (3) The AMA encourages incorporation of discharge criteria into practice parameters, clinical guidelines, and critical pathways that involve hospitalization.
- (4) The AMA promotes the local development, adaption and implementation of discharge criteria.
- (5) The AMA promotes training in the use of discharge criteria to assist in planning for patient care at all levels of medical education. Use of discharge criteria will improve understanding of the pathophysiology of disease processes, the continuum of care and therapeutic interventions, the use of health care resources and alternative sites of care, the importance of patient education, safety, outcomes measurements, and collaboration with allied health professionals.
- (6) The AMA encourages research in the following areas: clinical outcomes after care in different health care settings; the utilization of resources in different care settings; the actual costs of care from onset of illness to recovery; and reliable and valid ways of assessing the discharge needs of patients.
- (7) The AMA endorses the following principles in the development of evidence-based discharge criteria and an organized discharge process:
 - (a) As tools for planning patients' transition from one care setting to another and for determining whether patients are ready for the transition, discharge criteria are intended to match patients' care needs to the setting in which their needs can best be met.
 - (b) Discharge criteria consist of, but are not limited to:
 - (i) Objective and subjective assessments of physiologic and symptomatic stability that are matched to the ability of the discharge setting to monitor and provide care.
 - (ii) The patient's care needs that are matched with the patient's, family's, or caregiving staff's independent understanding, willingness, and demonstrated performance prior to discharge of processes and procedures of self care, patient care, or care of dependents.
 - (iii) The patient's functional status and impairments that are matched with the ability of the care givers and setting to adequately supplement the patients' function.
 - (iv) The needs for medical follow-up that are matched with the likelihood that the patient will participate in the follow-up. Follow-up is time-, setting-, and service-dependent. Special considerations must be taken to ensure follow-up in vulnerable populations whose access to health care is limited.
 - (c) The discharge process includes, but is not limited to:
 - (i) Planning: Planning for transition/discharge must be based on a comprehensive assessment of the patient's physiological, psychological, social, and functional needs. The discharge planning process should begin early in the course of treatment for illness or injury (prehospitalization for elective cases) with involvement of patient, family and physician from the beginning.
 - (ii) Teamwork: Discharge planning can best be done with a team consisting of the patient, the family, the physician with primary responsibility for continuing care of the patient, and other appropriate health care professionals as needed.

(iii) Contingency Plans/Access to Medical Care: Contingency plans for unexpected adverse events must be in place before transition to settings with more limited resources. Patients and caregivers must be aware of signs and symptoms to report and have a clearly defined pathway to get information directly to the physician, and to receive instructions from the physician in a timely fashion.

(iv) Responsibility/Accountability: Responsibility/accountability for an appropriate transition from one setting to another rests with the attending physician. If that physician will not be following the patient in the new setting, he or she is responsible for contacting the physician who will be accepting the care of the patient before transfer and ensuring that the new physician is fully informed about the patient's illness, course, prognosis, and needs for continuing care. If there is no physician able and willing to care for the patient in the new setting, the patient should not be discharged. Notwithstanding the attending physician's responsibility for continuity of patient care, the health care setting in which the patient is receiving care is also responsible for evaluating the patient's needs and assuring that those needs can be met in the setting to which the patient is to be transferred.

(v) Communication: Transfer of all pertinent information about the patient (such as the history and physical, record of course of treatment in hospital, laboratory tests, medication lists, advanced directives, functional, psychological, social, and other assessments), and the discharge summary should be completed before or at the time of transfer of the patient to another setting. Patients should not be accepted by the new setting without a copy of this patient information and complete instructions for continued care.

(8) The AMA supports the position that the care of the patient treated and discharged from a treating facility is done through mutual consent of the patient and the physician; and

(9) Policy programs by Congress regarding patient discharge timing for specific types of treatment or procedures be discouraged. (CSA Rep. 4, A-96; Reaffirmation I-96; Modified by Res. 216, A-97; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed: BOT Rep. 1, A-08)

D-160.945 Communication Between Hospitals and Primary Care Referring Physicians

Our AMA: (1) advocates for continued Physician Consortium for Performance Improvement® (PCPI) participation in the American College of Physicians (ACP), the Society of General Internal Medicine (SGIM), and the Society of Hospital Medicine (SHM) work to develop principles and standards for care transitions that occur between the inpatient and outpatient settings; (2) advocates for timely and consistent inpatient and outpatient communications to occur among the hospital and hospital-based providers and physicians and the patient's primary care referring physician; including the physician of record, admitting physician, and physician-to-physician, to decrease gaps that may occur in the coordination of care process and improve quality and patient safety; (3) will continue its participation with the Health Information Technology Standards Panel (HITSP) and provide input on the standards harmonization and development process; (4) continues its efforts with The Joint Commission, the Centers for Medicare & Medicaid Services, and state survey and accreditation agencies to develop accreditation standards that improve patient safety and quality; and (5) will explore new mechanisms to facilitate and incentivize communication and transmission of data for timely coordination of care (via telephone, fax, e-mail, or face-to-face communication) between the hospital-based physician and the primary physician. (BOT Rep. 1, A-08; Reaffirmed in lieu of Res. 731, A-09; Appended: Res. 722, A-11; Reaffirmed: CMS Rep. 3, I-12)

D-478.995 National Health Information Technology

1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden

to the physician and maintaining the art of medicine without compromising patient care. 2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C) advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care.; and (D) advocates for more research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems. 3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians' practices; and (B) develop minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs. 4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery. 5. Our AMA will seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology's (ONC) certification process. 6. Our AMA will collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability. 7. Our AMA will directly engage the EHR vendor community to promote improvements in EHR usability. (Res. 730, I-04 Reaffirmed in lieu of Res. 818, I-07 Reaffirmed in lieu of Res. 726, A-08 Reaffirmation A-10 Reaffirmed: BOT Rep. 16, A-11 Modified: BOT Rep. 16, A-11 Modified: BOT Rep. 17, A-12 Reaffirmed in lieu of Res. 714, A-12 Reaffirmed in lieu of Res. 715, A-12 Reaffirmed: BOT Rep. 24, A-13 Reaffirmed in lieu of Res. 724, A-13 Appended: Res. 720, A-13 Appended: Sub. Res. 721, A-13 Reaffirmed: CMS Rep. 4, I-13 Reaffirmation I-13 Appended: BOT Rep. 18, A-14 Appended: BOT Rep. 20, A-14 Reaffirmation A-14 Reaffirmed: BOT Rep. 17, A-15 Reaffirmed in lieu of Res. 208, A-15 Reaffirmed in lieu of Res. 223, A-15 Reaffirmation I-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 801
(I-16)

Introduced by: Medical Student Section

Subject: Increasing Access to Medical Devices for Insulin-Dependent Diabetics

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, The average list price of an insulin pump for Type 1 and Type 2 Diabetes Mellitus (T1DM and T2DM) is between \$4,995 and \$6,500, and pump supplies (infusion pump cartridges, glucose meter test strips, lancets, batteries, and syringes) can cost an additional \$250 per month;^{1,2} and

Whereas, Under Medicare Part B, diabetic patients must remit a 20% copayment for insulin pump devices and related supplies on an ongoing basis, after meeting their yearly Part B deductible;³ and

Whereas, T1DM patients using insulin pumps experience significant reductions in HbA1c, lower rates of retinopathy and peripheral nerve abnormality, fewer hospitalizations, and superior quality of life as compared to patients who use multiple daily injections (MDI);^{4,5,6} and

Whereas, Accumulating evidence has demonstrated the safety and efficacy of insulin pump therapy in T2DM patients, particularly among those with poor glycemic control on MDI, and has shown that pump therapy produces sustained and durable reductions in HbA1c, without increasing the risk of hypoglycemia;^{7,8,9,10,11} and

Whereas, On September 1st, 2015, the Centers for Medicare & Medicaid Services announced a forthcoming initiative to test a “Medicare Advantage Value-Based Insurance Design Model” for chronic conditions, including diabetes, in which participating plans “choose to reduce or eliminate cost sharing for items or services, including covered Part D drugs, that they have identified as high-value for a given target population”, with broad flexibility with respect to items and services eligible for reduced cost sharing;¹² and

¹ Boyd LC, Boyd ST. Insulin pump therapy training and management: an opportunity for community pharmacists. *J Manag Care Pharm.* 2008;14(8):790-4.

² FamilyHealthOnline. (2015) “Insulin Pumps”. Available at:

http://www.familyhealthonline.ca/fho/diabetes/DI_insulinPumps_MDb08.asp. Accessed April 17th, 2016.

³ Centers for Medicare and Medicaid Services. “Medicare’s Coverage of Diabetes Supplies and Services.” Available at: <https://www.medicare.gov/Pubs/pdf/11022.pdf>. Accessed March 30, 2016.

⁴ Pérez-garcía L, Goñi-iriarte MJ, García-mouriz M. Comparison of treatment with continuous subcutaneous insulin infusion versus multiple daily insulin injections with bolus calculator in patients with type 1 diabetes. *Endocrinol Nutr.* 2015;62(7):331-7.

⁵ Zabeen B, Craig ME, Virk SA, et al. Insulin Pump Therapy Is Associated with Lower Rates of Retinopathy and Peripheral Nerve Abnormality. *PLoS ONE.*

⁶ Pickup JC. Management of diabetes mellitus: is the pump mightier than the pen?. *Nat Rev Endocrinol.* 2012;8(7):425-33.

⁷ Leinung MC, Thompson S, Luo M, Leykina L, Nardacci E. Use of insulin pump therapy in patients with type 2 diabetes after failure of multiple daily injections. *Endocr Pract.* 2013;19(1):9-13.

⁸ Reznik Y, Cohen O, Aronson R, et al. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. *Lancet.* 2014;384(9950):1265-72

⁹ Didangelos T, Iliadis F. Insulin pump therapy in adults. *Diabetes Res Clin Pract.* 2011;93 Suppl 1:S109-13.

¹⁰ Aronson R, Reznik Y, Conget I, et al. Sustained efficacy of insulin pump therapy, compared with multiple daily injections, in type 2 diabetes: 12-month data from the OpT2mise randomized trial. *Diabetes Obes Metab.* 2016;

¹¹ Conget I, Castaneda J, Petrovski G, et al. The Impact of Insulin Pump Therapy on Glycemic Profiles in Patients with Type 2 Diabetes: Data from the OpT2mise Study. *Diabetes Technol Ther.* 2015;

¹² Centers for Medicare & Medicaid Services. (2015). “Medicare Advantage Value-Based Insurance Design Model.” Available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html>. Accessed March 30, 2016.

1 Whereas, United Healthcare recently studied implementation of a Value-Based Insurance
2 Design in their Diabetes Health Plan, which concluded that offering diabetes supplies, office
3 visits, and related prescription drugs at low or no cost to patients increased plan adherence and
4 improved patient health;^{13,14} and
5

6 Whereas, Existing AMA policy supports Medicare coverage of continuous glucose monitoring
7 systems for insulin-dependent diabetics (Medicare Coverage of Continuous Glucose Monitoring
8 Devices for Patients with Insulin-Dependent Diabetes H-330.885), and existing AMA Ethical
9 Opinion assigns physicians individually and collectively the ethical responsibility to ensure that
10 all persons have access to needed care regardless of their economic means (11.1.4 Financial
11 Barriers to Health Care Access); and
12

13 Whereas, Pursuant to its strategic focus area of Improving Health Outcomes, our AMA is
14 committed to a national effort to prevent Type 2 diabetes; and
15

16 Whereas, The estimated direct medical costs and indirect costs (disability, work loss, and
17 premature death) from diabetes in the United States in 2012 was \$245 billion;¹⁵ therefore be it
18

19 RESOLVED, That our American Medical Association work with relevant stakeholders to
20 encourage the development of plans for inclusion in the Medicare Advantage Value Based
21 Insurance Design Model that reduce copayments/coinsurance for diabetes prevention,
22 medication, supplies, and equipment including pumps and continuous glucose monitors, while
23 adhering to the principles established in AMA Policy H-185.939, Value-Based Insurance Design.
24 (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 08/29/16

RELEVANT AMA POLICY

Diabetic Documentation Requirements D-185.983

1. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority of the Centers for Medicare & Medicaid Services (CMS) and other health care insurers placing onerous barriers on diabetic patients to procure medically necessary durable medical equipment and supplies.
2. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority and policy of CMS and other insurers to practice medicine through their diabetes guidelines, and place excessive time and financial burdens without reimbursement on a physician assisting patients seeking reimbursement for supplies needed to treat their diabetes.

Citation: (Res. 730, A-13)

CMS Required Diabetic Supply Forms H-330.908

Our AMA requests that CMS change its requirement so that physicians need only re-write prescriptions for glucose monitors every twelve months, instead of a six month requirement, for Medicare covered diabetic patients and make the appropriate diagnosis code sufficient for the determination of medical necessity.

Citation: (Sub. Res. 102, A-00; Reaffirmation and Amended: Res. 520, A-02; Modified: CMS Rep. 4, A-12)

¹³ Managed Care. "Value-Based Insurance Design Helps Cut Plan's Diabetes Costs." Available at: <http://www.managedcaremag.com/archives/2013/2/value-based-insurance-design-helps-cut-plan's-diabetes-costs>. Accessed March 30, 2016.

¹⁴ Healthcare Web Summit. "Value-Based Plan Design for Diabetes" Available at: <http://www.healthwebsummit.com/diabetes030713.htm>. Accessed March 30, 2016.

¹⁵ Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA; 2014. Accessed Aug. 23, 2015. Available at: <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>.

Value-Based Insurance Design H-185.939

Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:

- a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.
- b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.
- c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.
- d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.
- e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.
- f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.
- g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties.
- h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.
- i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972).

Citation: CMS Rep. 2, A-13; Reaffirmed in lieu of Res. 122, A-15; Reaffirmed in lieu of: Res. 121, A-16

Medicare Coverage of Continuous Glucose Monitoring Devices for Patients with Insulin-Dependent Diabetes H-330.885

Our AMA supports efforts to achieve Medicare coverage of continuous glucose monitoring systems for patients with insulin-dependent diabetes.

Res. 126, A-14

Drug Issues in Health System Reform H-100.964

The AMA: (1) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.

(2) supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.

(3) reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.

(4) reaffirms AMA Policies H-120.974 and H-125.992, opposing the substitution of FDA B-rated generic drug products.

(5) supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.

(6) supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.

(7a) encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.

(7b) encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not

a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.

(8) recognizes the role of the pharmacist in counseling patients about their medicines in order to reinforce the message of the prescribing physician and improve medication compliance.

(9) reaffirms AMA Policies H-115.995 and H-115.997, opposing FDA-mandated patient package inserts for all marketed prescription drugs.

(10) opposes payment of pharmacists by third party payers on a per prescription basis when the sole purpose is to convince the prescribing physician to switch to a less expensive "formulary" drug because economic incentives can interfere with pharmacist professional judgment.

(11) reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.

(12) supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public disclosure of patient and reporter identities.

(13) opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.

(14) reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.

(15) encourages the use of three compendia (AMA's DRUG EVALUATIONS; United States Pharmacopeial-Drug Information, Volume I; and American Hospital Formulary Service-Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses.

(16) reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs.

(17) reaffirms AMA Policy H-120.983, urging the pharmaceutical industry to provide the same economic opportunities to individual pharmacies as given to mail service pharmacies.

Citation: (BOT Rep. 53, A-94; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CSA Rep. 3, A-97;

Amended: CSA Rep. 2, I-98; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-10; Reaffirmed in lieu of Res. 201, I-11)

Expansion of National Diabetes Prevention Program H-440.844

Our AMA: (1) supports evidence-based, physician-prescribed diabetes prevention programs, (2) supports the expansion of the NDPP to more CDC-certified sites across the country; and (3) will support coverage of the NDPP by Medicare and all private insurers.

Citation: (Sub. Res. 911, I-12)

Strategies to Increase Diabetes Awareness D-440.935

Our AMA will organize a series of activities for the public in collaboration with health care workers and community organizations to bring awareness to the severity of diabetes and measures to decrease its incidence.

Citation: (Res. 412, A-13)

Dysmetabolic Syndrome and Type 2 Diabetes in Children D-440.949

Our AMA (1) supports efforts to develop national-level data that would provide for the monitoring of the prevalence of diabetes among youth by type; and (2) encourages greater awareness by physicians of type 2 diabetes and its complications in children and will promote the availability of resources and information about the prevention and treatment of this growing public health threat.

Citation: (Res. 418, A-07)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 802
(I-16)

Introduced by: Medical Student Section

Subject: Eliminating Fail First Policy in Addiction Treatment

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, Health insurers utilize “fail first” policies (also referred to as Step Therapy), which require that patients with addiction attempt and fail an outpatient program prior to receiving coverage for inpatient treatment, even if a healthcare provider recommends an inpatient treatment, as a cost-saving measure;^{1,2} and

Whereas, Step therapy and fail-first protocols were associated with 4.7 times greater odds of a medication access or continuity problem;³ and

Whereas, As of 2014, the rate of drug overdose deaths has increased 137% since 2000, including a 200% increase in the rate of overdose deaths involving opioids;⁴ and

Whereas, The Mental Health Parity and Addiction Equity Act (MHPAEA) prevents group health plans and health insurance issuers that provide mental health or substance use disorder benefits from subjecting mental health and substance use disorder coverage to more restrictive limitations than those applied to general medical care;^{5,6} and

Whereas, “Fail first” policies are classified as non-quantifiable treatment limitations under MHPAEA regulations and can represent a violation of the act if they are more restrictive than limitations applied to medical and surgical benefits;^{7,8} and

Whereas, The AMA supports enforcement of the Mental Health Parity Act at the federal and state level (H-345.975); and

Whereas, The AMA opposes laws, policies, and procedures that would limit a patient's access to medically necessary pharmacological therapies for opioid use disorder (H-95.944) and recognizes that patients in need of treatment for alcohol or other drug-related disorders should be treated for these medical conditions by qualified professionals in a manner consonant with accepted practice guidelines and patient placement (H-95.951); and

¹ Olivencia, J. Roundtable Puts the Broken “Fail First” Drug Treatment Policy Under a Microscope. CSG Justice Center. June 16, 2014. Last accessed: August 9, 2016.

² Step Therapy and Fail First Policies Backgrounder. Available at: <https://failfirsthurts.org/ffh/wp-content/uploads/2012/10/WWP-Purple-Paper-Step-Therapy-and-Fail-First-Policies.pdf>. Last accessed: August 9, 2016.

³ Alanis-Hirsch, K. et al. Extended-Release Naltrexone: A Qualitative Analysis of Barriers to Routine Use. Journal of Substance Abuse Treatment. 2016 Mar; 62: 68-73.

⁴ Rudd, R. et al. Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014. Morbidity and Mortality Weekly Report. 2016;64(50):1378-382. CDC.

⁵ Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, Public Law 110-343.

⁶ Horgan, C.M. et al. Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services. Psychiatric Services. 2016;7(2): 162-68.

⁷ Goodell, S. et al. Health Policy Brief: Enforcing Mental Health Parity. Health Affairs. November 9, 2015.

⁸ United States Department of Labor. Frequently Asked Questions for Employees about the Mental Health Parity and Addiction Equity Act. <http://www.dol.gov/ebsa/faqs/faq-mhpaea2.html>. Accessed April 20, 2016.

- 1 Whereas, One of the five goals of the AMA Task Force to Reduce Prescription Opioid Abuse is
- 2 to enhance patients' access to treatment for opioid addiction; therefore be it
- 3
- 4 RESOLVED, That our American Medical Association advocate for the elimination of the "fail
- 5 first" policy implemented by insurance companies for addiction treatment. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 08/29/16

RELEVANT AMA POLICY

Maintaining Mental Health Services by States H-345.975

Our AMA:

1. supports maintaining essential mental health services at the state level, to include maintaining state inpatient and outpatient mental hospitals, community mental health centers, addiction treatment centers, and other state-supported psychiatric services;
2. supports state responsibility to develop programs that rapidly identify and refer individuals with significant mental illness for treatment, to avoid repeated psychiatric hospitalizations and repeated interactions with the law, primarily as a result of untreated mental conditions;
3. supports increased funding for state Mobile Crisis Teams to locate and treat homeless individuals with mental illness;
4. supports enforcement of the Mental Health Parity Act at the federal and state level; and
5. will take these resolves into consideration when developing policy on essential benefit services.

Citation: (Res. 116, A-12; Reaffirmation A-15)

Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.

Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16

Substance Use Disorders as a Public Health Hazard H-95.975

Our AMA: (1) recognizes that substance use disorders are a major public health problem in the United States today and that its solution requires a multifaceted approach;

- (2) declares substance use disorders are a public health priority;
- (3) supports taking a positive stance as the leader in matters concerning substance use disorders, including addiction;
- (4) supports studying innovative approaches to the elimination of substance use disorders and their resultant street crime, including approaches which have been used in other nations; and
- (5) opposes the manufacture, distribution, and sale of substances created by chemical alteration of illicit substances, herbal remedies, and over-the-counter drugs with the intent of circumventing laws prohibiting possession or use of such substances.

Citation: (Res. 7, I-89; Appended: Sub. Res. 401, Reaffirmed: Sunset Rep., I-99; Reaffirmed: CSAPH Rep. 1, A-09; Modified and Reaffirmed: CSAPH Rep. 1, A-09)

Harm Reduction Through Addiction Treatment H-95.956

The AMA endorses the concept of prompt access to treatment for chemically dependent patients, regardless of the type of addiction, and the AMA will work toward the implementation of such an approach nationwide. The AMA affirms that addiction treatment is a demonstrably viable and efficient method of reducing the harmful personal and social consequences of the inappropriate use of alcohol and other psychoactive drugs and urges the Administration and Congress to provide significantly increased funding for treatment of alcoholism and other drug dependencies and support of basic and clinical research so that the causes, mechanisms of action and development of addiction can continue to be elucidated to enhance treatment efficacy.

Citation: (Res. 411, A-95; Appended: Res. 405, I-97; Reaffirmation I-03; Reaffirmed: CSAPH Rep. 1, A-13)

Third-Party Payer Policies on Opioid Use Disorder Pharmacotherapy H-95.944

Our AMA opposes federal, state, third-party and other laws, policies, rules and procedures, including those imposed by Pharmacy Benefit Managers working for Medicaid, Medicare, TriCare, and commercial health plans, that would limit a patient's access to medically necessary pharmacological therapies for opioid use disorder, whether administered in an office-based opioid treatment setting or in a federal regulated Opioid Treatment Program, by imposing limitations on the duration of treatment, medication dosage or level of care.

Citation: (Res. 710, A-13)

Role of Self-Help in Addiction Treatment H-95.951

The AMA: (1) recognizes that (a) patients in need of treatment for alcohol or other drug-related disorders should be treated for these medical conditions by qualified professionals in a manner consonant with accepted practice guidelines and patient placement criteria; and (b) self-help groups are valuable resources for many patients and their families and should be utilized by physicians as adjuncts to a treatment plan; and (2) urges managed care organizations and insurers to consider self-help as a complement to, not a substitute for, treatment directed by professionals, and to refrain from using their patient's involvement in self-help activities as a basis for denying authorization for payment for professional treatment of patients and their families who need such care.

Citation: (Res. 713, A-98; Reaffirmed: CSAPH Rep. 2, A-08)

Opioid Treatment and Prescription Drug Monitoring Programs D-95.980

Our AMA will seek changes to allow states the flexibility to require opioid treatment programs to report to prescription monitoring programs.

Citation: (BOT Rep. 11, A-10)

The Reduction of Medical and Public Health Consequences of Drug Abuse H-95.954

Our AMA: (1) encourages national policy-makers to pursue an approach to the problem of drug abuse aimed at preventing the initiation of drug use, aiding those who wish to cease drug use, and diminishing the adverse consequences of drug use; (2) encourages policy-makers to recognize the importance of screening for alcohol and other drug use in a variety of settings, and to broaden their concept of addiction treatment to embrace a continuum of modalities and goals, including appropriate measures of harm reduction, which can be made available and accessible to enhance positive treatment outcomes for patients and society; (3) encourages the expansion of opioid maintenance programs so that opioid maintenance therapy can be available for any individual who applies and for whom the treatment is suitable. Training must be available so that an adequate number of physicians are prepared to provide treatment. Program regulations should be strengthened so that treatment is driven by patient needs, medical judgment, and drug rehabilitation concerns. Treatment goals should acknowledge the benefits of abstinence from drug use, or degrees of relative drug use reduction; (4) encourages the extensive application of needle and syringe exchange and distribution programs and the modification of restrictive laws and regulations concerning the sale and possession of needles and syringes to maximize the availability of sterile syringes and needles, while ensuring continued reimbursement for medically necessary needles and

syringes. The need for such programs and modification of laws and regulations is urgent, considering the contribution of injection drug use to the epidemic of HIV infection; (5) encourages a comprehensive review of the risks and benefits of U.S. state-based drug legalization initiatives, and that until the findings of such reviews can be adequately assessed, the AMA reaffirm its opposition to drug legalization; (6) strongly supports the ability of physicians to prescribe syringes and needles to patients with injection drug addiction in conjunction with addiction counseling in order to help prevent the transmission of contagious diseases; and (7) encourages state medical associations to work with state regulators to remove any remaining barriers to permit physicians to prescribe needles for patients.

Citation: (CSA Rep. 8, A-97; Reaffirmed: CSA Rep. 12, A-99; Appended: Res. 416, A-00; Reaffirmation I-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 2, I-13)

Reduction of Medical and Public Health Consequences of Drug Abuse: Update D-95.999

Our AMA encourages state medical societies to advocate for the expansion of and increased funding for needle and syringe-exchange programs and methadone maintenance and other opioid treatment services and programs in their states.

Citation: (CSA Rep. 12, A-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09)

Evaluating Health System Reform Proposals H-165.888

1. Our AMA will continue its efforts to ensure that health system reform proposals adhere to the following principles:

- A. Physicians maintain primary ethical responsibility to advocate for their patients' interests and needs.
- B. Unfair concentration of market power of payers is detrimental to patients and physicians, if patient freedom of choice or physician ability to select mode of practice is limited or denied. Single-payer systems clearly fall within such a definition and, consequently, should continue to be opposed by the AMA. Reform proposals should balance fairly the market power between payers and physicians or be opposed.
- C. All health system reform proposals should include a valid estimate of implementation cost, based on all health care expenditures to be included in the reform; and supports the concept that all health system reform proposals should identify specifically what means of funding (including employer-mandated funding, general taxation, payroll or value-added taxation) will be used to pay for the reform proposal and what the impact will be.
- D. All physicians participating in managed care plans and medical delivery systems must be able without threat of punitive action to comment on and present their positions on the plan's policies and procedures for medical review, quality assurance, grievance procedures, credentialing criteria, and other financial and administrative matters, including physician representation on the governing board and key committees of the plan.
- E. Any national legislation for health system reform should include sufficient and continuing financial support for inner-city and rural hospitals, community health centers, clinics, special programs for special populations and other essential public health facilities that serve underserved populations that otherwise lack the financial means to pay for their health care.
- F. Health system reform proposals and ultimate legislation should result in adequate resources to enable medical schools and residency programs to produce an adequate supply and appropriate generalist/specialist mix of physicians to deliver patient care in a reformed health care system.
- G. All civilian federal government employees, including Congress and the Administration, should be covered by any health care delivery system passed by Congress and signed by the President.
- H. True health reform is impossible without true tort reform.

2. Our AMA supports health care reform that meets the needs of all Americans including people with injuries, congenital or acquired disabilities, and chronic conditions, and as such values function and its improvement as key outcomes to be specifically included in national health care reform legislation.

3. Our AMA supports health care reform that meets the needs of all Americans including people with mental illness and substance use / addiction disorders and will advocate for the inclusion of full parity for the treatment of mental illness and substance use / addiction disorders in all national health

care reform legislation.

4. Our AMA supports health system reform alternatives that are consistent with AMA principles of pluralism, freedom of choice, freedom of practice, and universal access for patients.

Citation: (Res. 118, I-91; Res. 102, I-92; BOT Rep. NN, I-92; BOT Rep. S, A-93; Reaffirmed: Res. 135, A-93; Reaffirmed: BOT Reps. 25 and 40, I-93; Reaffirmed in lieu of Res. 714, I-93; Res. 130, I-93; Res. 316, I-93; Sub. Res. 718, I-93; Reaffirmed: CMS Rep. 5, I-93; Res. 124, A-94; Reaffirmed by BOT Rep. 1- I-94; CEJA Rep. 3, A-95; Reaffirmed: BOT Rep. 34, I-95; Reaffirmation A-00; Reaffirmation A-01; Reaffirmed: CMS Rep. 10, A-03; Reaffirmed: CME Rep. 2, A-03; Reaffirmed and Modified: CMS Rep. 5, A-04; Reaffirmed with change in title: CEJA Rep. 2, A-05; Consolidated: CMS Rep. 7, I-05; Reaffirmation I-07; Reaffirmed in lieu of Res. 113, A-08; Reaffirmation A-09; Res. 101, A-09; Sub. Res. 110, A-09; Res. 123, A-09; Reaffirmed in lieu of Res. 120, A-12)

Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction D-95.981

1. Our AMA:

- a. will collaborate with relevant medical specialty societies to develop continuing medical education curricula aimed at reducing the epidemic of misuse of and addiction to prescription controlled substances, especially by youth;
- b. encourages medical specialty societies to develop practice guidelines and performance measures that would increase the likelihood of safe and effective clinical use of prescription controlled substances, especially psychostimulants, benzodiazepines and benzodiazepines receptor agonists, and opioid analgesics;
- c. encourages physicians to become aware of resources on the nonmedical use of prescription controlled substances that can assist in actively engaging patients, and especially parents, on the benefits and risks of such treatment, and the need to safeguard and monitor prescriptions for controlled substances, with the intent of reducing access and diversion by family members and friends;
- d. will consult with relevant agencies on potential strategies to actively involve physicians in being ?a part of the solution? to the epidemic of unauthorized/nonmedical use of prescription controlled substances; and
- e. supports research on: (i) firmly identifying sources of diverted prescription controlled substances so that solutions can be advanced; and (ii) issues relevant to the long-term use of prescription controlled substances.

2. Our AMA, in conjunction with other Federation members, key public and private stakeholders, and pharmaceutical manufacturers, will pursue and intensify collaborative efforts involving a public health approach in order to:

- a. reduce harm from the inappropriate use, misuse and diversion of controlled substances, including opioid analgesics and other potentially addictive medications;
- b. increase awareness that substance use disorders are chronic diseases and must be treated accordingly; and
- c. reduce the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction.

Citation: (CSAPH Rep. 2, I-08; Appended: Res. 517, A-15; Reaffirmed: BOT Rep. 5, I-15)

Federal Drug Policy in the United States H-95.981

The AMA, in an effort to reduce personal and public health risks of drug abuse, urges the formulation of a comprehensive national policy on drug abuse, specifically advising that the federal government and the nation should: (1) acknowledge that federal efforts to address illicit drug use via supply reduction and enforcement have been ineffective (2) expand the availability and reduce the cost of treatment programs for substance use disorders, including addiction; (3) lead a coordinated approach to adolescent drug education; (4) develop community-based prevention programs for youth at risk; (5) continue to fund the Office of National Drug Control Policy to coordinate federal drug policy; (6) extend greater protection against discrimination in the employment and provision of services to drug abusers; (7) make a long-term commitment to expanded research and data collection; (8) broaden the focus of national and local policy from drug abuse to substance abuse;

and (9) recognize the complexity of the problem of substance abuse and oppose drug legalization.
 Citation: (BOT Rep. NNN, A-88; Reaffirmed: CLRPD 1, I-98; Reaffirmed: CSAPH Rep. 2, A-08;
 Modified: CSAPH Rep. 2, I-13)

Background on the Organization "Physicians and Lawyers for National Drug Policy" (PLNDP) D-95.986

Our AMA will: (1) express support to Physicians and Lawyers for National Drug Policy (PLNDP) for including in its statement of policy priorities the need for parity in insurance payments for addiction treatment; (2) encourage physicians to partner with lawyers and judges in their communities to become Lawyer and Physician Associates of PLNDP at no cost, and to work collaboratively in their communities to promote a more rational, public-health-focused approach to substance use and addiction; and (3) encourage individual members to join or collaborate with PLNDP efforts when they are consistent with and supportive of AMA policy goals.

Citation: (BOT Rep. 8, A-07)

Drug Abuse in the United States - the Next Generation H-95.976

Our AMA is committed to efforts that can help prevent this national problem from becoming a chronic burden. The AMA pledges its continuing involvement in programs to alert physicians and the public to the dimensions of the problem and the most promising solutions. The AMA, therefore:

- (1) supports cooperation in activities of organizations such as the National Association for Perinatal Addiction Research and Education (NAPARE) in fostering education, research, prevention, and treatment of substance abuse;
- (2) encourages the development of model substance abuse treatment programs, complete with an evaluation component that is designed to meet the special needs of pregnant women and women with infant children through a comprehensive array of essential services;
- (3) urges physicians to routinely provide, at a minimum, a historical screen for all pregnant women, and those of childbearing age for substance abuse and to follow up positive screens with appropriate counseling, interventions and referrals;
- (4) supports pursuing the development of educational materials for physicians, physicians in training, other health care providers, and the public on prevention, diagnosis, and treatment of perinatal addiction. In this regard, the AMA encourages further collaboration with the Partnership for a Drug-Free America in delivering appropriate messages to health professionals and the public on the risks and ramifications of perinatal drug and alcohol use;
- (5) urges the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the Federal Office for Substance Abuse Prevention to continue to support research and demonstration projects around effective prevention and intervention strategies;
- (6) urges that public policy be predicated on the understanding that alcoholism and drug dependence, including tobacco dependence as indicated by the Surgeon General's report, are diseases characterized by compulsive use in the face of adverse consequences;
- (7) affirms the concept that substance abuse is a disease and supports developing model legislation to appropriately address perinatal addiction as a disease, bearing in mind physicians' concern for the health of the mother, the fetus and resultant offspring; and
- (8) calls for better coordination of research, prevention, and intervention services for women and infants at risk for both HIV infection and perinatal addiction.

Citation: (BOT Rep. Y, I-89; Reaffirmed: Sunset Report, A-00; Reaffirmation A-09)

Treatment of Opioid Dependence D-120.953

Our AMA will work to end the limitation of 100 patients per certified physician treating opioid dependence after the second year of treatment as currently mandated by the Drug Addiction Treatment Act.

Citation: (Res. 524, A-1; Reaffirmation A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 803
(I-16)

Introduced by: Resident and Fellow Section
Subject: Reducing Perioperative Opioid Consumption
Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Regional anesthesia and acute pain medicine is a burgeoning field that specializes in
2 the use of multimodal analgesia strategies to manage perioperative pain; and
3

4 Whereas, Management and treatment of acute pain is distinctly different from the management
5 and treatment of pre-existing chronic pain; and
6

7 Whereas, There is an increased demand for physicians trained to manage acute pain medicine
8 teams with the goal of providing individualized, comprehensive, and timely pain management for
9 both medical and surgical patients in the hospital; and
10

11 Whereas, These acute pain management teams can expeditiously manage requests for
12 assistance when pain intensity levels exceed those set forth in quality standards, or to prevent
13 pain intensity from reaching such level; and
14

15 Whereas, Acute pain management teams can improve the quality of pain control, reduce the
16 time to discharge and reduce the morbidity and mortality of patients; and
17

18 Whereas, Pain control is an important hospital quality metric used to determine ultimate
19 reimbursements to hospitals; and
20

21 Whereas, Narcotics are often the sole analgesic employed or aggressively used to manage
22 perioperative pain; and
23

24 Whereas, Narcotic misuse and addiction has been related to their excess consumption in the
25 perioperative period; and
26

27 Whereas, Narcotic addiction has been recognized as one of the United States' worst health
28 problems; and
29

30 Whereas, The employment of regional anesthetics and multimodal analgesia strategies can
31 significantly reduce the consumption of narcotics both acutely and chronically; therefore be it
32

33 RESOLVED, That our American Medical Association encourage hospitals to adopt practices for
34 the management of perioperative pain that include services dedicated to acute pain
35 management and the use of multimodal analgesia strategies aimed at minimizing opioid
36 administration without compromising adequate pain control during the perioperative period.
37 (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.
Received: 09/12/16

References:

<http://www.edmariano.com/archives/592>

RELEVANT AMA POLICY

Protection for Physicians Who Prescribe Pain Medication H-120.960

Our AMA supports the following:

(1) the position that physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines protecting physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection; (2) education of medical students and physicians to recognize addictive disorders in patients, minimize diversion of opioid preparations, and appropriately treat or refer patients with such disorders; and (3) the prevention and treatment of pain disorders through aggressive and appropriate means, including the continued education of doctors in the use of opioid preparations.

Our AMA opposes harassment of physicians by agents of the Drug Enforcement Administration in response to the appropriate prescribing of controlled substances for pain management. (BOT Rep. 1, I-97; Reaffirm: Res. 237, A-99; Appended: Res. 506, A-01; Appended: Sub. Res. 213, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Reaffirmed: BOT Rep. 3, I-13; Reaffirmation A-15)

Opioid Treatment and Prescription Drug Monitoring Programs D-95.980

Our AMA will seek changes to allow states the flexibility to require opioid treatment programs to report to prescription monitoring programs. (BOT Rep. 11, A-10)

Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone D-120.985

1. Our AMA will incorporate into its web site a directory consolidating available information on the safe and effective use of opioid analgesics in clinical practice.
2. Our AMA, in collaboration with Federation partners, will collate and disseminate available educational and training resources on the use of methadone for pain management. (Sub. Res. 508, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Appended: Res. 515, A-14; Reaffirmed: BOT Rep. 14, A-15)

Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose. (Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16)

Drug Abuse Related to Prescribing Practices H-95.990

1. Our AMA recommends the following series of actions for implementation by state medical societies concerning drug abuse related to prescribing practices:

A. Institution of comprehensive statewide programs to curtail prescription drug abuse and to promote appropriate prescribing practices, a program that reflects drug abuse problems currently within the state, and takes into account the fact that practices, laws and regulations differ from state to state. The program should incorporate these elements: (1) Determination of the nature and extent of the prescription drug abuse problem; (2) Cooperative relationships with law enforcement, regulatory agencies, pharmacists and other professional groups to identify "script doctors" and bring them to justice, and to prevent forgeries, thefts and other unlawful activities related to prescription drugs; (3) Cooperative relationships with such bodies to provide education to "duped doctors" and "dated doctors" so their prescribing practices can be improved in the future; (4) Educational materials on appropriate prescribing of controlled substances for all physicians and for medical students.

B. Placement of the prescription drug abuse programs within the context of other drug abuse control efforts by law enforcement, regulating agencies and the health professions, in recognition of the fact that even optimal prescribing practices will not eliminate the availability of drugs for abuse purposes, nor appreciably affect the root causes of drug abuse. State medical societies should, in this regard, emphasize in particular: (1) Education of patients and the public on the appropriate medical uses of controlled drugs, and the deleterious effects of the abuse of these substances; (2) Instruction and consultation to practicing physicians on the treatment of drug abuse and drug dependence in its various forms.

2. Our AMA:

A. promotes physician training and competence on the proper use of controlled substances;

B. encourages physicians to use screening tools (such as NIDAMED) for drug use in their patients;

C. will provide references and resources for physicians so they identify and promote treatment for unhealthy behaviors before they become life-threatening; and

D. encourages physicians to query a state's controlled substances databases for information on their patients on controlled substances.

3. The Council on Science and Public Health will report at the 2012 Annual Meeting on the effectiveness of current drug policies, ways to prevent fraudulent prescriptions, and additional reporting requirements for state-based prescription drug monitoring programs for veterinarians, hospitals, opioid treatment programs, and Department of Veterans Affairs facilities.

4. Our AMA opposes any federal legislation that would require physicians to check a prescription drug monitoring program (PDMP) prior to prescribing controlled substances. (CSA Rep. C, A-81; Reaffirmed: CLRPD Rep. F, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Appended: Res. 907, I-11; Appended: Res. 219, A-12; Reaffirmation A-15; Reaffirmation: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15)

Reduction of Medical and Public Health Consequences of Drug Abuse: Update D-95.999

Our AMA encourages state medical societies to advocate for the expansion of and increased funding for needle and syringe-exchange programs and methadone maintenance and other opioid treatment services and programs in their states. (CSA Rep. 12, A-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 804
(I-16)

Introduced by: Young Physicians Section

Subject: Parity in Reproductive Health Insurance Coverage for Same-Sex Couples

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, The World Health Organization (WHO) has classified infertility as a global public health issue, and has “calculated that over 10% of women are inflicted (sic) – women who have tried unsuccessfully, and have remained in a stable relationship for five years or more. Estimates in women using a two year time frame, result in prevalence values 2.5 times larger;”¹ and

Whereas, In an Ethics Committee Opinion, the American Society for Reproductive Medicine (ASRM) states that “ethical arguments supporting denial of access to fertility services on the basis of marital status or sexual orientation cannot be justified;”² and

Whereas, This ASRM Ethics Committee Opinion also indicates that:

- Single individuals, unmarried heterosexual couples, and gay and lesbian couples have interests in having and rearing children;
- Overall results of research suggest that the development, adjustment, and well-being of children with lesbian and gay parents do not differ markedly from that of children with heterosexual parents;
- Data do not support restricting access to assisted reproductive technologies on the basis of a prospective parent's marital/partner status or sexual orientation; and
- Programs should treat all requests for assisted reproduction equally without regard to marital/partner status or sexual orientation;² and

Whereas, The American College of Obstetricians and Gynecologists (ACOG) said of physicians who refuse to provide infertility services to same-sex couples: “Allowing physicians to discriminate on the basis of sexual orientation would constitute a deeper insult, namely reinforcing the scientifically unfounded idea that fitness to parent is based on sexual orientation, and, thus, reinforcing the oppressed status of same-sex couples;”³ and

Whereas, According to AMA Policy H-65.973, our AMA will “support measures providing same-sex households with the same rights and privileges to health care, health insurance, and survivor benefits, as afforded opposite-sex households;” and

Whereas, On 26 June 2015, the Supreme Court ruled that states cannot ban same-sex marriage; and

Whereas, According to ASRM, "Six states (Connecticut, Illinois, Maryland, Massachusetts, New Jersey, and Rhode Island) provide comprehensive or near-comprehensive coverage for infertility treatment to at least some residents through state law mandates. These mandates require that private insurers cover diagnosis and treatment of infertility, including IVF. Although mandated coverage can result in better overall access, several state mandates carry significant restrictions (e.g., Maryland imposes a two-year waiting period, exempts religious employers, covers only married couples, and requires that the husband's sperm be used);"⁴ and

Whereas, Several insurance companies have been found to cover infertility treatments for heterosexual couples but decline those treatments for same-sex couples; and

Whereas, Some of these insurance companies will cover donor sperm insemination for heterosexual couples, but not for same-sex couples or single women; and

Whereas, The reasons for insurance companies to deny fertility coverage to same-sex couples are varied, but are ultimately discriminatory, as they would often cover fertility treatments for a heterosexual couple with azoospermia (lack of sperm), but not for a same-sex couple with a similar lack of available sperm; and

Whereas, For married same-sex couples, the Maryland legislature in 2015 eliminated restrictions that had (1) previously excluded lesbians from in vitro fertilization coverage (because the previous law called for the use of the husband's sperm, in order for the couple to receive coverage), and (2) previously required couples to demonstrate a history of infertility of at least two years' duration before being eligible for fertility treatments (but now allows lesbians to substitute six artificial insemination attempts instead);^{5,6} therefore be it

RESOLVED, That our American Medical Association support parity in insurance coverage for fertility treatments for same-sex couples, when insurance provides coverage for fertility treatments (New HOD Policy); and be it further

RESOLVED, That our AMA support local and state efforts to promote parity in reproductive health insurance coverage for same-sex couples when insurance provides coverage for fertility treatments. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/26/16

References:

1. "Infertility is a global public health issue" on the website of the World Health Organization, at <http://www.who.int/reproductivehealth/topics/infertility/perspective/en/>. Accessed 9/18/15.
2. "Access to fertility treatment by gays, lesbians, and unmarried persons: a committee opinion. Ethics Committee of the American Society for Reproductive Medicine. *Fertil Steril* 2013; 100: 1524-7.
3. ACOG Committee Opinion No 385. The limits of conscientious refusal in reproductive medicine. *Obstet Gynecol* 2007; 110:1203-8.
4. "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion. *Fertil Steril* 2015; in press.
5. "Maryland clears restrictions to in vitro fertilization coverage for same-sex couples." in Med City News, 7/10/15. Accessed at: <http://medcitynews.com/2015/07/in-vitro-fertilization-coverage-same-sex-couples/>.
6. "In vitro mandate bill for same-sex couples passes both chambers." In The Baltimore Sun, 3/24/15. Accessed at: <http://www.baltimoresun.com/news/maryland/politics/blog/bal-in-vitro-mandate-bill-for-samesex-couples-passes-both-chambers-20150324-story.html>.

RELEVANT AMA POLICY

H-65.973 Health Care Disparities in Same-Sex Partner Households

Our American Medical Association: (1) recognizes that denying civil marriage based on sexual orientation is discriminatory and imposes harmful stigma on gay and lesbian individuals and couples and their families; (2) recognizes that exclusion from civil marriage contributes to health care disparities affecting same-sex households; (3) will work to reduce health care disparities among members of same-sex households including minor children; and (4) will support measures providing same-sex households with the same rights and privileges to health care, health insurance, and survivor benefits, as afforded opposite-sex households.

(CSAPH Rep. 1, I-09; BOT Action in response to referred for decision Res. 918, I-09: Reaffirmed in lieu of Res. 918, I-09; BOT Rep. 15, A-11; Reaffirmed in lieu of Res. 209, A-12)

D-65.995 Health Disparities Among Gay, Lesbian, Bisexual and Transgender Families

Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and same sex parents in same sex households by supporting equality in laws affecting health care of members in same sex partner households and their dependent children.

(Res. 445, A-05; Modified: CSAPH Rep. 1, A-15)

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991

1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian gay bisexual and transgender (LGBT) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBT; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBT Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBT patients; (iii) encouraging the development of educational programs in LGBT Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBT people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBT communities to offer physicians the opportunity to better understand the medical needs of LGBT patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.

2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for women who have sex with women to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases.

3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBT health issues.

4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBT people.

CSA Rep. C, I-81 Reaffirmed: CLRPD Rep. F, I-91 CSA Rep. 8 - I-94 Appended: Res. 506, A-00 Modified and Reaffirmed: Res. 501, A-07 Modified: CSAPH Rep. 9, A-08 Reaffirmation A-12 Modified: Res. 08, A-16

Eliminating Health Disparities - Promoting Awareness and Education of Lesbian, Gay, Bisexual, and Transgender (LGBT) Health Issues in Medical Education H-295.878

Our AMA: (1) supports the right of medical students and residents to form groups and meet on-site to further their medical education or enhance patient care without regard to their gender, gender identity, sexual orientation, race, religion, disability, ethnic origin, national origin or age; (2) supports students and residents who wish to conduct on-site educational seminars and workshops on health issues in Lesbian, Gay, Bisexual, and Transgender communities; and (3) encourages the Liaison Committee on Medical Education (LCME), the American Osteopathic Association (AOA), and the Accreditation Council for Graduate Medical Education (ACGME) to include LGBT health issues in the cultural competency curriculum for both undergraduate and graduate medical education; and (4) encourages the LCME, AOA, and ACGME to assess the current status of curricula for medical student and residency education addressing the needs of pediatric and adolescent LGBT patients.

Res. 323, A-05 Modified in lieu of Res. 906, I-10 Reaffirmation A-11 Reaffirmation A-12 Reaffirmation A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 805
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire,
Rhode Island, Vermont

Subject: Health Insurance Companies Should Collect Deductible From
Patients After Full Payments To Physicians

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, One of the principles of the AMA is practice sustainability; and

2
3 Whereas, Health insurance companies and other payors serve as an intermediary between
4 physicians and patients; and

5
6 Whereas, This often disrupts the relationship and interferes with physicians and the
7 accompanying medical charges; and

8
9 Whereas, Health insurance companies created deductibles, co-insurance and even co-
10 payments to lower premium costs and transfer health care risk and cost to patients and
11 physicians; and

12
13 Whereas, High deductible health care plans have increased dramatically since the passage of
14 the Affordable Care Act (ACA) in quality and in the amount of the patient overall financial
15 responsibility; and

16
17 Whereas, Physicians are collecting less revenue from charges allocated towards deductibles as
18 compared to plans without deductibles since the ACA was implemented with the health
19 insurance exchange high deductible plans; therefore be it

20
21 RESOLVED, That our American Medical Association seek federal and state legislation that
22 requires health insurers to reimburse physicians the full negotiated payment rate for services to
23 enrollees in high deductible plans and that the health insurers collect any patient financial
24 responsibility, including deductibles and co-insurance, directly from the patient. (Directive to
25 Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 806
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire,
Rhode Island, Vermont

Subject: Pharmaceutical Industry Drug Pricing is a Public Health Emergency

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, The pharmaceutical industry has repeatedly raised prices for the past 10 years without regard to patient or societal affordability;¹ and

Whereas, These price increases have for the most part been unrelated to research or rate of return on investment; and

Whereas, The pharmaceutical industry has as a whole ignored any reasonable calls for restraint in price increases, putting a huge strain on the entire health care system;³ and

Whereas, These many price increases, some on a regular basis every few months, are unrelated to any R&D demands;⁴ and

Whereas, These price increases are no longer able to be absorbed by the insurance industry which will lead to marked rises in insurance premiums, causing large out of pocket expenses for essential medications; and

Whereas, These price increases are straining state and federal budgets, and will require either major tax increases or limits on medical care to many citizens;² and

Whereas, It is already AMA policy to request congress to repeal the Medicare prohibition on drug price negotiation;⁵ and

Whereas, It is already AMA policy to request FDA encourage increased competition in the generic drug market; and

Whereas, The high price of medication has led to adverse patient care with patients skipping or missing medications due to exorbitant pricing;² and

Whereas, Our patients need Congress to convene urgent hearings and demand action from the pharmaceutical industry regarding excessive price increases; therefore be it

RESOLVED, That our American Medical Association request that the Secretary of Health and Human Services declare pharmaceutical drug pricing a public health emergency under section 319 of the Public Health Service Act and that the Secretary take appropriate actions in response to the emergency, including investigations into the cause, treatment, or prevention of egregious pharmaceutical drug pricing. (Directive to Take Action)

References:

¹The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform
Aaron S. Kesselheim, MD, JD, MPH1; Jerry Avorn, MD1; Ameet Sarpatwari, JD, PhD1
JAMA. 2016;316(8):858-871. doi:10.1001/jama.2016.11237.

² "High Cost Generic Drugs" NEJM 2014;371;1859-1862

³"Surprise: generic drugs spike" Bloomberg News Dec 12, 2013

⁴ "Rapid price increases for generic drugs", NYT, July 8, 2014

⁵"Lawmakers look for ways to provide relief for rising cost of generic drugs", NYT, Nov 24,2014

Fiscal Note: Minimal - less than \$1,000.

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 807
(I-16)

Introduced by: Kentucky

Subject: Pharmacy Use of Medication Discontinuation Messaging Function

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Electronic prescribing of medications has been required as a component of
2 meaningful use; and
3

4 Whereas, Electronic prescribing software has the ability to support transmittal of medication
5 discontinuation messages; and
6

7 Whereas, Many pharmacies have elected to not activate this functionality; and
8

9 Whereas, Not using this functionality to its full extent can result in medications being
10 inappropriately continued and dispensed after a prescribing physician or other duly licensed
11 care provider has determined that it should be discontinued; and
12

13 Whereas, Continuation of medications after a physician or other duly licensed care provider has
14 discontinued them can result in patient harm; therefore be it
15

16 RESOLVED, That our American Medical Association strongly encourage all software providers
17 and those pharmaceutical dispensing organizations that create their own software to include the
18 functionality to accept discontinuation message transmittals in their electronic prescribing
19 software products (New HOD Policy); and be it further
20

21 RESOLVED, That our AMA strongly encourage all dispensing pharmacies accepting medication
22 prescriptions electronically to activate the discontinuation message transmittal functionality in
23 their electronic prescribing support software. (New HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 808
(I-16)

Introduced by: Medical Student Section

Subject: A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities

Referred to: Reference Committee J
(Candace E. Keller, Chair)

Whereas, The Centers for Medicare & Medicaid (CMS) is committed to using measures of hospital quality that directly reflect the patient perspective to improve the overall quality of hospital care;¹ and

Whereas, In accordance with the Affordable Care Act, CMS initiated the Hospital Value-Based Purchasing (VBP) Program, which rewards acute-care hospitals with incentive payments for the quality of care they provide Medicare beneficiaries;²

Whereas, The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is a data collection methodology for measuring patients' perceptions of their hospital experience;³ and

Whereas, The HCAHPS survey creates standardized, publicly-reported metrics that allow for fair comparisons of patient experience in hospitals across the nation;⁴ and

Whereas, The HCAHPS survey is the most studied system for measuring patients' experience of their care on an individual and hospital level and it is one measure within the HVBP program;⁴ and

Whereas, To withhold payouts due to poor quality of care for Medicare beneficiaries fails to account for situations in which high-value care is at odds with patient satisfaction and may disincentivize physicians to care for patients who are perceived as difficult to please, that is, underserved minorities, those with lower socioeconomic status, and those with mental health concerns;⁵ and

Whereas, Safety net hospitals⁶ typically do worse on patient experience metrics than their counterparts that provide less care to underserved populations;⁶ and

¹ CMS Quality Strategy (2016). Available at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf>

² HCAHPS: Patients' Perspectives of Care Survey. Centers for Medicare & Medicaid Services. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS.html>

³ Tefera L, Lehman W, Conway P. Measurement of the Patient Experience Clarifying Facts, Myths, and Approaches. JAMA Network 2016. Available at: <http://jama.jamanetwork.com/article.aspx?articleid=2503222>. Accessed March 27, 2016.

⁴ Jha AK, Orav EJ, Zheng J, Epstein AM. Patients' perception of hospital care in the United States. N Engl J Med. 2008;359(18):1921-1931.

⁵ Mehta SJ. Patient Satisfaction Reporting and Its Implications for Patient Care. The AMA Journal of Ethics 2015;17(7):616-621. doi:10.1001/journalofethics.2015.17.7.ecas3-1507

⁶ The Institute of Medicine defines safety net providers as "providers that organize and deliver a significant level of both health care and other health-related services to the uninsured, Medicaid, and other vulnerable populations," as well as providers "who by mandate or mission offer access to care regardless of a patient's ability to pay and whose patient population includes a substantial share of uninsured, Medicaid, and other vulnerable patients." <https://aspe.hhs.gov/report/environmental-scan-identify-major-research-questions-and-metrics-monitoring-effects-affordable-care-act-safety-net-hospitals/c-definition-safety-net-hospitals> .

Whereas, If institutions that have a greater safety net function have more challenging patient populations and fewer resources to devote to improving low scores, financial incentives could exacerbate existing inequities in care;⁶ and

Whereas, Existing AMA policy D-450.962 calls for the AMA to urge CMS to (a) evaluate the relationship and apparent disparity between patient satisfaction, using the Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) and Emergency Department Patient Experience of Care (ED-PEC) survey, and hospital performance on clinical process and outcome measures used in the hospital value based purchasing program; therefore be it

RESOLVED, That our American Medical Association study the potential healthcare disparities caused by Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) in Medicare reimbursement. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/29/16

RELEVANT AMA POLICY

Improve the HCAHPS Rating System D-450.960 - Our AMA will urge the Centers for Medicare & Medicaid Services to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scoring system so that it assigns a unique value for each rating option available to patients.

Res. 806, I-13

Pain Management and the Hospital Value-Based Purchasing Program D-450.962 - 1. Our AMA urges the Centers for Medicare & Medicaid Services (CMS) to: (a) evaluate the relationship and apparent disparity between patient satisfaction, using the Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) and Emergency Department Patient Experience of Care (ED-PEC) survey, and hospital performance on clinical process and outcome measures used in the hospital value based purchasing program; and (b) reexamine the validity of questions used on the HCAHPS and ED-PEC surveys related to pain management as reliable and accurate measures of the quality of care in this domain. 2. Our AMA urges CMS to suspend the use of HCAHPS and ED-PEC measures addressing pain management until their validity as reliable and accurate measures of quality of care in this domain has been determined. BOT Rep. 9, A-13 Modified: BOT Rep. 5, I-15

Patient Satisfaction Surveys and Quality Parameters as Criteria for Physician Payment D-385.958 - Our AMA will work with the Centers for Medicare & Medicaid Services (CMS) and non-government payers to ensure that (1) subjective criteria, such as patient satisfaction surveys, be used only as an adjunctive and not a determinative measure of physician quality for the purpose of physician payment; and (2) physician payment determination, when incorporating quality parameters, only consider measures that are under the direct control of the physician.

Res. 102, A-13 Reaffirmed: Res. 806, I-13 Reaffirmed in lieu of Res. 814, I-14

Establishing Capitation Rates H-400.955 - 1. Our AMA believes Geographic variations in capitation rates from public programs (e.g., Medicare or Medicaid) should reflect only demonstrable variations in practice costs and correctly validated variations in utilization that reflect legitimate and demonstrable differences in health care need. In particular, areas that have relatively low utilization rates due to cost containment efforts should not be penalized with unrealistically low reimbursement rates. In addition, these payments should be adjusted at the

individual level with improved risk adjustors that include demographic factors, health status, and other useful and cost-effective predictors of health care use. 2. Our AMA will work to assure that any current or proposed Medicare or Medicaid (including waivers) capitated payments should be set at levels that would establish and maintain access to quality care. 3. Our AMA seeks modifications as appropriate to the regulations and/or statutes affecting Medicare HMOs and other Medicare managed care arrangements to incorporate the revised Patient Protection Act and to ensure equal access to Medicare managed care contracts for physician-sponsored managed care organizations. 4. Our AMA supports development of a Medicare risk payment methodology that would set payment levels that are fair and equitable across geographic regions; in particular, such methodology should allow for equitable payment rates in those localities with relatively low utilization rates due to cost containment efforts.

CMS Rep. 3, A-95 CMS Rep. 7, I-95 Modified and Reaffirmed: Sub. Res. 120, A-97

Reaffirmation A-99 Reaffirmed: CMS Rep. 4, I-99 Reaffirmation A-00 Reaffirmation A-05

Reaffirmed: CMS Rep. 1, A-15

American Health Care Access, Innovation, Satisfaction and Quality D-450.966 - Our AMA will begin an international comparative study on health care quality that is a comprehensive and balanced study including comparisons of patient satisfaction, cancer outcomes, outcomes among more severe illnesses and injuries, rapidity of access and patient satisfaction as end points, and present their findings to the AMA House of Delegates at the 2012 Annual Meeting. Res. 104, A-11

Patient Satisfaction and Quality of Care H-450.982 - Our AMA believes that: (1) much may be gained by encouraging physicians to be sensitive to the goals and values of patients; and (2) efforts should be continued to improve the measurement of patient satisfaction and to document its relationship, if any, to favorable outcomes and other accepted criteria of high quality.

CMS Rep. E, A-89 Reaffirmed: Sunset Report, A-00 Reaffirmed: CMS Rep. 6, A-10

Reaffirmed BOT Rep. 9, A-13

Accountable Care Organization Principles H-160.915 - Our AMA adopts the following Accountable Care Organization (ACO) principles: 1. Guiding Principle - The goal of an ACO is to increase access to care, improve the quality of care and ensure the efficient delivery of care. Within an ACO, a physician's primary ethical and professional obligation is the well-being and safety of the patient. 2. ACO Governance - ACOs must be physician-led and encourage an environment of collaboration among physicians. ACOs must be physician-led to ensure that a physician's medical decisions are not based on commercial interests but rather on professional medical judgment that puts patients' interests first. A. Medical decisions should be made by physicians. ACOs must be operationally structured and governed by an appropriate number of physicians to ensure that medical decisions are made by physicians (rather than lay entities) and place patients' interests first. Physicians are the medical professionals best qualified by training, education, and experience to provide diagnosis and treatment of patients. Clinical decisions must be made by the physician or physician-controlled entity. The AMA supports true collaborative efforts between physicians, hospitals and other qualified providers to form ACOs as long as the governance of those arrangements ensure that physicians control medical issues. B. The ACO should be governed by a board of directors that is elected by the ACO professionals. Any physician-entity [e.g., Independent Physician Association (IPA), Medical Group, etc.] that contracts with, or is otherwise part of, the ACO should be physician-controlled and governed by an elected board of directors. C. The ACO's physician leaders should be licensed in the state in which the ACO operates and in the active practice of medicine in the ACO's service area. D. Where a hospital is part of an ACO, the governing board of the ACO should be separate, and independent from the hospital governing board. 3. Physician and patient participation in an ACO should be voluntary. Patient participation in an ACO should be

voluntary rather than a mandatory assignment to an ACO by Medicare. Any physician organization (including an organization that bills on behalf of physicians under a single tax identification number) or any other entity that creates an ACO must obtain the written affirmative consent of each physician to participate in the ACO. Physicians should not be required to join an ACO as a condition of contracting with Medicare, Medicaid or a private payer or being admitted to a hospital medical staff. 4. The savings and revenues of an ACO should be retained for patient care services and distributed to the ACO participants. 5. Flexibility in patient referral and antitrust laws. The federal and state anti-kickback and self-referral laws and the federal Civil Monetary Penalties (CMP) statute (which prohibits payments by hospitals to physicians to reduce or limit care) should be sufficiently flexible to allow physicians to collaborate with hospitals in forming ACOs without being employed by the hospitals or ACOs. This is particularly important for physicians in small- and medium-sized practices who may want to remain independent but otherwise integrate and collaborate with other physicians (i.e., so-called virtual integration) for purposes of participating in the ACO. The ACA explicitly authorizes the Secretary to waive requirements under the Civil Monetary Penalties statute, the Anti-Kickback statute, and the Ethics in Patient Referrals (Stark) law. The Secretary should establish a full range of waivers and safe harbors that will enable independent physicians to use existing or new organizational structures to participate as ACOs. In addition, the Secretary should work with the Federal Trade Commission to provide explicit exceptions to the antitrust laws for ACO participants. Physicians cannot completely transform their practices only for their Medicare patients, and antitrust enforcement could prevent them from creating clinical integration structures involving their privately insured patients. These waivers and safe harbors should be allowed where appropriate to exist beyond the end of the initial agreement between the ACO and CMS so that any new organizational structures that are created to participate in the program do not suddenly become illegal simply because the shared savings program does not continue. 6. Additional resources should be provided up-front in order to encourage ACO development. CMS's Center for Medicare and Medicaid Innovation (CMI) should provide grants to physicians in order to finance up-front costs of creating an ACO. ACO incentives must be aligned with the physician or physician group's risks (e.g., start-up costs, systems investments, culture changes, and financial uncertainty). Developing this capacity for physicians practicing in rural communities and solo-small group practices requires time and resources and the outcome is unknown. Providing additional resources for the up-front costs will encourage the development of ACOs since the 'shared savings' model only provides for potential savings at the back-end, which may discourage the creation of ACOs (particularly among independent physicians and in rural communities). 7. The ACO spending benchmark should be adjusted for differences in geographic practice costs and risk adjusted for individual patient risk factors. A. The ACO spending benchmark, which will be based on historical spending patterns in the ACO's service area and negotiated between Medicare and the ACO, must be risk-adjusted in order to incentivize physicians with sicker patients to participate in ACOs and incentivize ACOs to accept and treat sicker patients, such as the chronically ill. B. The ACO benchmark should be risk-adjusted for the socioeconomic and health status of the patients that are assigned to each ACO, such as income/poverty level, insurance status prior to Medicare enrollment, race, and ethnicity and health status. Studies show that patients with these factors have experienced barriers to care and are more costly and difficult to treat once they reach Medicare eligibility. C. The ACO benchmark must be adjusted for differences in geographic practice costs, such as physician office expenses related to rent, wages paid to office staff and nurses, hospital operating cost factors (i.e., hospital wage index) and physician HIT costs. D. The ACO benchmark should include a reasonable spending growth rate based on the growth in physician and hospital practice expenses as well as the patient socioeconomic and health status factors. E. In addition to the shared savings earned by ACOs, ACOs that spend less than the national average per Medicare beneficiary should be provided an additional bonus payment. Many physicians and physician groups have worked hard over the years to establish systems and

practices to lower their costs below the national per Medicare beneficiary expenditures. Accordingly, these practices may not be able to achieve significant additional shared savings to incentivize them to create or join ACOs. A bonus payment for spending below the national average would encourage these practices to create ACOs and continue to use resources appropriately and efficiently. 8. The quality performance standards required to be established by the Secretary must be consistent with AMA policy regarding quality. The ACO quality reporting program must meet the AMA principles for quality reporting, including the use of nationally-accepted, physician specialty-validated clinical measures developed by the AMA-specialty society quality consortium; the inclusion of a sufficient number of patients to produce statistically valid quality information; appropriate attribution methodology; risk adjustment; and the right for physicians to appeal inaccurate quality reports and have them corrected. There must also be timely notification and feedback provided to physicians regarding the quality measures and results. 9. An ACO must be afforded procedural due process with respect to the Secretary's discretion to terminate an agreement with an ACO for failure to meet the quality performance standards. 10. ACOs should be allowed to use different payment models. While the ACO shared-savings program is limited to the traditional Medicare fee-for-service reimbursement methodology, the Secretary has discretion to establish ACO demonstration projects. ACOs must be given a variety of payment options and allowed to simultaneously employ different payment methods, including fee-for-service, capitation, partial capitation, medical homes, care management fees, and shared savings. Any capitation payments must be risk-adjusted. 11. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) Patient Satisfaction Survey should be used as a tool to determine patient satisfaction and whether an ACO meets the patient-centeredness criteria required by the ACO law. 12. Interoperable Health Information Technology and Electronic Health Record Systems are key to the success of ACOs. Medicare must ensure systems are interoperable to allow physicians and institutions to effectively communicate and coordinate care and report on quality. 13. If an ACO bears risk like a risk bearing organization, the ACO must abide by the financial solvency standards pertaining to risk-bearing organizations.

Res. 819, I-10 Reaffirmation A-11 Reaffirmed: Res. 215, A-11 Reaffirmation: I-12 Reaffirmed: CMS Rep. 6, I-13 Reaffirmed: Sub. Res. 711, A-15 Reaffirmation I-15 Reaffirmation: A-16

Monitoring Medicaid Managed Care H-290.985 - As managed care plans increasingly become the source of care for Medicaid beneficiaries, the AMA advocates the same policies for the conduct of Medicaid managed care that the AMA advocates for private sector managed care plans. In addition, the AMA advocates that the following criteria be used in federal and/or state oversight and evaluation of managed care plans serving Medicaid beneficiaries, and insists upon their use by the Federation in monitoring the implementation of managed care for Medicaid beneficiaries: (1) Adequate and timely public disclosure of pending implementation of managed care under a state program, so as to allow meaningful public comment. (2) Phased implementation to ensure availability of an adequate, sufficiently capitalized managed care infrastructure and an orderly transition for beneficiaries and providers. (3) Geographic dispersion and accessibility of participating physicians and other providers. (4) Education of beneficiaries regarding appropriate use of services, including the emergency department. (5) Availability of off-hours, walk-in primary care. (6) Coverage for clinically effective preventive services. (7) Responsiveness to cultural, language and transportation barriers to access. (8) In programs where more than one plan is available, beneficiary freedom to choose his/her plan, enforcement of standards for marketing/enrollment practices, and clear and comparable disclosure of plan benefits and limitations including financial incentives on providers. (9) Beneficiary freedom to choose and retain a given primary physician within the plan, and to request a change in physicians when dissatisfied. (10) Significant participating physician involvement and influence in plan medical policies, including development and conduct of quality assurance, credentialing and utilization review programs. (11) Ability of plan participating

physicians to determine how many beneficiaries and the type of medical problems they will care for under the program. (12) Adequate identification of plan beneficiaries and plan treatment restrictions to out-of-plan physicians and other providers. (13) Intensive case management for high utilizers and realistic financial disincentives for beneficiary misuse of services. (14) Treatment authorization requirements and referral protocols that promote continuity rather than fragment the process of care. (15) Preservation of private right of action for physicians and other providers and beneficiaries. (16) Ongoing evaluation and public reporting of patient outcomes, patient satisfaction and service utilization. (17) Full disclosure of plan physician and other provider selection criteria, and concerted efforts to qualify and enroll traditional community physicians and other existing providers in the plan. (18) Absence of gag rules. (19) Fairness in procedures for selection and deselection. (20) Realistic payment levels based on costs of care and predicted utilization levels. (21) Payment arrangements that do not expose practitioners to excessive financial risk for their own or referral services, and that tie any financial incentives to performance of the physician group over significant time periods rather than to individual treatment decisions. (22) Our AMA urges CMS to direct those state Medicaid agencies with Medicaid managed care programs to disseminate data and other relevant information to the state medical associations in their respective states on a timely and regular basis.

CMS Rep. 5 A-96 Reaffirmed and Appended: Sub. Res. 704, I-97 Reaffirmation A-00
Reaffirmation I-04 Reaffirmed: CMS Rep. 1, A-14

Work of the Task Force on the Release of Physician Data H-406.991 - Principles for the Public Release and Accurate Use of Physician Data: The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data when it is used in conjunction with program(s) designed to improve or maintain the quality of, and access to, medical care for all patients and is used to provide accurate physician performance assessments in concert with the following Principles: 1. Patient Privacy Safeguards - All entities involved in the collection, use and release of claims data comply with the HIPAA Privacy and Security Rules (H-315.972, H-315.973, H-315.983, H-315.984, H-315.989, H-450.947). - Disclosures made without patient authorization are generally limited to claims data, as that is generally the only information necessary to accomplish the intended purpose of the task (H-315.973, H-315.975, H-315.983). 2. Data Accuracy and Security Safeguards - Effective safeguards are established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data (H-406.996, H-450.947, H-450.961). - Reliable administrative, technical, and physical safeguards provide security to prevent the unauthorized use or disclosure of patient or physician-specific health care data and physician profiles (H-406.996, H-450.947, H-450.961). - Physician-specific medical practice data, and all analyses, proceedings, records and minutes from quality review activities are not subject to discovery or admittance into evidence in any judicial or administrative proceeding without the physician's consent (H-406.996, H-450.947, H-450.961). 3. Transparency Requirements - When data are collected and analyzed for the purpose of creating physician profiles, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure (H-315.973, H-406.993, H-406.994, H-406.998, H-450.947, H-450.961). - The limitations of the data sources used to create physician profiles are clearly identified and acknowledged in terms understandable to consumers (H-406.994, H-450.947). - The capabilities and limitations of the methodologies and reporting systems applied to the data to profile and rank physicians are publicly revealed in understandable terms to consumers (H-315.973, H-406.994, H-406.997, H-450.947, H-450.961). - Case-matched, risk-adjusted resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients (H-

285.931). 4. Review and Appeal Requirements - Physicians are provided with an adequate and timely opportunity to review, respond and appeal the results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release (H-315.973, H-406.996, H-406.998, H-450.941, H-450.947, H-450.961). - When the physician and the rater cannot reach agreement, physician comments are appended to the report at the physician's request (H-450.947). 5. Physician Profiling Requirements - The data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians (H-406.994, H-406.997, H-450.947, H-450.961). - Data reporting programs only use accurate and balanced data sources to create physician profiles and do not use these profiles to create tiered or narrow network programs that are used to steer patients towards certain physicians primarily on cost of care factors (450.951).

- When a single set of claims data includes a sample of patients that are skewed or not representative of the physicians' entire patient population, multiple sources of claims data are used (no current policy exists). - Physician efficiency of care ratings use physician data for services, procedures, tests and prescriptions that are based on physicians' patient utilization of resources so that the focus is on comparative physicians' patient utilization and not on the actual charges for services (no current policy exists). - Physician-profiling programs may rank individual physician members of a medical group but do not use those individual rankings for placement in a network or for reimbursement purposes (no current policy exists). 6. Quality Measurement Requirements - The data are used to profile physicians based on quality of care provided - never on utilization of resources alone -- and the degree to which profiling is based on utilization of resources is clearly identified (H-450.947). - Data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties, such as the Physician Consortium for Performance Improvement. (H-406.994, H-406.998, H-450.947, H-450.961). - These evidence-based measures are endorsed by the National Quality Forum (NQF) and/or the AQA and HQA, when available. When unavailable, scientifically valid measures developed in conjunction with appropriate medical specialty societies and practicing physicians are used to evaluate the data (no current policy exists). 7. Patient Satisfaction Measurement Requirements - Until the relationship between patient satisfaction and other outcomes is better understood, data collected on patient satisfaction is best used by physicians to better meet patient needs particularly as they relate to favorable patient outcomes and other criteria of high quality care (H-450.982). - Because of the difficulty in determining whether responses to patient satisfaction surveys are a result of the performance of a physician or physician office, or the result of the demands or restrictions of health insurers or other factors out of the control of the physician, the use of patient satisfaction data is not appropriate for incentive or tiering mechanisms (no current policy exists). - As in physician profiling programs, it is important that programs that publicly rate physicians on patient satisfaction notify physicians of their rating and provide a chance for the physician to appeal that rating prior to its publication (no current policy exists).

BOT Rep. 18, A-09 Reaffirmation A-10 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10 Reaffirmation I-10 Reaffirmed in lieu of Res. 808, I-10 Reaffirmed in lieu of Res. 824, I-10 Reaffirmation A-11 Reaffirmed: BOT Rep. 17, A-13 Reaffirmed: Res. 806, I-13

Pain Medicine D-450.958 - Our AMA: (1) continues to advocate that the Centers for Medicare & Medicaid Services (CMS) remove the pain survey questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); (2) continues to advocate that CMS not incorporate items linked to pain scores as part of the CAHPS Clinician and Group Surveys (CG-CAHPS) scores in future surveys; and (3) encourages hospitals, clinics, health plans, health systems, and academic medical centers not to link physician compensation,

employment retention or promotion, faculty retention or promotion, and provider network participation to patient satisfaction scores relating to the evaluation and management of pain. BOT Rep. 5, I-15

AMA Principles on Maintenance of Certification (MOC) H-275.924 - 1. Changes in specialty-board certification requirements for MOC programs should be longitudinally stable in structure, although flexible in content. 2. Implementation of changes in MOC must be reasonable and take into consideration the time needed to develop the proper MOC structures as well as to educate physician diplomats about the requirements for participation. 3. Any changes to the MOC process for a given medical specialty board should occur no more frequently than the intervals used by that specialty board for MOC. 4. Any changes in the MOC process should not result in significantly increased cost or burden to physician participants (such as systems that mandate continuous documentation or require annual milestones). 5. MOC requirements should not reduce the capacity of the overall physician workforce. It is important to retain a structure of MOC programs that permits physicians to complete modules with temporal flexibility, compatible with their practice responsibilities. 6. Patient satisfaction programs such as The Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient survey are neither appropriate nor effective survey tools to assess physician competence in many specialties. 7. Careful consideration should be given to the importance of retaining flexibility in pathways for MOC for physicians with careers that combine clinical patient care with significant leadership, administrative, research and teaching responsibilities. 8. Legal ramifications must be examined, and conflicts resolved, prior to data collection and/or displaying any information collected in the process of MOC. Specifically, careful consideration must be given to the types and format of physician-specific data to be publicly released in conjunction with MOC participation. 9. Our AMA affirms the current language regarding continuing medical education (CME): "Each Member Board will document that diplomats are meeting the CME and Self-Assessment requirements for MOC Part II. The content of CME and self-assessment programs receiving credit for MOC will be relevant to advances within the diplomat's scope of practice, and free of commercial bias and direct support from pharmaceutical and device industries. Each diplomat will be required to complete CME credits (AMA PRA Category 1 Credit?, American Academy of Family Physicians Prescribed, American College of Obstetricians and Gynecologists, and/or American Osteopathic Association Category 1A)." 10. In relation to MOC Part II, our AMA continues to support and promote the AMA Physician's Recognition Award (PRA) Credit system as one of the three major credit systems that comprise the foundation for continuing medical education in the U.S., including the Performance Improvement CME (PICME) format; and continues to develop relationships and agreements that may lead to standards accepted by all U.S. licensing boards, specialty boards, hospital credentialing bodies and other entities requiring evidence of physician CME. 11. MOC is but one component to promote patient safety and quality. Health care is a team effort, and changes to MOC should not create an unrealistic expectation that lapses in patient safety are primarily failures of individual physicians. 12. MOC should be based on evidence and designed to identify performance gaps and unmet needs, providing direction and guidance for improvement in physician performance and delivery of care. 13. The MOC process should be evaluated periodically to measure physician satisfaction, knowledge uptake and intent to maintain or change practice. 14. MOC should be used as a tool for continuous improvement. 15. The MOC program should not be a mandated requirement for licensure, credentialing, reimbursement, network participation or employment. 16. Actively practicing physicians should be well-represented on specialty boards developing MOC. 17. Our AMA will include early career physicians when nominating individuals to the Boards of Directors for ABMS member boards. 18. MOC activities and measurement should be relevant to clinical practice. 19. The MOC process should not be cost prohibitive or present barriers to patient care. 20. Any assessment should be used to guide physicians' self-directed study. 21. Specific content-based feedback after any assessment tests should be provided to physicians in a timely

manner. 22. There should be multiple options for how an assessment could be structured to accommodate different learning styles. 23. Physicians with lifetime board certification should not be required to seek recertification. 24. No qualifiers or restrictions should be placed on diplomats with lifetime board certification recognized by the ABMS related to their participation in MOC. 25. Members of our House of Delegates are encouraged to increase their awareness of and participation in the proposed changes to physician self-regulation through their specialty organizations and other professional membership groups.

CME Rep. 16, A-09 Reaffirmed: CME Rep. 11, A-12 Reaffirmed: CME Rep. 10, A-12 Reaffirmed in lieu of Res. 313, A-12 Reaffirmed: CME Rep. 4, A-13 Reaffirmed in lieu of Res. 919, I-13 Appended: Sub. Res. 920, I-14 Reaffirmed: CME Rep. 2, A-15 Appended: Res. 314, A-15 Modified: CME Rep. 2, I-15 Reaffirmation A-16 Reaffirmed: Res. 309, A-16

Appropriate Payment Level Differences by Place and Type of Service H-330.925 - Our

AMA (1) encourages CMS to adopt policy and establish mechanisms to fairly reimburse physicians for office-based procedures; (2) encourages CMS to adopt a site neutral payment policy for hospital outpatient departments and ambulatory surgical centers; (3) advocates for the use of valid and reliable data in the development of any payment methodology for the provision of ambulatory services; (4) advocates that in place of the Consumer Price Index for all Urban Consumers (CPI-U), CMS use the hospital market basket index to annually update ambulatory surgical center payment rates; (5) encourages the use of CPT codes across all sites-of-service as the only acceptable approach to payment methodology; and (6) will join other interested organizations and lobby for any needed changes in existing and proposed regulations affecting payment for ambulatory surgical centers to assure a fair rate of reimbursement for ambulatory surgery.

Sub. Res. 104, A-98 Reaffirmation I-98 Appended: CMS Rep. 7, A-99 Reaffirmation A-00 Reaffirmation I-03 Reaffirmation A-11 Reaffirmed: CMS Rep. 3, A-13 Reaffirmed: Sub. Res. 104, A-14 Reaffirmed: Res. 116, A-14 Modified: CMS Rep. 3, A-14 Reaffirmation A-14 Reaffirmation A-15

Remove Pain Scores from Quality Metrics D-450.955 - Our AMA will work with the Centers for Medicare and Medicaid Services to remove uncontrolled pain scores from quality metrics that impact reimbursement for services rendered in the nursing facilities and from the five star rating system for nursing facilities.

Res. 236, A-16

CMS - Standards of Care, Hospital Admissions H-335.994 - The AMA supports federal government funding for an independent study to examine and assess the present impact on the quality of medical care from mandated utilization review, medical necessity standards, methods of reimbursement, denial of hospital admissions for illness, and surgical or invasive procedures. Sub. Res. 25, A-88 Reaffirmed: Sunset Report, I-98 Reaffirmed: CMS Rep. 4, A-08

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 809
(I-16)

Introduced by: Medical Student Section

Subject: Addressing the Exploitation of Restricted Distribution Systems by
Pharmaceutical Manufacturers

Referred to: Reference Committee J
(Candace E. Keller, Chair)

Whereas, A litany of prescription drugs have recently experienced significant price increases shortly after changes of ownership, such as colchicine, Thiola, Daraprim, and Makena, which in the past five years have seen price increases of 2000%, 2000%, 5000%, and 15,000%, respectively;^{1,2,3,4,5,6} and

Whereas, The mechanism by which companies are able to implement such price hikes involves, in part, the transition from a traditional wholesaler-based supply chain model to a “restricted”, “controlled”, or “closed” distribution system at the discretion of the manufacturer;^{7,8} and

Whereas, A restricted distribution system is a tightly-controlled supply chain model in which a drug is only available to patients via specific specialty pharmacies, enabling drug manufacturers to stringently control the distribution of their products; and

Whereas, Per the 1984 Hatch-Waxman Act and current FDA guidelines, in order for a generic manufacturer to receive FDA approval to sell a generic variant of a brand-name drug, it must demonstrate bioequivalence, necessitating the purchase of non-trivial quantities of the brand-name drug, a process that is greatly complicated by restricted distribution;^{9,10} and

¹ Langreth, R. and Koons, C. (2015) 2,000% Drug Price Surge Is a Side Effect of FDA Safety Program. Bloomberg Business, Available at: <http://www.bloomberg.com/news/articles/2015-10-06/2-000-drug-price-surge-is-a-side-effect-of-fda-safety-program>

² Marketed Unapproved Drugs Compliance Policy Guide § 440.100 Marketed New Drugs Without Approved NDAs or ANDAs. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf>

³ Brozak, S. (2014) Retrophin, Gilead, And Our Healthcare Values. Forbes, Available at: <http://www.forbes.com/sites/stephenbrozak/2014/09/12/retrophin-gilead-and-our-healthcare-values/#2299c6f9fca4>

⁴ Patel Y, Rumore MM. Hydroxyprogesterone caproate injection (makena) one year later: to compound or not to compound that is the question. P T. 2012;37(7):405-11.

⁵ Stobbe, M. (2011) Premature Labor Drug Spikes from \$10 to \$1,500. NBC News, Available at: <http://www.nbcnews.com/id/41994697/ns/health-pregnancy/t/premature-labor-drug-spikes/>

⁶ Lorenzetti, L. (2015) This 62-Year-Old Drug Just Got 5000% More Expensive. Fortune, Available at: <http://fortune.com/2015/09/21/turing-pharmaceuticals-drug-prices-daraprim/>

⁷ Carrier, M and Kesselheim A. (2015) The Daraprim Price Hike and a Role for Antitrust. Health Affairs Blog, Available at: <http://healthaffairs.org/blog/2015/10/21/the-daraprim-price-hike-and-a-role-for-antitrust/>

⁸ Mahoney, M. (2015) New Pyrimethamine Dispensing Program: What Pharmacists Should Know. Pharmacy Times, Available at: <http://www.pharmacytimes.com/contributor/monica-v-golik-mahoney-pharmd-bcps-aq-id/2015/07/new-pyrimethamine-dispensing-program-what-pharmacists-should-know#sthash.lruZY1k5.dpuf>

⁹ Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA. (2013). United States Food and Drug Administration. Available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377465.pdf>

¹⁰ Tucker D., Wells G., and Sheer, M. (2014) REMS: The Next Pharmaceutical Enforcement Priority? Antitrust. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2410950

Whereas, Often, though not always, a restricted distribution system implemented by FDA mandate as part of a Risk Evaluation & Mitigation Strategy (REMS) when the drug in question is associated with considerable health risks or other regulatory or clinical concerns such as counterfeiting and abuse;^{7,8,11,12,13,14} and

Whereas, Restricted distribution systems, even when implemented by FDA mandate per a REMS, are being exploited to block generic entry into the market by making it virtually impossible for generic manufacturers to obtain the necessary materials to perform bioequivalence testing, and the potential for exploitation is even greater when restricted distribution is implemented unilaterally at the manufacturer's discretion;^{10,15,16,17} and

Whereas, Provisions of the Food and Drug Administration Amendments Act of 2007 sought to address circumstances in which REMS can pose barriers to generic entry, but "it remains unclear whether the FDA even has any authority to enforce the prohibition against companies using a REMS to block generic entry" and the FDA has stated that it lacks an enforcement mechanism;^{10,12,14,15,16} and

Whereas, The FDA has a backlog of some 4,300 generic drug applications pending approval as of December 2015 and the median approval time rose from 27 months in 2010 to 36 months in 2013, despite the infusion of \$300 million from generic manufacturers in 2012 per the Generic Drug User Fee Amendments, which was intended to facilitate faster approval;^{18,19,20} and

Whereas, On March 1, 2016, Senator Susan Collins introduced S. 2615 "Increasing Competition in Pharmaceuticals Act", which directs the FDA to act within 150 days on generic drug applications when there is only one competing product available, and creates a "generic priority review voucher" program to speed approval of other generics;^{21,22} and

Whereas, Existing AMA policy seeks to address "the already high and escalating costs of generic prescription drugs" (H-110.988) while recognizing their cost-saving potential (H-125.984); therefore be it

RESOLVED, That our American Medical Association advocate with interested parties for legislative or regulatory measures that require prescription drug manufacturers to seek Federal Drug Administration and Federal Trade Commission approval before establishing a restricted distribution system (New HOD Policy); and be it further

¹¹ Kirschenbaum BE. Specialty pharmacies and other restricted drug distribution systems: financial and safety considerations for patients and health-system pharmacists. *Am J Health Syst Pharm*. 2009;66(24 Suppl 7):S13-20.

¹² Battaglia, L. (2013) Risky Conduct with Risk Mitigation Strategies? The Potential Antitrust Issues Associated with REMS. *Antitrust Healthcare Chronicle*, Available at: <http://www.hlregulation.com/files/2013/10/Lauren-Battaglia-article1.pdf>

¹³ Oral Cancer Agents Are Changing The Distribution Channel. (2006) *Oncology Business Review*, Available at: <https://obroncology.com/journal-current-dtl.php?recordID=8>

¹⁴ Risk evaluation and mitigation strategies, 21 U.S.C. § 355-1 (2010).

¹⁵ Tucker D., Wells G., and Sheer, M. (2014) REMS: The Next Pharmaceutical Enforcement Priority? *Antitrust*. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2410950

¹⁶ Fabish, A. (2015). REMS Abuse And Antitrust Injury: Round Peg, Square Hole. *Law360*. Available at: <http://www.law360.com/articles/723053/rem-abuse-and-antitrust-injury-round-peg-square-hole>

¹⁷ Fabish, A. (2015). Why REMS Abuse Doesn't Belong In Antitrust Litigation. *Law360*. Available at: <http://www.law360.com/articles/645875/why-rem-abuse-doesn-t-belong-in-antitrust-litigation>

¹⁸ Herrick, D. (2015) What Is Increasing the Cost of Generic Drugs? Part I: The Supply Chain. *National Center for Policy Analysis*, Available at: <http://www.ncpa.org/pdfs/st371.pdf>

¹⁹ Kaplan, S. (2015) One Reason for High Drug Prices: a Huge Backlog of Unapproved Generic Drugs. *STAT*, Available at: <http://www.statnews.com/2015/12/29/generic-drugs-backlog/>

²⁰ Barlas S. Generic prices take flight: the FDA is struggling to ground them. *P T*. 2014;39(12):833-45.

²¹ To Increase Competition in the Pharmaceutical Industry, S. S. 2615, 114th Cong. (2016). Print. Available at: <https://www.congress.gov/bill/114th-congress/senate-bill/2615/text>

²² Brennan, Zachary. (2016) More Competition: Senator Proposes Priority Reviews for Some Generics, New Voucher Program. *Regulatory Affairs Professional Society*. Available at: <http://www.raps.org/Regulatory-Focus/News/2016/03/03/24466/More-Competition-Senator-Proposes-New-Priority-Reviews-for-Some-Generics-New-Voucher-Program/>

1 RESOLVED, That our AMA support the mandatory provision of samples of approved out-of-
 2 patent drugs upon request to generic manufacturers seeking to perform bioequivalence assays
 3 (New HOD Policy); and be it further
 4

5 RESOLVED, That our AMA advocate with interested parties for legislative or regulatory
 6 measures that expedite the FDA approval process for generic drugs, including but not limited to
 7 application review deadlines and generic priority review voucher programs. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/29/16

RELEVANT AMA POLICY

Cost of New Prescription Drugs H-110.998 - Our AMA urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs.

Res. 112, I-89 Reaffirmed: Res. 520, A-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of Res. 229, I-14

Reducing Prescription Drug Prices D-110.993 - Our AMA will (1) continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs; and (2) encourage state medical associations and others that are interested in pharmaceutical bulk purchasing alliances, pharmaceutical assistance and drug discount programs, and other related pharmaceutical pricing legislation, to contact the National Conference of State Legislatures, which maintains a comprehensive database on all such programs and legislation.

CMS Rep. 3, I-04 Modified: CMS Rep. 1, A-14 Reaffirmation A-14 Reaffirmed in lieu of Res. 229, I-14

Inappropriate Extension of Patent Life of Pharmaceuticals D-110.994 - Our AMA will continue to monitor the implementation of the newly-enacted reforms to the Hatch-Waxman law to see if further refinements are needed that would prevent inappropriate extension of patent life of pharmaceuticals, and work accordingly with Congress and the Administration to ensure that AMA policy concerns are addressed.

BOT Rep. 21, A-04 Reaffirmed: BOT Rep. 19, A-14

The Evolving Culture of Drug Safety in the United States: Risk Evaluation and Mitigation Strategies (REMS) H-100.961 - Our AMA urges that: (1) The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) require sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; (c) clearly specify that sponsors must assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available; and (d) conduct a long-term assessment of the prescribing patterns of drugs with REMS requirements. (2) The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information. (3) To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common

definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed. (4) REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner. (5) The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) urge sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; and (c) recommend that sponsors assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available. (6) The FDA, in concert with the pharmaceutical industry, evaluate the evidence for the overall effectiveness of REMS with ETASU in promoting the safe use of medications and appropriate prescribing behavior. (7) The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information. (8) To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed. (9) REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner. (10) The FDA solicit input from the physician community before establishing any REMS programs that require prescriber training in order to ensure that such training is necessary and meaningful, requirements are streamlined and administrative burdens are reduced.

CSAPH Rep. 8, A-10 Reaffirmed: Res. 917, I-10 Appended: CSAPH Rep. 3, I-12

Pharmaceutical Cost H-110.987 - 1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives. 2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition. 3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry. 4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system. 5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies. 6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation. 7. Our AMA supports legislation to shorten the exclusivity period for biologics. 8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens. 9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and will report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.

CMS Rep. 2, I-15

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988 - 1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs. 2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients. 3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs. 4. Our AMA supports measures that increase price transparency for generic prescription drugs.
Sub. Res. 106, A-15 Reaffirmed: CMS 2, I-15

Study of Actions to Control Pharmaceutical Costs H-110.992 - Our AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs.
Sub. Res. 114, A-01 Reaffirmed: Res. 533, A-03 Reaffirmed: CMS Rep. 4, A-13 Reaffirmed in lieu of Res. 229, I-14 Reaffirmed: CMS 2, I-15

Cost of Prescription Drugs H-110.997 - Our AMA: (1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;(2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;(3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;(4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;(5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;(6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and(7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.
BOT Rep. O, A-90 Sub. Res. 126 and Sub. Res. 503, A-95 Reaffirmed: Res. 502, A-98 Reaffirmed: Res. 520, A-99 Reaffirmed: CMS Rep. 9, I-99 Reaffirmed: CMS Rep.3, I-00 Reaffirmed: Res. 707, I-02 Reaffirmation A-04 Reaffirmed: CMS Rep. 3, I-04 Reaffirmation A-06 Reaffirmed in lieu of Res. 814, I-09 Reaffirmed in lieu of Res. 201, I-11

Generic Drugs H-125.984 - Our AMA believes that: (1) Physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice. (2) It should be recognized that generic drugs frequently can be less costly alternatives to brand-name

products. (3) Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products (i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician. (4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA's MedWatch program. (5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products. (6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength). (7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process.

CSA Rep. 6, A-02 Reaffirmed: CSAPH Rep. 2, A-07 Reaffirmation A-08 Reaffirmation A-09
Reaffirmed in lieu of Res. 525, A-10 Reaffirmed in lieu of Res. 224, I-14

Cost Sharing Arrangements for Prescription Drugs H-110.990 - Our AMA: 1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients; 2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and 3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition.

CMS Rep. 1, I-07 Reaffirmation A-08 Reaffirmed: CMS Rep. 1, I-12 Reaffirmed in lieu of Res. 105, A-13

Generic Changes in Medicare (Part D) Plans D-330.911 - 1. Our AMA will investigate the incidence and reasoning behind the conversion of one generic drug to another generic drug of the same class in Medicare Advantage drug plans. 2. Our AMA will request the Centers for Medicare & Medicaid Services to ensure that pharmaceutical vendors, when they do ask for generic transitions of drugs, list the drugs they believe are more cost effective along with their tier price and alternative drug names.

Res. 124, A-14

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 810
(I-16)

Introduced by: Women Physicians Section

Subject: Medical Necessity of Breast Reconstruction and Reduction Surgeries

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, Macromastia is a common medical condition in the United States that results in symptoms including skin excoriation, restriction of physical activities, nerve compression, postural and skeletal changes, breast/back/neck/shoulder pain, headache, and bra strap grooving resulting in permanent skin changes; and

Whereas, Symptoms associated with macromastia can significantly impact quality of life, activity, and health; and

Whereas, Macromastia is a recognized condition that meets medical necessity criteria for insurance coverage under certain conditions; and

Whereas, Many insurance policies base approval for coverage on required removal of certain weights of tissue intraoperatively during reduction mammoplasty and these requirements are often based on height/weight/ body mass index (BMI) or body surface area (BSA) criteria; and

Whereas, A wide variety of breast sizes, densities, and/or weights may exist for any specific body height or weight and therefore BMI/BSA may not be the best predictors of medical necessity in all cases; and

Whereas, Health outcomes have not been shown to specifically correlate with baseline, preoperative breast size or specific weight of tissue resected intraoperatively; and

Whereas, Patient satisfaction and symptom improvement are significantly positive after surgical reduction mammoplasty; therefore be it

RESOLVED, That our American Medical Association support efforts to adapt medical necessity and insurance coverage decisions for assessment of preoperative symptomatology for macromastia without requirements for weight of volume resected during breast reduction surgery. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

References:

State Laws on Breast Reconstruction. Available at

<https://www.plasticsurgery.org/reconstructive-procedures/breast-reconstruction/breast-reconstruction-resources/state-laws-on-breast-reconstruction.html>.

RELEVANT AMA POLICY

Breast Reconstruction H-55.973

Our AMA: (1) believes that reconstruction of the breast for rehabilitation of the postmastectomy cancer patient should be considered reconstructive surgery rather than aesthetic surgery; (2) supports education for physicians and breast cancer patients on breast reconstruction and its availability; (3) recommends that third party payers provide coverage and reimbursement for medically necessary breast cancer treatments including but not limited to prophylactic contralateral mastectomy and/or oophorectomy; and (4) recognizes the validity of contralateral breast procedures needed for the achievement of symmetry in size and shape, and urges recognition of these ancillary procedures by Medicare and all other third parties for reimbursement when documentation of medical necessity is provided.

CCB/CLRPD Rep. 3, A-14

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 811
(I-16)

Introduced by: Texas

Subject: Opposition to CMS Mandating Treatment Expectations and Practicing Medicine

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, It is the goal of physicians to provide quality evidenced-based care to individual
2 patients based upon their varied acute medical conditions and underlying co-morbidities; and
3

4 Whereas, It is the appropriate responsibility of the federal Center for Medicare & Medicaid
5 Services (CMS) to oversee the quality and effectiveness of care paid for by the federal
6 government; and
7

8 Whereas, It is NOT appropriate for CMS to mandate clinical treatment for all patients, in all
9 circumstances regardless of the patient's condition or comorbidities, such as mandating
10 reporting of administration of 30cc/kg of crystalloid fluid for all patients with potential serious
11 infections, regardless of circumstance or comorbidities; and
12

13 Whereas, Administration of 30cc/kg of crystalloid fluid for all patients with potential serious
14 infections, regardless of circumstance, acuities and comorbidities can lead to intentional harm of
15 patients including loss of airway, generate complications such as pulmonary edema which may
16 require intubation, and death; and
17

18 Whereas, Physician treatment that causes harm to a patient is a violation of the Hippocratic
19 Oath, the Code of Medical Ethics, the Medical Practice Act, and may be found to constitute
20 'willful and wanton' negligence; and
21

22 Whereas, A current CMS-mandated reporting quality core measures requires "Resuscitation
23 with 30 ml/kg crystalloid fluid" for patients with potential serious infections, regardless of their
24 clinical circumstance and the interpretation of these Core Measures Sets (Go to
25 www.qualitynet.org/hospitals-inpatient/specifications manual) by Quality Net
26 (www.Qualitynet.org¹) do not recognize any exception for congestive heart failure, renal failure,
27 or liver failure or recognize any alternatives such as pressors or intravascular expansions such
28 as use of albumin in cirrhotic live patients; and

¹ Please see the response from Quality Net (www.Qualitynet.org). This is the CMS support site, which is as follows: There are no exclusions to the 30 ml/kg amount based on comorbidities such as heart failure (HF), end stage renal disease (ESRD) or the patient's weight. The question has been presented to the measure stewards who have indicated the rationale is based on the sepsis literature. The literature supports addressing the most urgent life threatening condition first which is severe sepsis with hypotension or lactate ≥ 4 . After this has been stabilized changes in fluid management to address HF, ESRD or other conditions can be put into place to prevent potential or developing adverse effects of the fluid volume.

1 Whereas, Individual hospitals can lack the appropriate interpretation of CMS core measure²,
2 resulting in inappropriate sanctions of physicians for appropriate medical care; therefore be it
3

4 RESOLVED, That our American Medical Association oppose CMS creating mandatory
5 standards of care that may potentially harm patients, disrupt the patient-physician relationship,
6 and fail to recognize the importance of appropriate physician assessment, evidence-based
7 medicine and goal-directed care of individual patients (New HOD Policy); and be it further
8

9 RESOLVED, That our AMA communicate to hospitals that some CMS mandatory standards of
10 care do not recognize appropriate physician treatment and may cause unnecessary harm to
11 patients (Directive to Take Action); and be it further
12

13 RESOLVED, That our AMA communicate to members, state and specialty societies, and the
14 public the dangers of CMS' quality indicators potentially harming the patient-physician
15 relationship. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

² Investigation results: "it is clear that patient [name] had Cirrhosis and severe anasarca and so can lead to fluid overload by administering CMS recommended 30ml/kg crystalloid fluids" with a response of "There are no exclusions to the 30 ml/kg amount based on comorbidities such as heart failure (HF), end stage renal disease (ESRD) or the patient's weight" and "Effective 07/01/2016: The ONLY acceptable fluids are crystalloid or balanced crystalloid solutions" and "Decision is upheld, variance remains".

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 812
(I-16)

Introduced by: Michigan

Subject: Enact Rules and Payment Mechanisms to Encourage Appropriate Hospice and Palliative Care Usage

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, Hospice and palliative care are being underutilized, resulting in unnecessary and expensive care during the last six months of life for many patients with complicated medical issues; and

Whereas, Hospice has been impacted by an administrative cut in addition to a series of cuts applied to most Medicare providers as part of health care reform and budget reduction efforts¹; and

Whereas, Beginning in October 2009, the Centers for Medicare and Medicaid Services began a seven-year phase out of the Budget Neutrality Adjustment Factor (BNAF), a key element in the Medicare hospice wage index that will ultimately result in a permanent reduction in hospice reimbursement rates of 4.2 percent²; and

Whereas, The 2009 Affordable Care Act imposed an additional change to the Medicare hospice formula that will further cut hospice payments by approximately 11.8 percent over the next 10 years through the introduction of a "productivity adjustment" on the calculation of annual payment updates for hospice; therefore be it

RESOLVED, That our American Medical Association (AMA) amend existing AMA Policy H-85.955, Hospice Care, by addition to read as follows:

Our AMA: (1) approves of the physician-directed hospice concept to enable the terminally ill to die in a more homelike environment than the usual hospital; and urges that this position be widely publicized in order to encourage extension and third party coverage of this provision for terminal care; (2) encourages physicians to be knowledgeable of patient eligibility criteria for hospice benefits and, realizing that prognostication is inexact, to make referrals based on their best clinical judgment; (3) supports modification of hospice regulations so that it will be reasonable for organizations to qualify as hospice programs under Medicare; (4) believes that each patient admitted to a hospice program should have his or her designated attending physician who, in order to provide continuity and quality patient care, is allowed and encouraged to continue to guide the care of the patient in the hospice program; (5) supports changes in Medicaid regulation and reimbursement of palliative care and hospice services to broaden eligibility criteria concerning the length of expected survival for pediatric patients and others, to allow provision of concurrent life-prolonging and

¹ Hospice action network. Reimbursement. Accessed at <http://hospiceactionnetwork.org/get-informed/issues/reimbursement/> on March 29, 2016.

² Ibid

1 palliative care, and to provide respite care for family care givers; and (6) advocates that
 2 the Centers for Medicare and Medicaid Services enact rules and payment mechanisms
 3 to encourage appropriate hospice and palliative care utilization for eligible patients; and
 4 (7) seeks amendment of the Medicare law to eliminate the six-month prognosis under
 5 the Medicare Hospice benefit and support identification of alternative criteria,
 6 meanwhile supporting extension of the prognosis requirement from 6 to 12 months as
 7 an interim measure. (Modify Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

Hospice Care H-85.955

Our AMA: (1) approves of the physician-directed hospice concept to enable the terminally ill to die in a more homelike environment than the usual hospital; and urges that this position be widely publicized in order to encourage extension and third party coverage of this provision for terminal care; (2) encourages physicians to be knowledgeable of patient eligibility criteria for hospice benefits and, realizing that prognostication is inexact, to make referrals based on their best clinical judgment; (3) supports modification of hospice regulations so that it will be reasonable for organizations to qualify as hospice programs under Medicare; (4) believes that each patient admitted to a hospice program should have his or her designated attending physician who, in order to provide continuity and quality patient care, is allowed and encouraged to continue to guide the care of the patient in the hospice program; (5) supports changes in Medicaid regulation and reimbursement of palliative care and hospice services to broaden eligibility criteria concerning the length of expected survival for pediatric patients and others, to allow provision of concurrent life-prolonging and palliative care, and to provide respite care for family care givers; and (6) seeks amendment of the Medicare law to eliminate the six-month prognosis under the Medicare Hospice benefit and support identification of alternative criteria, meanwhile supporting extension of the prognosis requirement from 6 to 12 months as an interim measure.

CCB/CLRPD Rep. 3, A-14

Hospice Services Under Medicare D-140.962

1. Our AMA recognizes the benefits to patients and their families that hospice represents in end-of-life care, and reaffirms that physicians (a) have a responsibility to see that hospice services are authorized in appropriate circumstances and settings, and (b) should be allowed and encouraged to remain actively involved in managing their patients' hospice care, in collaboration with hospice staff.
2. Our AMA will collaborate with interested organizations, including hospice organizations, and other medical societies, to develop educational materials and programs for physicians to ensure that hospice services are provided in the most cost-effective, appropriate settings.
3. Our AMA will call on the Centers for Medicare & Medicaid Services, in conjunction with stakeholder groups, to thoroughly study the Medicare hospice benefit, including its structure, payment methodology, quality assurance and regulatory scheme.

Citation: (Res. 4, A-10)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813
(I-16)

Introduced by: American Academy of Pediatrics

Subject: Physician Payment for Information Technology Costs

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, In 2009, the federal government developed and funded an incentive program to
2 encourage physicians to adopt electronic health records (American Recovery and Reinvestment
3 Act (ARRA), HiTech Act, Meaningful Use Program); and
4

5 Whereas, Most physicians have adopted electronic health records, at significant costs to their
6 practices; and
7

8 Whereas, Physicians are having significant difficulty qualifying for maximum Meaningful Use
9 payments; and
10

11 Whereas, Physicians are incurring significant ongoing information technology costs that are not
12 covered by ongoing Meaningful Use payment options; and
13

14 Whereas, Meaningful Use payments will be phased out in the near future (2021); and
15

16 Whereas, There is recent evidence that physicians spend two hours with the electronic health
17 record for every one hour of patient care; and
18

19 Whereas, Physician payment has not increased to help physicians pay for their ongoing costs
20 for adopting and implementing electronic health records; therefore be it
21

22 RESOLVED, That our American Medical Association assist in gathering and providing data that
23 physicians can use to convince public and private payers that payment must cover the
24 increasing information technology costs of physicians. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 814
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire,
Rhode Island, Vermont

Subject: Addressing Discriminatory Health Plan Exclusions or
Problematic Benefit Substitutions for Essential Health
Benefits Under the Affordable Care Act

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Improving patient outcomes is an American Medical Association goal; and

2
3 Whereas, The Affordable Care Act requires that benefits are provided without discrimination
4 based on health condition, race, color, national origin, age, disability, sex, sexual orientation or
5 gender identity; and

6
7 Whereas, Covered benefits in states still vary widely, including gaps in coverage, arbitrary limits,
8 discriminatory benefit designs and/or cost-sharing on the basis of age, sex, gender, degree of
9 medical dependency, gender identity, disability, and quality of life; and

10
11 Whereas, Gaps in women's health coverage persist because insurers often exclude health
12 services women are likely to need, leaving women vulnerable to higher costs and denied claims
13 that threaten economic security and physical health; and

14
15 Whereas, Six categories of services are frequently excluded from insurance coverage that
16 disproportionately affect women such as treatment of conditions resulting from non-covered
17 services, (e.g. (e.g. Treatment of an infection after a non-covered prophylactic mastectomy)
18 maternity care, gender transition, maintenance therapy, genetic testing, self-inflicted conditions,
19 fetal surgeries, and preventive services; and

20
21 Whereas, Parity violations persist for a number of critical services, including, but not limited to
22 mental health and substance abuse disorders, and gaps persist in coverage for pediatric
23 services, including dental and vision services, habilitative services and prescription drugs; and

24
25 Whereas, Service exclusions and benefit substitutions are often described in health plan
26 materials in language that is difficult to fully comprehend; therefore be it

1 RESOLVED, That our American Medical Association work with state medical societies and their
2 state regulators to facilitate the following:

- 3 1. Prohibit health plans from imposing arbitrary limits that are unreasonable or potentially
4 discriminatory for coverage of the Essential Health Benefits.
- 5 2. Require any insurer, whose plans contain exclusions that are not in the state Essential
6 Health Benefits benchmark plan, demonstrate that its benefits are substantially similar and
7 actuarially equivalent to the benchmark, in compliance with federal regulations.
- 8 3. Define the state habilitative Essential Health Benefits definition that goes beyond the federal
9 minimum definition.³
- 10 4. Review current plans for discriminatory exclusions and require insurers to revise these plans
11 if discriminatory exclusions present;
- 12 5. Review consumer complaints for incidents of discriminatory benefit and formulary design,
13 cost-sharing, problematic Essential Health Benefits substitutions or exclusions.
- 14 6. Prohibit insurer benefit substitutions in the Essential Health Benefits (Directive to Take
15 Action); and be it further
16

17 RESOLVED, That our AMA work with federal regulators to:

- 18 1. Improve the Essential Health Benefits benchmark plan selection process to ensure arbitrary
19 limits and exclusions do not impede access to healthcare and coverage.
- 20 2. Develop policy to prohibit Essential Health Benefits substitutions that do not exist in a state's
21 benchmark plan or selective use of exclusions or arbitrary limits to prevent high-cost claims
22 or that encourage high-cost enrollees to drop coverage.
- 23 3. Review current plans for discriminatory exclusions and submit any specific incidents of
24 discrimination through an administrative complaint to Office for Civil Rights. (Directive to
25 Take Action)

References

¹ The Commonwealth Fund, August 2016, <http://www.commonwealthfund.org/>

² The National Women's Law Center, State of Women's Coverage: Health Plan Violations of the Affordable Care Act (NWLC 2015), National Women's Law Center, <http://nwlc.org/wpcontent/uploads/2015/04/stateofwomenscoverage2015final.pdf>

³ The federal definition of habilitative services is health care services that help a person keep, learn or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings. Found in the CMS glossary of medical terms and finalized in 2016.

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/11/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 815
(I-16)

Introduced by: Washington

Subject: Preservation of Physician-Patient Relationships and
Promotion of Continuity of Patient Care

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, Medicare (CMS) is rapidly moving towards bundled payment models (e.g. the Comprehensive Care Joint Replacement Model and the Cardiac Bundled Payment Model); and

Whereas, Bundled payments involve setting one price per patient per episode of care; and

Whereas, There is interest in bundles encompassing chronic conditions and long-term diseases including diabetes, obesity and cancer; and

Whereas, This promotes coordinated care but also requires data collection, reviewing care processes and cost accounting; and

Whereas, CMS has both voluntary Bundled Payment for Care Improvement Initiatives as well as mandatory bundled payments; and

Whereas, Bundled payment models can encourage in-hospital referrals, in turn interfering with established relationships between patients and their preferred physicians; therefore be it

RESOLVED, That our American Medical Association support policies that encourage the freedom of patients to choose the health care delivery system that best suits their needs and provides them with a choice of physicians (New HOD Policy); and be it further

RESOLVED, That our AMA support the freedom of choice of physicians to refer their patients to the physician practice or hospital that they think is most able to provide the best medical care (New HOD Policy); and be it further

RESOLVED, That our AMA support policies that encourage patients to return to their established primary care provider after emergency department visits, hospitalization or specialty consultation. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 10/13/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 816
(I-16)

Introduced by: Senior Physicians Section

Subject: Support for Seamless Physician Continuity of Patient Care

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

Whereas, With an aging population and shortage of physicians facing America, the AMA Senior Physicians Section (AMA-SPS) will work to engage senior physicians (age 65 and older), both active and retired, to ensure high-quality care and safety for patients by collaboration with other stakeholders in the changing health care system; and

Whereas, Senior physicians (and others) come out of training programs where continuity was considered one of the critical foundations of a quality medical practice; and

Whereas, There has been extreme growth of the present day practice of separating inpatient care from office care as far as the role of the physician is concerned; and

Whereas, Systems are not yet commonplace that assure seamless care between the inpatient and office care settings; and

Whereas, Those physicians and others who choose to provide care in both the inpatient and office settings are being precluded by health insurance system policies; therefore be it

RESOLVED, That our American Medical Association clearly support the concept of seamless continuity of care between hospital inpatient and outpatient care (New HOD Policy); and be it further

RESOLVED, That our AMA study whether there are instances of health insurers or HMO's precluding physicians via contracts from providing care to their patients in the in-patient setting for which the physician has clinical privileges. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/13/16

RELEVANT AMA POLICY

Admitting Officer and Hospitalist Programs H-285.964

AMA policy states that: (1) managed care plan enrollees and prospective enrollees should receive prior notification regarding the implementation and use of "admitting officer" or "hospitalist" programs; (2) participation in "admitting officer" or "hospitalist programs" developed and implemented by managed care or other health care organizations should be at the voluntary discretion of the patient and the patient's physician; (3) hospitalist programs when initiated by a hospital or managed care organization should be developed consistent with AMA policy on medical staff bylaws and implemented with the formal approval of the organized medical staff by at least the same notification and voting threshold required to approve a bylaws change to assure that the principles and structure of the autonomous and self-governing medical staff are retained; (4) Hospitals and other health care organizations should not compel physicians by contractual obligation to assign their patients to "Hospitalists" and that no punitive measure should be imposed on physicians or patients who decline participation in "hospitalists programs"; and (5) AMA opposes any hospitalist model that disrupts the patient/physician relationship or the continuity of patient care and jeopardizes the integrity of inpatient privileges of attending physicians and physician consultants.

Sub. Res. 714, I-95 Amended by CMS Rep. 4, A-98 Reaffirmed: Res. 819, A-99 Reaffirmation I-99 Reaffirmed: Res. 812, A-02 Reaffirmed: BOT Rep. 15, A-05 Reaffirmed in lieu of Res. 734, A-05 Modified: Res. 731, A-07

Preserving Physician/Patient Relationships During Hospitalizations H-225.946

1. Our AMA advocates that hospital admission processes should include: a determination of whether the patient has an existing relationship with an actively treating primary care or specialty physician; where the patient does not object, prompt notification of such actively treating physician(s) of the patient's hospitalization and the reason for inpatient admission or observation status; to the extent possible, timely communication of the patient's medical history and relevant clinical information by the patient's primary care or specialty physician(s) to the hospital-based physician; notice to the patient that he/she may request admission and treatment by such actively treating physician(s) if the physician has the relevant clinical privileges at the hospital; honoring requests by patients to be treated by their physician(s) of choice; and allowing actively treating physicians to treat to the full extent of their hospital privileges.

2. Our AMA advocates that a medical staff incorporate the above principles into medical staff bylaws, rules and regulations.

Res. 812, I-15 Modified: CMS Rep. 06, A-16

The Emerging Use of Hospitalists: Implications for Medical Education D-225.999

(1) Our AMA, through its Council on Medical Education and Council on Medical Service, will collect data on the following areas: (a) the emergence of educational opportunities for hospitalist physicians at the residency level, including the curriculum of hospitalist tracks within residency training programs; (b) the availability and content of continuing medical education opportunities for hospitalist physicians; (c) the policies of hospitals and managed care organizations related to the maintenance of hospital privileges for generalist physicians who do not typically care for inpatients; and (d) the quality and costs of care associated with hospitalist practice.

(2) Our Council on Medical Education and Council on Medical Service will monitor the evolution of hospitalist programs, with the goal of identifying successful models.

(3) Our AMA will encourage dissemination of information about the education implications of the emergence of hospitalism to medical students, resident physicians, and practicing physicians.

CME Rep. 2, A-99 Reaffirmed: CME Rep. 2, A-09

Voluntary Use of Hospitalists and Required Consent H-225.960

It is the policy of our AMA that the use of a hospitalist physician as the physician of record during a hospitalization must be voluntary and the assignment of responsibility to the hospitalist physician must be based on the consent of the patient's personal physician and the patient.

CME Rep. 2, A-99 Reaffirmation I-99 Reaffirmed: Res. 812, A-02 Reaffirmed with change in title: BOT Rep. 15, A-05 Reaffirmed in lieu of Res. 734, A-05 Reaffirmed: CME Rep. 1, A-15

Reference Committee K

BOT Report(s)

- 09 Product-Specific Direct-to-Consumer Advertising of Prescription Drugs

CSAPH Report(s)

- 01 Urine Drug Testing
- 03 Genome Editing and its Potential Clinical Use
- 04 Hormone Therapies: Off-Label Uses and Unapproved Formulations

Resolution(s)

- 901 Disclosure of Screening Test Risks and Benefits, Performed Without a Doctor's Order
- 902 Removing Restrictions on Federal Public Health Crisis Research
- 903 Prevention of Newborn Falls in Hospitals
- 904 Improving Mental Health at Colleges and Universities for Undergraduates
- 905 Chronic Traumatic Encephalopathy (CTE) Awareness
- 906 Universal Color Scheme for Respiratory Inhalers
- 907 Clinical Implications and Policy Considerations of Cannabis Use
- 908 Faith and Mental Health
- 909 Promoting Retrospective and Cohort Studies on Pregnant Women and Their Children
- 910 Disparities in Public Education as a Crisis in Public Health and Civil Rights
- 911 Importance of Oral Health in Medical Practice
- 912 Neuropathic Pain Recognized as a Disease
- 913 Improving Genetic Testing and Counseling Services in Hospitals and Healthcare Systems
- 914 Needle / Syringe Disposal
- 915 Women and Alzheimer's Disease
- 916 Women and Pre-Exposure Prophylaxis (PrEP)
- 917 Youth Incarceration in Adult Prisons
- 918 Ensuring Cancer Patient Access to Pain Medication
- 919 Coal-Tar Based Sealcoat Threat to Human Health and the Environment
- 920 Haptenation and Hypersensitivity Disorders Communication
- 921 Raise the Minimum Age of Legal Access to Tobacco to 21 Years
- 922 Responsible Parenting and Access to Family Planning
- 923 Reverse Onus in the Manufacture and Use of Chemicals
- 924 AMA Advocacy for Environmental Sustainability and Climate
- 925* Graphic Warning Label on all Cigarette Packages

* contained in Handbook Addendum

REPORT OF THE BOARD OF TRUSTEES

B of T Report 9-I-16

Subject: Product-Specific Direct-to-Consumer Advertising of Prescription Drugs
(Second Resolve, Resolution 927-I-15; Resolution 514-A-16)

Presented by: Patrice A. Harris, MD, MA, Chair

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 INTRODUCTION

2
3 The second resolve of Substitute Resolution 927-I-15, “Ban Direct-To-Consumer Advertisements
4 of Prescription Drugs and Implantable Medical Devices,” referred for decision by the House of
5 Delegates (HOD), and then directed for a report back¹ by the Board of Trustees asked:

6
7 That Policy H-105.988, “Direct-to-Consumer Advertising of Prescription Drugs and
8 Implantable Medical Devices,” be rescinded.

9
10 Resolution 514-A-16, “Opposing Tax Deductions for Direct-to-Consumer Advertising,” introduced
11 by the California Delegation and referred by the HOD asked:

12
13 That our American Medical Association oppose allowing costs for direct-to-consumer
14 advertising of prescription medications, medical devices, and controlled drugs to be considered
15 deductible business expenses for tax purposes.

16
17 AMA Policy H-105.986, “Ban Direct-to-Consumer Advertisements of Prescription Drugs and
18 Implantable Devices,” supports a ban on direct-to-consumer advertising for prescription drugs and
19 implantable medical devices. Policy H-105.988 contains a detailed set of guidelines for
20 establishing what the AMA considers to be acceptable product-specific direct-to-consumer
21 advertisements (DTCA) for prescription drugs and implantable medical devices. Although AMA
22 policy supports a ban on DTCA, it may be reasonable and prudent to maintain a policy that
23 provides a framework to evaluate the appropriateness and/or usefulness of DTCA, based
24 principally on the fact that the Supreme Court has ruled that DTCA is protected commercial free
25 speech and therefore, this practice will likely continue in the future. This report summarizes
26 concerns and findings on the impact of DTCA and whether the AMA should maintain a
27 comprehensive policy on what constitutes acceptable product-specific DTCA. Additionally, this
28 report briefly considers whether establishing policy opposing industry tax credits for DTCA is
29 advisable.

30 31 BACKGROUND

32 33 *Food and Drug Administration Regulation of DTCA*

34
35 Pharmaceutical companies began marketing prescription drugs directly to consumers in the early
36 1980s. In 1983, the Food and Drug Administration (FDA) imposed a moratorium on DTCA, to

which the industry agreed. Two years later, based on the legal view that DTCA is constitutionally protected free speech, the FDA concluded that it lacked the legal authority to prevent this type of advertising and agreed to allow it as long as DTCAs: (1) were not false or misleading; (2) presented a fair balance between benefit and risk information; and (3) revealed all material facts about risks in the form of a so-called “brief summary.” The latter required that ads provide sufficient information about warnings, precautions, and side effects associated with prescription drug products. Based on these substantial informational requirements, most product-specific DTCAs in the 1980s and 1990s were largely restricted to print media.

In 1999, the FDA acted to facilitate DTCA via broadcast media by finalizing the Agency’s “Guidance for Industry: Consumer-Directed Broadcast Advertisements.”² This Guidance relaxed the responsibilities for the industry with respect to providing risk information in DTCA. The key new provision was that the FDA now required pharmaceutical manufacturers to provide only risk information related to the major side effects and contraindications of the advertised drugs in the audio or visual portion of the broadcast (referred to as the “major statement”) and make “adequate provision” for obtaining the full prescribing information in connection with the advertisement.³ The latter could be accomplished by referral to a company-designated toll free phone number or web page, a print advertisement for the product or referral to the patient’s physician or pharmacist for additional information.

With these changes, the appearance of DTCA in broadcast media increased substantially. By 2006, the industry was spending \$5.4 billion annually on DTCA. The *2007 Food and Drug Administration Amendments Act* gave the FDA the authority to require submission of any television drug advertisement for advisory review not later than 45 days before the ad is publicly disseminated. Although the FDA can make certain recommendations for the DTCA based on information included in the drug’s package insert (including addressing efficacy of the drug in specific populations), it has no authority to require changes except for specific disclosure about serious risks, or the date of approval, if the ad would otherwise be deemed false or misleading. In 2012, the FDA issued draft guidance for industry on how it planned to implement the requirement for the pre-dissemination review of DTCA.³ This guidance establishes several categories of television ads subject to pre-dissemination review (e.g., initial ads for a new drug, any drug with a Risk Evaluation and Mitigation Strategy, controlled substances, and any drug with a black box warning). The FDA’s Office of Prescription Drug Promotion (OPDP) is responsible for reviewing prescription drug advertising and promotional labeling to ensure the information contained in the promotional materials is not false or misleading. OPDP also encourages health care providers to report misleading ads through the Bad Ad program.

The regulatory structure around certain aspects of DTCA may change as the FDA moves to enact new regulations regarding risk communication. In 2015, the FDA sought public comments on new guidance for pharmaceutical marketers on communicating risks to consumers in print advertisements. The Agency’s proposal is based on accumulated research showing that reprinting highly technical language in print advertisements does very little to communicate risks to consumers. Rather, the FDA is proposing that companies use a new “consumer brief summary” focused on the most important risk information in a way most likely to be understood by consumers. This would move the requirements for risk communication in print advertisements in the same direction as previously made for broadcast advertisements.

DTCA-Pro or Con?

The United States is one of only two countries in the world that allows DTCA in broadcast, print, and electronic media; the other is New Zealand. Last year the industry spent \$5.4 billion on such

advertising, a 58% increase from 2012, and equivalent to the peak spending last achieved in 2006.⁴ During the same time period, the proportion of total DTCA spending devoted to television increased from 57% to 69%. Considerable debate has focused on whether DTCA is beneficial or harmful to patients or the patient/physician relationship, and whether physician prescribing behavior is significantly affected.

The following lists the major pro and con arguments that have been made regarding DTCA:

Arguments in Support of DTCA

- Educates patients and encourages patient responsibility for their health.
- Increases patient awareness of medical conditions and treatment options.
- Encourages patients to contact their physician, or otherwise engage the healthcare system.
- Results in cost savings; by seeking medical attention, patients have their conditions managed in a more prompt fashion, avoiding unneeded hospital stays or more costly interventions.
- Stimulates thoughtful dialogue and strengthens a patient's relationship with their health care provider.
- Encourages patient adherence, with drug ads serving as reminder aids.
- Reduces underdiagnoses and undertreatment of certain conditions or diseases.
- Removes the stigma associated with certain diseases.

Arguments Opposing DTCA

- Misinforms patients by omitting important information or using an inappropriate literacy level.
- Advertisements often do not exhibit fair balance and may overemphasize or create heightened expectations of drug benefits.
- Drives demand for a new drug before its safety profile in the general population is established, exacerbating harm.
- Leads to the "medicalization" of natural conditions, cosmetic issues, or trivial ailments.
- Promotes inappropriate prescribing and drives choice of more expensive branded products, increasing costs.
- Harms the patient-doctor relationship; wastes appointment time, especially when the advertised drug is inappropriate for the patient's disease or condition.
- Is not sufficiently regulated by the FDA.

While it may seem relatively easy to validate these arguments, the available research suggests both beneficial and harmful effects of DTCA, with each of the arguments above supported by some evidence. Accordingly, the question of whether DTCA results in net benefit or harm remains unsettled even today. Several reviews are available on the subject.⁶⁻¹⁷

Another aspect of DTCA is how it can be structured to improve patient or public health benefits and/or reduce the potential for harm. Some suggested remedies include mandatory FDA preclearance, a moratorium or delay in the advertising for new products, better transparency involving online webpages or advertising, including quantitative information about risks and benefits in the advertisement, using communication strategies to improve patient comprehension about risks and benefits, and including cost information.⁸ The FDA continues to study ways in which patients react to DTCA. A recent study, updating a previous 2002 FDA phone survey, found that 46% and 52% of respondents believed that DCTA did not include enough information about

benefits and risks, respectively, suggesting that the educational effects of DTCA can be substantially improved.¹⁸

There has been renewed Congressional interest in instituting a time-limited moratorium on DTCA for newly approved drugs based on the fact that new and important safety data not evident during the limited clinical trials conducted for FDA approval often emerge during the early marketing phase. The *Responsibility in Drug Advertising Act of 2016* (H.R. 4565) introduced by Rosa DeLauro seeks to establish a 3-year moratorium on advertising for new prescription drugs. Another approach is legislation introduced by Senator Franken. The *Protecting Americans from Drug Marketing Act* would eliminate the tax deduction that pharmaceutical companies can take on monies spent on prescription drug advertising. The AMA has expressed tentative support for this approach, which is consistent with a policy stance that seeks to scale back or eliminate DTCA.

SHOULD AMA POLICY H-105.988 BE RETAINED

DTCA comes in three forms: product-claim ads, reminder ads, and help-seeking ads. AMA policy H-105.988 addresses product-claim ads. Reminder ads (drug and dosage form) make no claims, so the “fair balance” requirement and other legal standards or risk information requirements (i.e., “brief summary” and “adequate provision”) are not required. Help-seeking ads are disease- or condition-specific and do not advertise a specific drug.

Current AMA Policy on what constitutes an acceptable DTCA has evolved over more than 20 years. With input from the FDA, the AMA developed an internal set of guidelines in 1993 for “acceptable” DTCAs appearing in the organization’s consumer publications. These guidelines eventually became an integral part of Policy H-105.988 with adoption of BOT Report 38-A-99, “Direct-to Consumer Advertising of Prescription Drugs,” by the HOD.¹⁹ Policy H-105.988 was further amplified by adoption of BOT Report 9-A-06, “Direct-to-Consumer Advertising of Prescription Drugs.”⁶ In addition to modifying the existing AMA guidelines for an acceptable DTCA, BOT 9-A-06 also called for FDA pre-approval of all product-claim DTCAs, as well as adequate funding of the FDA to effectively regulate DTCA; a moratorium on DTCA for newly approved prescription drugs until physicians are sufficiently educated about them; and a periodic assessment of DTCA by the Agency for Healthcare Research and Quality. AMA Ethical Opinion E-9.6.7, “Direct-to-Consumer Advertisements of Prescription Drugs,” provides additional guidance for physicians on how to respond in a responsible fashion to specific patient requests and inquiries prompted by DCTA.

The Pharmaceutical Research and Manufacturers of America (PhRMA) updated its voluntary principles for the conduct of DTCA in 2008 (see Appendix). In most respects, these voluntary standards are compatible with existing AMA guidelines for an acceptable DTCA. While companies pledge to adhere to these standards, some criticism has been leveled at individual companies for consistently failing to comply with the guiding principles, especially as they relate to minimizing exposure of children to adult content.²⁰ Given that it is unlikely that DTCA will be eliminated, it makes sense to have a policy in place stressing acceptable attributes and related recommendations.

CONCLUSION

Research suggests that DTCA can be both beneficial and detrimental, with several position points on both sides. Research is ongoing on how DTCA influences patients and physicians and other prescribers, and several remedies have been suggested to improve the likelihood of patient benefit and to reduce potential harm from this practice. DTCA differs from other forms of advertising because a learned intermediary (i.e., the prescriber) is required for the consumer to gain access to

1 the product. The seminal question for this report is whether the AMA should retain a policy that
2 articulates features comprising what the organization considers to be acceptable for DTCA, in the
3 face of policy supporting a ban on the practice. The Board of Trustees agrees that since DTCA is
4 legally permitted, this framework should be retained and recommends modest amendments to the
5 current policy, including support for eliminating tax deductions for DTCA spending.

6 7 RECOMMENDATION

8
9 The Board of Trustees recommends that the following statements be adopted in lieu of Second
10 Resolve, Resolution 927-1-15 and Resolution 514-A-16, and the remainder of the report be filed.

- 11
12 1. That Policy H-105.988, “Direct-to-Consumer (~~DTC~~) Advertising (DTCA) of Prescription
13 Drugs and Implantable Devices,” be amended by addition and deletion to read as follows:

14
15 It is the policy of our AMA:

16 1. to support a ban on direct-to-consumer advertising for prescription drugs and implantable
17 medical devices.

18
19 2. That until such a ban is in place, 1. That our AMA considers acceptable only those our AMA
20 opposes product-claims-specific DTCA advertisements that does not satisfy the following
21 guidelines:

22 (a) The advertisement should be indication-specific and enhance consumer education
23 about ~~both~~ the drug or implantable medical device, and the disease, disorder, or condition for
24 which the drug or device is used.

25 (b) In addition to creating awareness about a drug or implantable medical device for the
26 treatment or prevention of a disease, disorder, or condition, the advertisement should convey a
27 clear, accurate and responsible health education message by providing objective information
28 about the benefits and risks of the drug or implantable medical device for a given indication.
29 Information about benefits should reflect the true efficacy of the drug or implantable medical
30 device as determined by clinical trials that resulted in the drug’s or device’s approval for
31 marketing.

32 (c) The advertisement should clearly indicate that the product is a prescription drug or
33 implantable medical device to distinguish such advertising from other advertising for non-
34 prescription products.

35 (d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer
36 patients to their physicians for more information. A statement, such as “Your physician may
37 recommend other appropriate treatments,” is recommended.

38 (e) The advertisement should exhibit fair balance between benefit and risk information when
39 discussing the use of the drug or implantable medical device product for the disease, disorder,
40 or condition. The amount of time or space devoted to benefit and risk information, as well as
41 its cognitive accessibility, should be comparable.

42 (f) The advertisement should present information about warnings, precautions, and potential
43 adverse reactions associated with the drug or implantable medical device product in a manner
44 (e.g., at a reading grade level) such that it will be understood by a majority of consumers,
45 without distraction of content, and will help facilitate communication between physician and
46 patient.

47 (g) The advertisement should not make comparative claims for the product versus other
48 prescription drug or implantable medical device products; however, the advertisement should
49 include information about the availability of alternative non-drug or non-operative
50 management options such as diet and lifestyle changes, where appropriate, for the disease,
51 disorder, or condition.

(h) In general, product-claims specific DTCA advertisements should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA advertisements, a disclaimer should be prominently displayed.

(i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.

(j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.

(k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.

~~2. That our AMA opposes product specific DTC advertisements, regardless of medium, that do not follow the above AMA guidelines.~~

3. That the FDA review and pre-approve all DTCA advertisements for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.

4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA.

5. That DTCA advertisements for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.

6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA advertisements.

7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.

8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.

1 9. That our AMA encourages physicians to be familiar with the above AMA guidelines for
2 product-claims-specific DTCA and with the Council on Ethical and Judicial Affairs (~~CEJA~~)
3 Ethical Opinion E-5.0159.6.7 and to adhere to the ethical guidance provided in that Opinion.
4

5 10. That the Congress should request the Agency for Healthcare Research and
6 Quality (~~AHRQ~~) or other appropriate entity to perform periodic evidence-based reviews of
7 DTCA in the United States to determine the impact of DTCA on health outcomes and the
8 public health. If DTCA is found to have a negative impact on health outcomes and is
9 detrimental to the public health, the Congress should consider enacting legislation to increase
10 DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation,
11 every effort should be made to not violate protections on commercial speech, as provided by
12 the First Amendment to the U.S. Constitution.
13

14 11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a
15 deductible business expense for tax purposes.
16

17 12. That our AMA continues to monitor DTCA, including new research findings, and work
18 with the FDA and the pharmaceutical and medical device industries to make policy changes
19 regarding DTCA, as necessary.
20

21 13. That our AMA supports “help-seeking” or “disease awareness” advertisements (i.e.,
22 advertisements that discuss a disease, disorder, or condition and advise consumers to see their
23 physicians, but do not mention a drug or implantable medical device or other medical product
24 and are not regulated by the FDA). (Modify Current HOD Policy)
25

- 26 2. That Policy H-105.986, “Ban Direct-to-Consumer Advertisements of Prescription Drugs and
27 Implantable Devices,” be rescinded as it is now incorporated into amended Policy H-105.988.
28 (Rescind HOD Policy)

Fiscal Note: Less than \$500

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Appendix
PhRMA Guiding Principles on Direct-to-Consumer Advertisements of Prescription Drugs

1. These Principles are premised on the recognition that DTC advertising of prescription medicines can benefit the public health by increasing awareness about diseases, educating patients about treatment options, motivating patients to contact their physicians and engage in a dialogue about health concerns, increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated, and encouraging compliance with prescription drug treatment regimens.
2. In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling. Accordingly, companies should continue to base promotional claims on FDA approved labeling and not promote medicines for off-label uses, including in DTC advertisements.
3. DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed. During the development of new DTC television advertising campaigns, companies should seek and consider feedback from appropriate audiences, such as health care professionals and patients, to gauge the educational impact for patients and consumers.
4. DTC television and print advertising of prescription drugs should clearly indicate that the medicine is a prescription drug to distinguish such advertising from other advertising for non-prescription products.
5. DTC television and print advertising should foster responsible communications between patients and health care professionals to help patients achieve better health and a more complete appreciation of both the health benefits and the known risks associated with the medicine being advertised.
6. In order to foster responsible communication between patients and health care professionals, companies should spend an appropriate amount of time to educate health professionals about a new medicine or a new therapeutic indication and to alert them to the upcoming advertising campaign before commencing the first DTC advertising campaign. In determining what constitutes an appropriate time, companies should take into account the relative importance of informing patients of the availability of a new medicine, the complexity of the risk-benefit profile of that new medicine and health care professionals' knowledge of the condition being treated. Companies are encouraged to consider individually setting specific periods of time, with or without exceptions, to educate health care professionals before launching a branded DTC television or print advertising campaign. Companies should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources.
7. Working with the FDA, companies should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown safety risk.
8. Companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.
9. DTC print advertisements for prescription medicines should include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events. DTC television advertisements for prescription medicines should direct patients to a print advertisement containing FDA's toll-free MedWatch telephone number and website, and/or should provide the company's toll-free telephone number.
10. Companies that choose to feature actors in the roles of health care professionals in a DTC television or print advertisement that identifies a particular product should acknowledge in the advertisement that actors are being used. Likewise, if actual health care professionals appear in such advertisements, the advertisement should include an acknowledgement if the health care professional is compensated for the appearance.
11. Where a DTC television or print advertisement features a celebrity endorser, the endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser. Companies should maintain verification of the basis of any actual or implied endorsements made by the celebrity endorser in the DTC advertisement, including whether the endorser is or has been a user of the product if applicable.
12. DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition.
13. DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.
14. DTC television and print advertising should be designed to achieve a balanced presentation of both the benefits and the risks associated with the advertised prescription medicine. Specifically, risks and safety information, including the substance of relevant boxed warnings, should be presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content. In addition, DTC television advertisements should support responsible patient education by directing patients to health care professionals as well as to print advertisements and/or websites where additional benefit and risk information is available.
15. All DTC advertising should respect the seriousness of the health conditions and the medicine being advertised.
16. In terms of content and placement, DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved. In particular, DTC television and print advertisements containing content that may be inappropriate for children should be placed in programs or publications that are reasonably expected to draw an audience of approximately 90 percent adults (18 years or older).
17. Companies are encouraged to promote health and disease awareness as part of their DTC advertising.
18. Companies should include information in all DTC advertising, where appropriate, about help for the uninsured and underinsured.

REPORT 1 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-16)
Urine Drug Testing
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. The Council on Science and Public Health initiated this report to help promulgate urine drug testing (UDT) as a medical management tool that can be used to better serve patient populations.

Methods. English-language articles were selected from a search of the PubMed database through August 5, 2016 using the search terms “urine drug testing” and “opioids,” and “urine drug testing” and “controlled substances.” Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society websites were conducted to identify clinical guidelines and position statements.

Results. Many urine drug tests (UDTs) utilized in clinical care are grounded in immunoassay (IA) technology. IA UDTs are designed to detect a specific drug or a class of drugs as either present or absent based on a designated threshold concentration. Results based on IAs are considered presumptive and are often used as an initial screening test (i.e., qualitatively positive or negative) in clinical UDT. Point-of-care (POC) tests are typically non-instrumented IA devices (strips, dipcards) that can be used in clinics and are presumptive, qualitative, variable, and have a number of other limitations. The current gold standard and method of confirmatory testing after IA in UDT is separation of a specimen and specific identification of drugs/metabolites using gas or liquid chromatography-mass spectrometry (GC-, LC-MS). Recently, liquid chromatography-tandem mass spectrometry (LC-MS/MS) has been utilized, with success, as screening technique. The detection period for drug exposure varies depending on the disposition characteristics of the drug, dose, and frequency of use. Unexpected findings are common in clinical UDT. Proper interpretation of UDTs can be complex depending on the type of assay, possible adulteration, detection time and thresholds, and therapeutic response.

Conclusion. UDT is an objective means to detect the use of nonprescribed or illicit drugs and to confirm the presence of prescribed drugs. The elements of the drug test such as the composition of the drug test panel and the testing method/technology should be determined by the patient’s physician. Therefore, it is important for physicians to understand the elements of UDT in order to make informed decisions. The value of UDT depends on clinicians appreciating the strengths and weaknesses of the test or the laboratory and their relationship with the laboratory. Understanding the drugs that are detected in IAs and those detectable only via confirmatory methods, cross reactivity, and detection thresholds are critical, as well as the fact that these parameters can change over time. Aberrant UDT results can be used as an objective measure and used to motivate patient change and stimulate healthy physician-directed patient education. Although specific training and application to individual clinical management are outside of the scope of this report, the Council recommends the development of practical guidance to assist clinicians in implementing UDT in their practices and understanding how UDT results may affect patient management.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-16

Subject: Urine Drug Testing

Presented by: Bobby Mukkamala, MD, Chair

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

INTRODUCTION

Over the past two decades, the rate of opioid prescribing, especially for patients with chronic non-cancer pain, has increased dramatically. It is estimated that between 9.6 and 11.5 million Americans are currently being prescribed long-term opioid therapy.¹ The overall increase in prescribing has been associated with a parallel increase in unintentional overdoses and deaths from prescription opioids.² In 2014, a total of 47,055 drug overdose deaths occurred in the United States; 61% of these involved some type of opioid, including heroin. Overdose deaths from heroin have quadrupled in recent years, and the majority of past year users of heroin report they used opioids in a nonmedical fashion prior to heroin initiation; hence, the availability of pharmaceutical opioids is relevant to the national heroin use and overdose death epidemics. In the most recent available report, benzodiazepines were involved in 31% of the opioid-related overdoses.³ Despite clinical recommendations to the contrary, the rate of opioid and benzodiazepine co-prescribing also continues to rise.³⁻⁵

Identifying patients at risk for drug misuse is a challenge. There is no definitive way for physicians to predict which of their patients will develop misuse problems with controlled substances. Because of this, deciding which individual patients to evaluate with drug testing is an arduous task and in its place “universal precautions” have been recommended by some authors so that drug testing becomes a standard process when patients are receiving chronic opioid therapy.⁶

Urine is the most commonly used biological fluid or specimen used for drug testing. It is non-invasive to collect, a more than adequate volume is usually available, it is easier to process than other matrices,⁷ and the time during which most analytes can be detected after exposure is sufficiently long (1-3 days for most).⁸ This report therefore focuses on urine drug testing (UDT) and not on the testing of alternative specimens such as oral fluid, blood/serum, hair, or other body tissues or fluids (see Appendix). It is important to emphasize that drug testing can identify the presence or absence of a substance in the tissue or body fluids of an individual and can therefore confirm recent substance use (the undesired use of an unauthorized substance or the failure to adhere to use of a prescribed agent). UDT addresses use, but cannot diagnose, rule out, or rule in substance use disorder or addiction. Cases of non-use can indicate diversion but cannot provide proof of such behavior.

A large national diagnostic laboratory recently published an analysis of more than 3 million urine specimens obtained as part of physician monitoring for prescription drug misuse in 2015.⁴ This analysis revealed a 54% rate of drug misuse based on UDT. Among those patients with abnormal findings, 45% had a similar class, non-prescribed, or illicit drug(s) detected; 23% had a different

class, non-prescribed, or illicit drug(s) found; and 32% had at least one prescribed drug that was not detected. Benzodiazepines, followed by opioids, were the most common non-prescribed agents found in UDT samples. These results highlight the lack of patient adherence to recommended treatment plans for controlled substances and the potential for harmful drug combinations.⁴ A sub-analysis of more than 150,000 specimens for controlled substances and illicit drugs detected heroin in 1.56% of the samples (age range 18 to 65+), underscoring the increasing threat of heroin use in the United States.⁹ The concurrent use of benzodiazepines among heroin users was nearly 30%, mostly in a nonmedical fashion.

Accordingly, UDT is currently considered the most objective tool for monitoring and documenting treatment adherence to prescribed controlled substances and signs of drug misuse. When utilized properly, it is an objective indicator clinicians can employ within the confines of a patient-physician relationship along with other risk mitigation tools such as prescription drug monitoring programs (PDMPs) to help guide pain management strategies while balancing patient needs, safety, and reducing risk.¹⁰ UDT in its clinical applications is not intended to stigmatize or penalize patients, but to monitor for signs of misuse, provide clinically useful information, and promote honest dialogue so that a change in therapy or intervention can be introduced if (or when) needed.¹¹

Outside of pain management practice, and the treatment of anxiety disorders or attention deficit hyperactivity disorder (ADHD), UDT is used in addiction medicine to detect unauthorized use of potentially addictive substances. It is also used in quasi-clinical physician health programs and related programs to monitor the status of continuous abstinence from alcohol and other drugs and the ongoing recovery in health care professionals who are receiving or have received treatment for a substance use disorder.

Evidence suggests that combining UDT with other risk mitigation strategies such as pill counts, treatment agreements, and patient education can reduce substance misuse by at least 50%.¹⁰ The Council on Science and Public Health initiated this report to promulgate UDT as a medical management tool that can be used to better serve patient populations.

CURRENT AMA POLICY

AMA Policy H-95.985, “Drug Screening and Mandatory Drug Testing,” states that physicians should be familiar with the strengths and limitations of drug screening techniques and programs and it lists several other details of drug testing that this report will update and clarify. Policy H-95.984, “Issues in Employee Drug Testing,” advocates for education of physicians and the public regarding drug testing and supports the monitoring of evolving legal issues surrounding the testing of employees. These policies highlight that employment/workplace-related drug testing and clinical drug testing have different aims, ask different questions, and may use different testing methodologies.

METHODS

English-language articles were selected from a search of the PubMed database through August 5, 2016 using the search terms “urine drug testing” and “opioids,” and “urine drug testing” and “controlled substances.” Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society websites were conducted to identify clinical guidelines and position statements.

FORENSIC VERSUS CLINICAL URINARY DRUG TESTING

Historically drug testing has been forensic in nature and has assumed most donors will provide a negative specimen. In patient-centered UDT in a clinical setting, the majority of specimens provided are expected to be positive for a broad range of drugs that are prescribed for medical purposes which adds to the complexity of the testing and the interpretation of data. Most UDT today that involves drug testing laboratories includes elements of both forensic drug testing and clinical drug testing. Drug testing in clinical settings also includes toxicology testing, usually in hospital emergency departments or emergency psychiatry settings, used to help accurately diagnose possible drug poisoning or overdose. Clinical drug testing is often inaccurately labeled as “toxicology testing” involving “tox screens” when the goal of testing is not to identify a case of acute poisoning but is to assist in treatment planning for a chronic disease, such as chronic non-cancer pain or addiction.

Forensic Urine Drug Testing

In forensic drug testing, results are meant to stand up to legal challenges and meet the rules of evidence in legal proceedings. Chain-of-custody procedures, secure storage of samples, and stringent method validations are utilized with the aim of minimizing or eliminating false positive results, and rigorous laboratory certification programs are used to assure quality. The personnel running the tests in a forensic UDT laboratory usually have training in chemistry or forensic science and they understand chain-of-custody and medicolegal requirements.

Federally Regulated UDT. Mandatory guidelines for federal workplace UDT exist and are regulated by the Substance Abuse and Mental Health Services Administration (SAMHSA); only SAMHSA-certified laboratories can perform workplace drug testing on federal employees. The list of drugs tested under the federal program (often referred to as the SAMHSA-5 or federal-5) is limited and includes only five classes of drugs: amphetamines, marijuana, cocaine, opiates (natural opiates such as codeine and morphine, a metabolite of heroin, but not other synthetic opioids such as oxycodone, hydrocodone, buprenorphine and methadone), and phencyclidine (PCP) (see Table 1). The SAMHSA-5 derives from Congressional legislation mandating drug testing of interstate truck drivers and other commercial vehicle operators; its finite group of analytes is also referred to as the DOT-5, for the U.S. Department of Transportation which regulates commercial vehicle use across state lines.

Federally regulated testing follows a screen-and-confirm paradigm in which lower cost, less specific, and often less sensitive screening methodologies are initially used and more costly, more sensitive, and more specific methods are used to confirm positive screening results. Positive test results based on immunoassays (IA) are only considered presumptive because of cross reactivity and differing sensitivity and specificity (see below). Presumptive positive results must be confirmed using definitive chromatography-mass spectrometry methods and all confirmed results must be evaluated by Medical Review Officers (MROs), who serve as a common point of contact between all participants in a UDT. MROs are licensed physicians who have expertise in drug disposition, training in drug collection procedures and the federal program, and have passed a certification exam.¹²

The concentrations required to generate a positive test result vary for each analyte, but are high (in order to minimize false positive results) compared to clinically-relevant concentrations for the prescription drugs included. The federal UDT program, does, however, set a standard for analytical quality, procedure, and measurement in forensic laboratories as well as in clinical laboratories.

Nonregulated Forensic UDT. Many states and private employers have adopted drug-free workplace programs that include UDT similar to the SAMHSA program. A multitude of other UDT applications exist including pre-employment testing, for-cause testing (in response to on the job impairment or after a workplace accident), reasonable suspicion testing, random workplace testing, return to work testing, school testing, sports testing, as well as testing in the criminal justice system, testing in child custody cases, Department of Transportation testing for required occupations, testing in the military (which is the model for the use of drug testing to prevent drug use),⁷ and medical examiner (post-mortem) testing. Most of these testing applications have a testing panel that is broader than the SAMHSA-5 and can therefore include additional analytes such as oxycodone, oxymorphone, and other opioids, benzodiazepines, barbiturates, stimulants, anabolic steroids, emerging designer drugs such as synthetic cannabinoids and cathinones, and others.

Clinical Urine Drug Testing

Clinical drug testing is part of the medical evaluation within an established patient-clinician relationship. It is used for diagnosis, treatment monitoring, or the promotion of long-term recovery from a substance use disorder and in other clinical settings such as pain management.⁷ The goal of clinical UDT is to meet the standards of medical practice, not the legal requirements of forensic testing. UDT can improve a clinician's ability to manage therapy with controlled substances and assist in, but not make the diagnosis of, a substance use disorder or addiction. Personnel running the testing in a clinical setting have a broad spectrum of laboratory training, often as a medical technologist, but do not usually have chain-of-custody or evidentiary training. Although most dedicated toxicology testing laboratories started as forensic in nature, some now specialize in testing and interpreting clinical and pain management samples and better understand the needs of physicians and their patients.^{13,14}

URINE DRUG TESTING METHODS

The U.S. Food and Drug Administration (FDA) classifies laboratory developed tests, including point-of-care (POC) UDT testing devices, as waived, moderate, or high complexity under the Clinical Laboratory Improvement Amendments (CLIA).^{15,16} Waived tests are typically easy to use and pose no reasonable risk if performed incorrectly. Once a CLIA certificate of waiver is obtained, the device or test must be used exactly according to manufacturer's instructions. Moderate and high complexity tests carry a significantly increased risk of inaccurate results, require specialized personnel who have been trained to run the instrumentation, use complex methodologies with multiple steps, and require certification with CLIA.^{15,16}

Quality Assurance

Laboratory accreditation programs ensure the integrity of analytical results by providing laboratories a set of standards. The standards guarantee that tests are subjected to rigorous quality assurance criteria, are delivered in a manner that promotes proper interpretation, and are performed by qualified individuals. There are several voluntary accreditation programs including CLIA, SAMHSA, the College of American Pathologists (CAP), The American Society of Crime Laboratory Directors (ASCLAD), New York State Department of Health (NYSDOH), and International Organization for Standardization/International Electrotechnical Commission (ISO/IEC). Each accreditation program has requirements specific for the focus of the laboratory services whether it be medical testing, workplace drug testing, or some other application.

Laboratories typically develop their own testing methods with rigorous quality controls. Most accreditation programs have proficiency testing that is a peer-based competency evaluation program to ensure accurate and reliable test results. The National Institute of Standards and Technology and the Department of Justice recently established the Organization of Scientific Area Committees (OSAC) in order to support the development and promulgation of forensic science standards and guidelines. The Toxicology Subcommittee focuses on standards and guidelines related to the analysis of biological samples for alcohol, drugs, or poisons, and the interpretation of these results.¹⁷ As clinical UDT is a combination of both forensic and medical requirements, there are currently no standards specifically for its application, but accreditation programs for pain management are likely forthcoming.¹⁸

Requirements for laboratory directors vary depending on the type of testing and the accreditation body, but most require at a minimum a doctoral degree in a physical science, certification from a major body, and a degree of laboratory experience.¹⁸ The qualifications and competency of individuals in UDT laboratories are evaluated by three major certification bodies: the American Board of Clinical Chemistry, the National Registry of Certified Chemists, and the American Board of Forensic Toxicology. Both personnel at the director level and technical personnel have annual continuing education requirements depending on certification/licensure and laboratory accreditation requirements.

Types of Urine Drug Tests

Immunoassays. Many UDTs are grounded in IA biology and technology. IAs are based on competitive binding and use antibodies (ABs) to detect the presence of drugs, drug metabolites, or drug classes. In IAs, a known amount of labeled drug/metabolite is added to a specimen. Any drug/metabolite in the specimen will compete with the labeled drug/metabolite for binding with an AB. The amount of labeled antigen-AB complex remaining in the specimen is determined by the amount of drug/metabolite present in the specimen competing for the binding site.¹⁵ IAs can use enzymatic, chemiluminescent, fluorescent, or colorimetric labeling for detection.

Many IA-based UDTs are designed to detect a specific drug or a class of drugs as either present or absent based on a designated cutoff, or threshold concentration for detection. A negative result could mean that no drug is present, or that the drug concentration is below the threshold. The results of these kinds of tests are considered presumptive; their results can represent either true or false positives, or true or false negatives.

IA UDTs include waived, moderate, and high complexity laboratory tests under CLIA. Many of these tests are available as commercial kits that contain reagents, calibrators, and controls. Urine samples can be analyzed via IA tests at the POC or can be sent to a laboratory where the IA test is performed by laboratory personnel. Methods and instructions differ in complexity and detail, some with many intricate steps and others with one step. The CLIA-waived IA tests include the POC devices described below. Some moderate and high-complexity IA instrumented devices have been adapted for use in larger medical practices and hospital laboratories, but rigorous and costly CLIA certification requirements have limited the implementation of the instruments in these settings.^{15,18} Some clinical entities such as methadone clinics (federally-licensed Opioid Treatment Programs or OTPs), large pain clinics, and outpatient or residential addiction treatment facilities may have the economies of scale to purchase their own analyzers, obtain CLIA certification, and use these instruments on-site.

The main advantage of IA UDT is its ability to rapidly detect the presence of substances in urine. One major disadvantage is the limited range of drugs that the assays are able to detect. Because an

AB is used for detection, there must be an AB developed specifically for the drug, metabolite, or class of drug. This requirement restricts the number of compounds that can be screened for based on IA. Most commercial IAs include only the SAMHSA-5 panel of drugs, which limits their clinical utility (even if a physician is not aware of this limitation). Some specialized IAs include semisynthetic and synthetic opioids, benzodiazepines, and other drugs. IAs are typically designed to have a high sensitivity (the ability to detect) balanced with lower degrees of specificity (the AB only binds to the target),¹⁵ but the performance characteristics and limitations of the IA UDT vary between tests. Information supplied by the manufacturer should be given appropriate attention; the sensitivity and selectivity can affect the rate of false positive and false negative results and the designated threshold (being too high) could be clinically irrelevant. Home UDT kits available for retail purchase and used by individuals outside of health care settings use IA methods.

Another confounding variable among IAs is cross-reactivity. Some compounds, despite no structural similarities to the target analyte, may bind to the AB and generate a false positive result. An extensive list of cross-reacting drugs for IAs exists that can cause false positive results (see Table 2).^{15,19-22} Other medications and dietary supplements a patient is taking can significantly impact test results. Additionally, some IAs rely on the ability of an AB to bind to a class of drugs and a lack of cross-reactivity among important members of the class can result in false negative results. For example, many opioid IAs react to the natural opiates codeine and morphine, but may not react with the semisynthetic opioids hydrocodone or oxycodone. In hospital or clinic settings, a physician may order a drug test for opiates, and what is tested for by the IA methodology is only the natural opiates; the clinician may be unaware that in the context of drug-testing, the word “opiates” refers only to the natural compounds such as codeine, morphine, and the metabolites of heroin, without testing for “opioids.” Many primary metabolites may not be reactive with IA UDTs as well. It is essential to understand the limitations of a specific IA test in this regard.

Unique challenges are associated with IA results for a drug class. IA UDTs do not unequivocally identify which member of a drug class is present in a positive specimen. Even if an IA is labeled “morphine” it may still produce a positive result for any number of opioids, including heroin (and multiple opioids). Conversely, IAs to detect benzodiazepines can have considerable variability in class cross-reactivity depending on which molecule the IA AB is based on. For example, test information may state that the IA will cross-react with alprazolam. A specimen from a patient taking alprazolam containing predominately the major urinary metabolite (α -hydroxyalprazolam) will return a false negative result. Benzodiazepine IAs have very high rate of false negative results and require knowledge of the metabolic pathways of the drugs to properly interpret their results.²³⁻
²⁵ Challenges are also found in the testing of stimulants. Many over the counter products contain sympathomimetics which will generate a false-positive result on an IA for stimulants when the clinician is looking for adherence to psychostimulant therapy or is attempting to detect unauthorized use of methamphetamine or psychostimulants. Prescription drugs such as bupropion, fluoxetine, and others can also produce false-positive IA results for stimulants (see Table 2).

Physicians and other prescribers typically utilize IA-based tests as an initial screening test (i.e., qualitatively positive or negative) in opioid-based pain management monitoring programs. Another issue in the clinical use of IA testing is whether confirmation of results is necessary. In some situations the results of an IA UDT may be sufficient, given an understanding of the possible high rates of false positive and false negative results. However, many organizations, including the Federation of State Medical Boards, recommend definitive identification of positive screening results.²⁶ The definitive identification of IA-based presumptive results requires more sophisticated technology for confirmation. Gas or liquid chromatography-mass spectrometry (GC-MS or LC-MS), discussed below, is the standard method of confirming preliminary (screening test) results generated via IA. Without understanding the limitations of testing devices or the laboratories

conducting the testing, presumptive UDT testing may not be useful. Testing devices are on a continuum from less expensive/less sensitive and specific (e.g., POC devices) to more expensive/more sensitive and specific (confirmatory testing). Clinicians must be reminded that most drug tests they order are IA tests; actions they take in the care of their patient and treatment plan decisions should not be made based on a non-confirmed result from a presumptive test.

Point-of-Care Devices. POC tests are typically non-instrumented IA devices (strips, dipcards, cups with imbedded test strips) that can be used in the clinic (at the “point of” care). Testing can therefore occur outside of a laboratory and is not subject to any accreditation standard. These tests are typically granted CLIA-waived status, they lack quality assurance and quality control, and ensuring the integrity of materials following transportation or storage is largely unregulated. Test results are subjective in nature, usually based on a color-changing dye. POC tests are typically performed by health care workers who have many other office-related duties and who are not specifically trained in drug testing. Although POC tests seem simple and are comparatively affordable, they still require proficiency in execution and good laboratory practice is required to obtain reliable results. Product-use instructions and related information accompanying the test device are important to read and understand, and are often not followed.²⁷ Choosing a device that includes reliable customer support is beneficial. Some instrumented benchtop and small floor POC devices have the capability to link with electronic health records. These devices are of moderate complexity and require certification with CLIA,¹⁵ can be expensive, and usually contain the SAMHSA-5 routine drug panel. They do, however, eliminate the visual interpretation and decision-making associated with the use of non-instrumented devices.

Understanding the limitations of a POC device is important. IA-based POC devices are presumptive, qualitative, variable, have limited sensitivities, offer limited testing menus, cannot distinguish between members of a drug class, and cannot differentiate a drug from its metabolite.^{7,28} The possibility of cross-reactivity with other prescription, over-the-counter, and dietary supplement medications exists, which increases the probability of false positive and false negative results. Many POC IA products have not been optimized for use in a medical setting and are designed with federally-regulated UDT in mind.¹⁵ Threshold concentrations and the drug targets may provide inadequate results for clinicians. The device information provided by the manufacturer includes often-unread advice that presumptive positive IA results must be confirmed with definitive testing, which is not a requirement for clinical UDT, but could be required based on the conditions of the CLIA waiver.¹³ IA-based POC devices do, however, offer rapid results within minutes and can allow physicians to make presumptive in-office clinical decisions, if needed, before results are confirmed. This type of POC test can be useful as long as clinicians are well informed of the limitations.

Analytical Methods (GC-MS, LC-MS, LC-MS/MS). The current gold standard in UDT is separation of a specimen using GC-MS, LC-MS, or LC tandem mass spectrometry (LC-MS/MS). Separation via chromatography allows each compound in the specimen to be isolated and enter the mass spectrometer individually. The mass spectrometer provides a unique identifying fingerprint for each molecule. The use of GC- or LC-MS depends on the compounds being detected; volatile, nonpolar compounds are more suited for GC (often parent drugs). Chromatography-mass spectrometry is considered high complexity testing, is subject to FDA guidelines, and requires CLIA certification to operate.

GC- or LC-MS can be used for confirmatory testing after IA. Recently, LC-MS/MS has been used as a screening method⁷ to identify many unique drugs and/or metabolites from different classes of drugs (see Table 1), for example opioids (natural, semi-synthetic, and synthetic), benzodiazepines, and stimulants in lieu of IA. Although LC-MS/MS is a more sophisticated technique than GC- or

LC-MS, it can separate and identify many drugs from many classes in a single analysis from a single specimen. With this advantage, a test profile or panel can include many different analytes and detect relatively low concentrations of drug or metabolite from low volumes of starting material and be ideal for an analytical qualitative screening method. More sensitive quantitative GC-MS and LC-MS analytical methods that are drug class specific can then be used for confirmatory testing if desired. There are limitations, however, with MS technology; the greater the number of analytes included in an analysis, the lower the sensitivity of the assay; and not all substances are capable of detection—the structure of the drug or its metabolites must be known, therefore, some emerging drugs of abuse and designer drugs remain a challenge for MS detection.

Other reasons that these analytical methods may be necessary include the specific identification of a drug; IA can provide information about the class of a drug only. Additionally, a number of drugs, such as tramadol, carisoprodol, and designer drugs such as synthetic cathinones and cannabinoids, are not readily detected using IA and require chromatography testing. Sometimes specialty analytical testing is necessary, for example only GC-MS with a chiral column will be able to distinguish between d-methamphetamine (the illicit drug of abuse) and l-methamphetamine (the compound in Vick's inhalers). Chromatography-MS tests also can aid in validating disputed test results. Analytical methods also are quantitative methods, allowing the amount of drug excreted in urine to be quantified with the use of calibration curves and reference standards. Although this can be useful for gauging adherence, quantitative GC-MS, LC-MS, or LC-MS/MS data cannot be used to verify dosage exposure.⁷ POC testing has a high rate of false positive and negative results, which is not a concern with GC-MS, LC-MS, or LC-MS/MS. Chromatography-MS instrumentation is relatively expensive, reading and interpreting mass spectrum data requires expertise, and the cost for a test is variable depending on the testing panel chosen.

TESTING: WHY, WHO, WHEN, AND WHAT

While UDT is an objective means to detect the use of nonprescribed or illicit drugs, the design of the testing program (including the clinical questions to ask and answer), the patient population to test, the frequency of testing, and the drug test panel are all determined by the ordering clinician and should be patient-centered.²⁹ One of the most common failings of UDT in clinical practice is its application only to high risk patients or those who are suspected of drug misuse.³⁰ Despite the objective evidence UDT can provide as a clinical tool and recommendations for its use as a risk mitigation strategy, UDT is underutilized and misapplied, and a lack of understanding exists that functions as a barrier for introducing successful testing programs into clinical care.³¹⁻³⁸

Why Test?

Standard methods of adherence monitoring for prescribed substances, for example, self-reporting^{8,39-41} and monitoring of symptoms or patient behaviors,⁴² are unreliable for controlled substances. As noted above, a high rate of substance misuse occurs in the patients receiving prescriptions for controlled substances. Seminal studies⁴³⁻⁴⁵ evaluating the use of UDT in patients with chronic pain revealed that approximately 50% of UDTs yielded appropriate results; the others showed illicit drugs and/or nonprescribed medications, absence of prescribed opioid(s), and/or specimen adulteration. In many cases, abnormal test results are not accompanied by behavioral clues or differences in other demographic or clinical variables.⁴⁴ UDT is objective and an abnormal result is the most frequently detected signal of opioid misuse. It is similarly useful in managing patients prescribed benzodiazepines or psychostimulants. UDT plays an important role in providing a more complete diagnostic picture for clinicians.⁴⁶ As noted earlier, the identification of a drug or metabolite in a UDT provides evidence of exposure to that drug and information about recent use of drugs, but it can only provide this information if the substance is present in the urine at levels

above the threshold of detection. UDTs cannot identify the presence of a substance use disorder or the presence of physical dependence.⁷ Before implementing UDT, physicians should understand the question they want to answer, understand the advantages and limitations of the testing technology and the interpretation of data, and ensure that the cost of testing aligns with the expected benefits for their patients.

Whom to Test?

Practice guidelines on pain management intended to promote safe and competent opioid prescribing recommend various measures to mitigate risk including UDT, but some disagreement persists on who should be subjected to routine UDT and its frequency.^{7,26,29,47-51}

UDT can be useful in many medical specialty practices including but not limited to palliative medicine,⁵² psychiatry,⁷ geriatrics,⁵³ adolescent medicine,⁵⁴ addiction medicine,²⁹ and primary care.^{55,56} The routine use of UDT in pain medicine⁵⁷ is recommended in several clinical guidelines.^{21,26,48,58-60} As stated previously, UDT utilized in emergency settings is typically intended to diagnose acute drug poisonings or make immediate treatment decisions as opposed to chronic care situations. An American College of Emergency Physicians policy does address the use of UDT in the context of psychiatric patients.⁶¹ Although medically appropriate opioid use in pregnancy is not uncommon, there has been a renewed focus on maternal opioid dependence, opioid exposure during pregnancy, and the increase in infants born with neonatal abstinence syndrome.⁶²⁻⁶⁹ UDT can aid in obtaining a complete picture of drug exposure. Two studies in the Kaiser Health System involving nearly 50,000 obstetric patients demonstrated improved maternal and fetal outcomes when treatment for substance use disorders were linked with prenatal visits and UDT allowing for resources to be appropriately allocated for postnatal care.^{70,71} The American Society of Addiction Medicine (ASAM) supports the use of UDT during pregnancy.^{7,66} The American Congress of Obstetricians and Gynecologists (ACOG) also supports the use of UDT during pregnancy when substance use is suspected, but not during routine well care visits.⁷²⁻⁷⁴

Given the challenges inherent in deciding whom to test and the issues described in the paragraphs above on why to test, many clinicians have adopted recommendations to utilize “universal precautions” in opioid prescribing. This approach informs patients at the onset of a plan of care that the standard procedure for the clinician’s practice is to test *every* patient at the initiation of opioid therapy, and periodically on a random basis during the course of care. This avoids any patient feeling singled out and reduces the potential for stigma, discrimination, and clinical errors based on incomplete clinical information.

When to Test?

Although uniform agreement is lacking, an evolving consensus recommends testing new patients before prescribing controlled substances for a chronic disorder, in those seeking increased doses, in patients who resist a full evaluation, in those requesting specific controlled substances, in patients displaying aberrant behaviors, in pain management patients recovering from addiction, and special populations.^{8,47,48} It is recommended that tests be administered at unscheduled and unpredictable times (random testing) so specimen donors are less likely to try to circumvent the test (see below).⁷ Considerations about how often to test are influenced by concerns about cost and the proper stewardship of health care resources; both underutilization and overutilization of clinical drug testing are concerns. The recommended periodicity of testing in given clinical situations continues to be addressed. Currently, ASAM is developing a guideline for addiction medicine specialists engaged in varying levels of care (outpatient, intensive outpatient/partial hospitalization, residential) and within various special populations (for example, health professionals or others in

safety-sensitive occupations who are receiving addiction care). Other specialty societies have been encouraged to develop similar guidelines for their physician members and the populations they serve.

What to Test For?

Clinical drug testing should be individualized and not determined from a device, kit, or forced panel of drugs. It is important to know the clinical question to be answered to properly utilize UDT as a management tool. Although no device or testing panel may be ideal, any testing should be patient-centered. Testing should not be limited to only prescribed controlled substances; it is advantageous to include substances that have been problematic for that patient in the past if a history of drug misuse exists. Local patterns of substance misuse should be considered when designing the testing panel as well.⁷

The choice of drugs to include on a testing panel is complicated by the fact that many drugs and illicit substances are subject to misuse based on their “rewarding” properties and they may not be included in or detected on a standard drug test. Internet-based and other sources exist that are dedicated to informing users about chemistry, laws, laboratory tests, and how to evade detection of the most commonly tested substances. Additionally, there is a new and ever-evolving drug industry based on “designer drugs” which are being synthesized to evade existing drug tests and laws.⁷⁵

INTERPRETATION OF UDT RESULTS

The valid detection period for drug exposure varies depending on the disposition characteristics of the drug, dose, and frequency of use. Specific characteristics of a urine sample include its appearance, temperature within 4 minutes of voiding, pH, creatinine concentration, and specific gravity.⁸ The color of urine is based on the concentration of its constituents^{8,76} and can vary based on medications, foods, or disease states; excess hydration can cause it to appear colorless. Concentrated urine specimens are usually more reliable than dilute specimens.

Manipulation/Adulteration, Specimen Validity Testing, Normalization, and Collection

One drawback of a urine specimen is that it is easy to tamper with. Collection in a medical setting is typically unmonitored and the potential for manipulation exists and should be considered. Dilution is usually done in an attempt to lower the concentration of illicit substance(s) below detection levels. Specimens that are excessively dilute will have low creatinine levels. Commercial “cleansing” beverages exist that when consumed in large volumes dilute urine and contain B vitamins to restore urine color.

Urine spiking with a specific substance is done to simulate adherence to medication taking and is not uncommon. For example, patients who know they will be subjected to adherence testing but who have not been taking the prescribed medication per instructions can add crushed drugs hidden under a fingernail to a urine specimen to generate a positive test result.²⁸ Diversion is sale or distribution of a prescribed medication to an unintended recipient. UDT cannot detect diversion, but a negative specimen may indicate diversion or some other maladaptive drug-taking behavior (i.e., periods of reduced medication use or abstinence followed by bingeing).⁸ These behaviors can occur with buprenorphine prescribed for the treatment of opioid addiction, though the patient’s aberrant behavior can be easily recognized when confirmatory testing data is interpreted and the relative amounts of parent compound and the primary metabolite, norbuprenorphine (if present) are evaluated.

Substitution is the switching of donor urine with drug-free synthetic urine, urine from another individual, or urine from an animal.⁷⁷ This is easily detected in many cases because house pets produce urine that has a very different pH from human urine. Test results are typically reported as “specimen incompatible with human urine” (or similar) when testing procedures include pH analysis.

Adulteration is the addition of oxidizing chemicals or other substances directly to the specimen that may interfere with the UDT. Some adulterants can be other drugs such as dextromethorphan or salicylates, which are known to cause false negative results with some IA UDTs; other adulterants are common household products or substances that are otherwise easily obtainable including salt, vinegar, bleach, soap, Visine®, glutaraldehydes, chromate-containing compounds, and sodium nitrate.¹⁴ Being aware of this, many clinicians will not utilize any drug testing methodology that does not include testing for common commercially-available adulterants.

Most testing laboratories will perform specimen validity testing (SVT) on urine specimens.⁷⁸ SVT includes testing the specimen for creatinine, specific gravity, pH, nitrates, chromates, and other easy-to-obtain over-the-counter adulterant products, and assuring that values are consistent with those of normal human urine. Values outside of typical ranges may indicate the specimen has been tampered with or adulterants have been added.¹⁴ Many laboratories will also normalize urine samples since urine drug concentrations vary significantly between individuals and can have an effect on UDT; if a urine specimen is dilute, a drug may be present, but below a measurable level. Normalization is a mathematical method using specific gravity or creatinine concentrations to adjust for dilution, thereby allowing the UDT results to be interpreted or compared. Often this can be useful when comparing serial analyte measurements or to minimize false negative results.^{8,14}

To minimize specimen tampering many collection protocols require patients to leave outerwear and personal belongings in exam rooms, and to show pocket contents. Some relatively inexpensive POC collection devices (cups) incorporate validity testing such as temperature, pH, specific gravity, and oxidation and add an extra layer of assurance to specimen collection. Some testing laboratories will provide staff to physicians’ offices to facilitate collections; third party collectors exist as well. Some third party vendors will send a single collector to a location and many third-party specimen collection sites exist for the employment drug testing market, for use by professional sports leagues for their testing protocols, or for monitoring programs for licensed health professionals, rather than for clinical drug testing. Once the specimen is collected, it should be refrigerated to minimize drug degradation, especially if testing is delayed. As noted, chain-of-custody handling of specimens between the site of collection and the laboratory bench are components of forensic and some employment-related testing, rather than clinical drug testing.

Interpretation of Results

Clinicians’ predictions of UDT results are often inaccurate²¹ and evidence suggests a majority of physicians have a poor understanding of how to interpret UDT results. Others may have a false sense of confidence about interpreting their patients’ UDT results because they lack specific knowledge or don’t fully understand the breadth of abnormal or unexpected toxicology findings that are possible.^{10,33,79-81}

Unexpected findings are common in clinical UDT; results are much more than just a positive or negative result. There are complexities to consider in order to properly interpret UDT such as the type of assay, possible adulteration, detection time, detection thresholds, and therapeutic response. Therapeutic response can be variable and can be affected by drug potency, chemical properties, metabolism, dose, preparation, drug-drug or drug-herbal interactions, and the patient (diet, drug

ingestion, weight, genetic makeup, disease state).^{82,83} Appropriate interpretation of toxicology testing results requires a working knowledge of drug metabolism; although beyond the scope of this report, there are many intricate details involved in opioid pharmacokinetics and pharmacodynamics to consider.^{82,83}

If POC devices are being utilized, consultation of product inserts is recommended and choosing devices with readily available customer support is advantageous. If a laboratory is used for UDT, then contacting the professionals at the laboratory, such as a toxicologists or laboratory director, is recommended whenever the clinician feels a need for guidance on interpretation of reported results. Additionally, physicians should be sure to obtain a full prescription and over-the-counter medication history (including dietary and herbal supplements), and use this information in the context of the UDT or provide this information to the testing laboratory since it could be relevant to interpreting UDT results.

CONCLUSIONS

UDT is an objective means to detect the use of nonprescribed or illicit drugs and to confirm the presence of prescribed drugs. The elements of the drug test such as the composition of the drug test panel (the list of analytes in a given test) and the testing method/technology should be determined by the ordering clinician. Therefore, it is important for physicians to understand the elements of UDT in order to make informed decisions. The value of UDT depends on clinicians appreciating the strengths and weaknesses of the test or the laboratory and their relationship with the laboratory. Understanding the drugs that are detected in IAs and those detectable only via confirmatory methods, cross-reactivity, and detection thresholds is critical, as is the fact that these parameters can change over time. Some clinicians have adapted the SAMHSA workplace drug testing model for clinical drug testing with success (IA screen with MS confirmation), but the range of analytes in the SAMSHA-5 itself is likely too narrow to be of use in most clinical scenarios. Some laboratories offer LC-MS/MS UDT without IA and have been successful; other labs rely only on IA and find that acceptable for their clientele. Just as clinicians use HbA1c as an objective measure for the diagnosis of pre-diabetes, aberrant UDT results can be used as an objective measure³⁰ and used to motivate patient change and stimulate healthy physician-directed patient education. Although specific training and application to individual clinical management are outside of the scope of this report, the Council recommends the development of practical guidance to assist clinicians in implementing UDT in their practice and understanding how UDT results may affect patient management.

RECOMMENDATIONS

The Council on Science and Public Health recommends the following recommendations be adopted and the remainder of the report be filed:

1. That Policy H-95.985, "Drug Screening and Mandatory Drug Testing," be amended by addition and deletion as follows:

~~Drug Screening and Mandatory Drug Testing~~

The AMA believes that physicians should be familiar with the strengths and limitations of drug ~~screening~~ testing techniques and programs:

1. Due to the limited specificity of the inexpensive and widely available non-instrumented devices such as point-of-care drug testing devices ~~screening techniques, forensically~~

acceptable clinical drug testing programs must should include the ability to access highly specific, analytically acceptable ~~technically more complicated and more expensive~~ confirmation techniques, which ~~unequivocally~~ definitively establishes the identities and quantities of drugs, in order to further analyze results from presumptive testing methodologies. Physicians should consider the value of data from non-confirmed preliminary test results, and should not make major clinical decisions without using confirmatory methods to provide assurance about the accuracy of the clinical data.

2. Results from ~~such~~ drug testing programs can yield accurate evidence of prior exposure to drugs. Drug testing does not provide any information about pattern of use of drugs, dose of drugs taken, abuse of or physical dependence on drugs, the presence or absence of a substance use disorder, or about mental or physical impairments that may result from drug use.

3. Before implementing a drug testing program, physicians should: (a) understand the objectives and questions they want to answer with testing; (b) understand the advantages and limitations of the testing technology; (c) be aware of and educated about the drugs chosen for inclusion in the drug test; and (d) ensure that the cost of testing aligns with the expected benefits for their patients., and Physicians also should be satisfied that the selection of drugs (analytes) and subjects to be tested as well as and the screening and confirming confirmatory techniques that are used meet the stated objectives.

4. Since physicians often are called upon to interpret results, they should be familiar with the disposition characteristics pharmacokinetic properties of the drugs to be tested before interpreting any results. and the use to which the results will be put. If interpretation of any given result is outside of the expertise of the physician, assistance from appropriate experts should be pursued. (Modify Current HOD Policy)

2. That our AMA, in conjunction with the AMA Opioid Task Force, develop practical guidance and educational materials to assist physicians with implementing urine drug testing as part of a risk mitigation strategy when opioid analgesics are prescribed for chronic use. (Directive to Take Action)

Fiscal note: \$30,000

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Table 1. Drugs often included in urine drug testing (UDT) (adapted from⁸).

Drug/Drug Class	Drug or Metabolite Included in Testing
Amphetamines	Amphetamine ^a
	Methamphetamine ^a
	MDA ^a
	MDEA ^a
	MDMA ^a
	Phentermine
Barbiturates	Butalbital
	Phenobarbital
Benzodiazepines	Alprazolam
	Clonazepam
	Diazepam
	Flurazepam
	Lorazepam
	Nordiazepam
	Oxazepam
	Temazepam
Cocaine^a	Benzoylcegonine ^a
Heroin	Heroin (diacetylmorphine)
	6-AM ^a
	6-acetylcodeine
Marijuana^a	THCA ^a
Opioids	Buprenorphine
	Norbuprenorphine
	Codeine ^a
	Norcodeine
	Dihydrocodeine
	Fentanyl
	Hydrocodone
	Norhydrocodone
	Hydromorphone
	Meperidine
	Normeperidine
	Methodone
	EDDP
	Morphine ^a
	Oxycodone
	Noroxycodone
	Oxymorphone
	Tapentadol
	Tramadol
	O-desmethyl-tramadol
	N-desmethyl-tramadol
PCP^a	PCP ^a
Carisoprodol	Carisoprodol
	Meprobamate
Anticonvulsants	Gabapentin
	Pregabalin

^aDrugs/metabolites included in federally regulated SAMHSA UDT

6-AM=6-monoacetylmorphine; EDDP=2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine;

MDA=3,4-methylenedioxyamphetamine; MDEA=3,4-methylenedioxyethylamphetamine;

MDMA=3,4-methylenedioxymethamphetamine; PCP=phencyclidine;

THCA=delta-9-tetrahydrocannabinol-9-carboxylic acid

Table 2. Compounds causing potential false positive results with immunoassay testing.

IA Test	Compound Causing a Potential False Positive		
Amphetamines	Amantadine	Isometheptene	Phenylephrine
	Aripiprazole	Isoxsuprine	Phenylethylamine
	Benzphetamine	Labetalol	Phenylpropanolamine
	Brompheniramine	m-Chlorophenylpiperazine	Promethazine
	Bupropion	(mCPP)	Propranolol
	Cathine	MDA	Propylhexedrine
	Cloroquine	MDMA	Pseudoephedrine
	Chlorpromazine	MDPV	Pyrovalerone
	Ciprofloxacin	Mefenamic acid	Ranitidine
	Clobenzorex	Mephentermine	Ritodrine
	Desipramine	Metformin	Salbutamol
	Dimethylamylamine	Methamphetamine ^a	Selegiline
	Doxepin	l-methamphetamine (Vick's	Sodium Cyclamate
	Ephedra	Inhaler)	Thioridazine
	Ephedrine	Methylphenidate	Tolmetin
	Fenfluramine	Metronidazole	Trazadone
	Fenproporex	Ofloxacin	Trimethobenzamide
	Fluorescein	Phenmetrazine	Trimipramine
	Fluoxetine	Phenothiazines	Tyramine
	Ginkgo	Phentermine	
Barbiturates	NSAIDS (ibuprofen, naproxen)	Phenytoin	Tolmetin
Benzodiazepines	Chlorpromazine	Flurbiprofen	Oxaprozin
	Efavirenz	Indomethacin	Sertraline
	Fenoprofen	Ketoprofen	Tolmetin
Buprenorphine	Codeine	Morphine	Tramadol
	Dihydrocodeine	Methadone	
Cocaine	Coca leaf tea ^a	Ecgonine methyl ester	Topical anesthetics
	Ecgonine	Tolmetin	containing cocaine ^a
Fentanyl	Trazadone	Risperidone	
Marijuana (THC)	Acetylsalicylic acid	Efavirenz	Proton pump inhibitors
	Baby wash/Soap	Hemp-containing foods ^a	(pantoprazole)
	Dronabinol ^a	NSAIDs (ibuprofen, naproxen)	Rifampin
Methadone	Chlorpromazine	Doxylamine	Tolmetin
	Clomipramine	Phenothiazine compounds	Quetiapine
	Cyamemazine	Olanzapine	Tapentadol
	Diphenhydramine		Thioridazine
Opiates	Dextromethorphan	Procaine	Verapamil
	Diphenhydramine	Quinine (tonic water)	Ranitidine
	Doxylamine	Fluoroquinolones	Rifampin
	Heroin ^a	(ciprofloxacin, gatifloxacin, levofloxacin, moxifloxacin)	Tolmetin
	Poppy seeds ^a		Verapamil
Phencyclidine	Dextromethorphan	Imipramine	Mesoridazine
	Diphenhydramine	Ketamine	Thioridazine
	Doxylamine	Lamotrigine	Tramadol
	Ibuprofen	Meperidine	Venlafaxine, O-desmethyl-venlafaxine
Tricyclic Antidepressants	Carbamazepine	Diphenhydramine	Promethazine
	Cyclobenzaprine	Hydroxyzine	Quetiapine
	Cyproheptadine		

^aContain or metabolize to target analyteTable information from^{15,19-22}

MDA=3,4-methylenedioxyamphetamine; MDMA=3,4-methylenedioxymethamphetamine;

MDPV= Methylenedioxypropylvalerone; NSAIDS=non-steroidal anti-inflammatory drugs

Table 3. Common causes of false negative results with immunoassay testing.

Potential Causes of False Negative IA Test	Example
Lack of cross reactivity for the desired tested drug class	An IA targeted for natural opiates does not readily detect semisynthetic opioids such as oxycodone.
Drug metabolites do not cross react with IA	An IA detects alprazolam but does not reliably detect the predominant metabolite, α -hydroxyalprazolam. Opioid normetabolites are also a concern (e.g., norhydrocodone).
Threshold of IA is too high	Many IAs were developed for workplace UDT and have thresholds > 300 ng/mL (and as high as 2,000 ng/mL). A more appropriate threshold for clinical UDT is \leq 100 ng/mL.
Specimen is dilute	Fluid intake can cause drug concentration to fall below the threshold concentration.
Adulterated or substituted specimen	Added adulterants can mask the presence of some drugs. Substituted specimens can contain urine from another person, animal, synthetic urine, or some other fluid.
Desired drugs not included in testing	Many commonly abused prescription drugs require separate IAs to detect and could be overlooked in a POC device (e.g., natural opiates, oxycodone, synthetic opioids, methadone, tapentadol, buprenorphine) and others may not be included in IA presumptive testing (e.g., carisoprodol).

IA=immunoassay; UDT=urine drug testing; POC=point-of-care testing

Appendix: Alternative Specimens for Drug Testing

Although urine is the most common matrix used for drug testing, other matrices are available including oral fluid, blood/serum, breath, hair, nails, and sweat. Differences in the collection and interpretation for each specimen type as well as some strengths and weaknesses are associated with each matrix.^{8,14}

Matrix	Detection Window	Collection	Interpretation	Strengths	Weaknesses
Oral Fluid	Acute use: ~4 hrs Chronic use: 24-48 hrs	Non-invasive; observed; non-standardized procedures; use of collection device highly recommended	Disposition of parent drug exceeds metabolites; drug concentrations 10-100x lower than urine	Harder to adulterate; use for shy bladder, renal impairment, suspected urine tampering	Some drugs a challenge (e.g. transdermal buprenorphine); sample volume could be hard to obtain; POC devices developed for forensic use and not recommended for clinical testing
Blood/Serum	Limited to current drug use (hours)	Invasive; difficult to properly store and transport	Disposition of parent drug exceeds metabolites	Can detect low levels of drug (usually in a legal context)	Generally requires lengthy testing procedures; expensive
Breath	Limited to current drug use (hours)	Non-invasive	Limited to the evaluation of alcohol	Well correlated with blood alcohol levels	Most other drugs not sufficiently volatile for breath analysis
Hair	Weeks, months, years (depending on hair length)	Non-invasive; easy to collect; difficult to cheat; easy to store	External contamination possible; color bias; hair treatments may alter drug disposition; drugs may not be detectable for weeks following exposure; segmental analysis variable	Possible use for past drug use	Not all drugs equally incorporated; labor intensive sample preparation; low drug concentrations; expensive; not recommended for clinical testing
Nails⁸⁴	Fingernails: 3-5 months Toenails: 8-14 months	Non-invasive; nail clippings	Disposition of parent drug usually exceeds metabolites	Possible use for past drug use	Mechanisms of incorporation not fully understood
Sweat^{85,86}	~1 week	Non-invasive; adherent patch	Less sensitive than urine	Extended detection time	Unreliable adherence so limited utility; rash; external contamination

REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-16)
Genome Editing and its Potential Clinical Use
(Reference Committee K)

EXECUTIVE SUMMARY

Objectives. The promise of gene therapy has increased substantially over the last decade due to rapid advancements in two technologies: DNA sequencing and genome engineering. Concurrently, techniques have been discovered that allow modification of the genome with a level of efficiency and precision that had not previously been achieved. One such technique, termed CRISPR-Cas9, has triggered a surge of research efforts to harness it for correcting mutations that are disease-causing, and to understand how it could be used as a therapeutic intervention in individuals with disease. Along with the scientific and medical advances in genome editing, ethical concerns also are evident, especially about the permanent editing of fertilized embryos. The Council on Science and Public Health has initiated this report to inform physicians and the House of Delegates about the remarkable advances in genome editing seen in recent years and its potential clinical applications in gene therapy, as well as concerns about it and proposals to ensure its responsible use.

Data Sources. Literature searches were conducted in the PubMed database for English-language articles published between 2006 and 2016 using the search terms “gene editing,” “genome editing,” and “CRISPR.” To capture reports not indexed on PubMed, a Google search was conducted using the same search terms. Genome editing information posted on the websites of the National Academies of Sciences, Engineering, and Medicine and the American Society of Human Genetics also was reviewed. Additional articles were identified by manual review of the references cited in these publications.

Results. Progress in gene therapy is likely to accelerate with the CRISPR-Cas9 genome editing techniques, which allows for precise and permanent modification of the genome without the complications that accompany other gene therapy techniques. The most immediate uses of genome editing have been in biomedical research settings. However, the relative ease of using CRISPR-Cas9 and other programmable nucleases has triggered the modeling of human disease and proof-of-concept studies in a number of species and in human cell lines. Early phase clinical trials are beginning to test genome editing as a therapeutic tool in select diseases. Translation of applications to the clinic will require the careful consideration of a number of factors, including the safety of the technology, its possible use in editing the germline, and high costs that could result in access problems and health disparities.

Conclusions. The last few years have seen unprecedented progress in the development of genome editing mechanisms and their potential applications for gene therapy. Much work remains to ensure the safety and effectiveness of genome editing, and questions remain about the appropriate use of germline editing. The Council supports continued research into the clinical applications of genome editing, but urges caution and thoughtful consideration before clinical germline editing is undertaken.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-I-16

Subject: Genome Editing and its Potential Clinical Use

Presented by: Bobby Mukkamala, MD, Chair

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

BACKGROUND

The promise of gene therapy has increased substantially over the last decade due to rapid advancements in two technologies: DNA sequencing and genome engineering. Next-generation DNA sequencing techniques, reviewed by this Council in 2012, have allowed analysis of the genome and discovery of the genetic basis of disease with unprecedented speed and accuracy.^{1,2} Concurrently, techniques have been discovered that allow modification of the genome with a level of efficiency and precision that had not previously been achieved.³ One such technique, termed CRISPR-Cas9,⁴ has triggered a surge of research efforts to harness it for correcting mutations that are disease-causing, and to understand how it could be used as a therapeutic intervention in individuals with disease.⁵ Along with the scientific and medical advances in genome editing, ethical concerns also are evident, especially about the permanent editing of fertilized embryos, altering the genome of every differentiated cell that arises from that embryo and the offspring of that individual.⁶

The Council on Science and Public Health has initiated this report to inform physicians and the House of Delegates about the remarkable advances in genome editing seen in recent years and its potential clinical applications in gene therapy, as well as concerns about it and proposals to ensure its responsible use.

METHODS

Literature searches were conducted in the PubMed database for English-language articles published between 2006 and 2016 using the search terms “gene editing,” “genome editing,” and “CRISPR.” To capture reports not indexed on PubMed, a Google search was conducted using the same search terms. Genome editing information posted on the websites of the National Academies of Sciences, Engineering, and Medicine and the American Society of Human Genetics also was reviewed. Additional articles were identified by manual review of the references cited in these publications.

GENE THERAPY

The concept of gene therapy, broadly defined as the use of genes or other genetic sequences to counteract or replace malfunctioning genes that cause disease, arose decades ago. Yet it has been slow in becoming a widespread therapeutic option, due in part to the complex mechanisms required to deliver genetic material to the cell and drive appropriately timed therapeutic gene expression, while avoiding the disruption of endogenous cellular function.⁷ The first successful attempt at gene therapy occurred in the early 1990s in two children with severe combined immune deficiency

(SCID) caused by defects in the adenosine deaminase (ADA) gene. Normal copies of the *ADA* gene were inserted into their T-cells at repeated time points, resulting in sustained immune function.⁸ Other gene therapy trials in the 1990s and 2000s were considered successful, but they were small, early-phase trials, and limited to only a few participants with very rare genetic diseases that were well characterized at the time. Challenges to using gene therapy more widely persisted, including the transient expression of genes inserted to the cell but not permanently into the cell's genomic DNA (called "transgenes"), requiring continual therapy; limitations in the ability of viral vectors to deliver functional genes to cells; insertional mutagenesis, the propensity of genetic sequences to randomly insert into genomic DNA, causing mutations and resultant disease; and immune responses to the introduced foreign DNA.^{7,9}

Nevertheless, research to overcome gene therapy barriers continued, and important successes have been realized. In 2015, it was reported that gene therapy was successful in several patients with Wiskott-Aldrich syndrome (WAS), a severe primary immunodeficiency caused by mutations in the *WAS* gene.¹⁰ The trial was one of the first to use an engineered viral vector that could limit insertional mutagenesis and reduce associated complications. Other gene therapy successes have included the use of modified T-cells to treat relapses in acute lymphoblastic leukemia;¹¹ restoration of vision in patients with Leber congenital amaurosis, an inherited abnormality of the retina that causes blindness;¹² and reduction of bleeding episodes in patients with severe hemophilia B.¹³ Another milestone was achieved in 2012 with the approval by the European Medicines Agency (EMA) of the first gene therapy product available in Europe. Alipogene tiparvovec, marketed as Glybera, is designed for the treatment of the rare disease lipoprotein lipase deficiency.¹⁴ This year, the EMA also approved Strimvelis, a gene therapy product for the treatment of ADA-caused SCID.^{15,16} No human gene therapy products have been approved to date by the FDA, although development of products is underway in the biotechnology industry.¹⁷

Genome Editing

Progress in gene therapy is likely to accelerate with newly discovered techniques that allow for precise and permanent modification of the genome without the complications that accompany other gene therapy techniques. The risk for insertional mutagenesis is drastically reduced because the therapeutic genetic sequences used are engineered to insert into the cell's genomic DNA at precise locations.⁷ Additionally, because the therapeutic sequence is inserted into the cell's genomic DNA rather than being expressed as a transgene, expression of it can be more tightly controlled.⁷ Termed "genome editing" or "genome engineering," these techniques are being tested for gene therapy applications that could correct or inactivate disease-causing mutations, introduce protective mutations, insert functional genes, or disrupt foreign DNA (such as that present in viral or bacterial infections).¹⁸

HOW DOES GENOME EDITING WORK?

DNA Editing

The genome editing process is illustrated in the Figure (see page 14). It is dependent on an engineered DNA-cleaving enzyme (a nuclease) that is programmed to cut genomic DNA at specific locations. Four major classes of nucleases can be engineered for site-specific editing; of these four classes, the CRISPR-Cas9 class can be easily targeted to almost any location in the genome and carries out its nuclease activity most efficiently.¹⁹ The Cas9 nuclease was first discovered in bacterial adaptive immunity experiments. Bacterial genomes carry DNA sequences called "clustered regularly interspaced short palindromic repeats" (or "CRISPR"), which are located in close proximity to the coding sequence of a CRISPR-associated ("Cas") DNA-cleaving enzyme. In

bacteria, the CRISPR sequences act as guides for Cas9's nuclease activity, providing a defense mechanism against phage infection.¹⁹ Further studies demonstrated that Cas9 could be engineered to cleave the DNA of many organisms' cells, including humans', at specific locations by providing it with the correct guide.^{19,20}

Once Cas9 is engineered to cleave genomic DNA at a specific location, it can be inserted into the cell to carry out its nuclease activity. It finds the location it has been engineered to recognize and cuts both strands of the DNA (Figure). When the DNA strand is cut, the cell uses its own DNA repair mechanisms to attempt to repair the cut. Two different repair mechanisms result in different outcomes. In one mechanism, called non-homologous end joining (NHEJ), the two ends of the DNA strand that have been cut are directly rejoined.¹⁸ However, this process is often inaccurate and results in the insertion or deletion of a small number of nucleotides, disrupting normal gene function (Figure). This is the genome editing mechanism used to inactivate a gene. By cutting a gene in its coding region and forcing repair through NHEJ, the small insertions or deletions that occur in the coding region suppress gene function or inactivate the gene altogether.¹⁸ An example of the way in which this type of genome editing could be used therapeutically is in sickle cell disease.³ Sickle cell disease is caused by mutations in the *HBB* gene, which render γ -globin dysfunctional. Functional γ -globin can be restored by upregulating the expression of the *HBG* gene. However, *HBG* is suppressed by the gene *Bcl11A*. By using genome editing to inactivate *Bcl11A*, *HBG* gene function is activated and γ -globin expression can be restored.³

The other repair mechanism used by cells after the DNA strand has been cut is called homologous recombination (HR). In HR, the cell uses a DNA fragment that exactly matches the sequences surrounding the cut as a template to direct repair (Figure). Genome editing takes advantage of the use of these DNA fragments to direct repair; an exogenous DNA fragment containing a new gene or a corrected sequence of nucleotides, along with sequences that match those surrounding the site of the DNA cut, is inserted into the cell along with Cas9.¹⁸ When Cas9 cuts the DNA in the location it has been engineered to recognize, the cell uses the exogenous DNA fragments as a template to repair the cut (Figure). This is the genome editing mechanism that is used to correct a mutation or insert a functional gene. The exogenous DNA repair fragment can be engineered to carry a correction to a mutation or a new functional gene that will be incorporated into the genome. In the example of sickle cell disease discussed above, this method could be used to either correct the mutation in the *HBB* gene, or insert a functional *HBB* gene in another location, restoring γ -globin expression.³

Delivery mechanisms

For genome editing to occur, the engineered nuclease has to be introduced into target cells. This can occur either *ex vivo* or *in vivo*. In *ex vivo* delivery, a portion of the cell population that is targeted for editing is removed from the body, undergoes genome editing, and then is returned to the host. In this mechanism, the engineered nuclease and DNA repair fragments (for HR editing) can be introduced into the cultured target cells through several methods, including electroporation, a pulse of electricity that briefly opens pores in the cell membrane to allow the nuclease and DNA repair fragments to enter; or non-pathogenic viruses that insert the nuclease and DNA repair fragments directly into the cell.¹⁸ *Ex vivo* delivery results in high editing rates, and therefore is often used for gene therapy applications. However, because it is difficult for some target cell populations to survive manipulation outside of the body, *ex vivo* delivery is usually limited to tissues with adult stem cell populations that are amenable to culture and manipulation, such as those from the hematopoietic system.¹⁸

In *in vivo* delivery, the engineered nuclease and DNA repair fragments are delivered to targeted cells in their native environment within the body. This has been achieved by using non-pathogenic viral vectors with affinity for the target tissue; the viruses are packaged with the nuclease and the DNA repair fragments (for HR editing), which are deposited directly into the cell when the virus “infects” it.¹⁸ *In vivo* delivery is preferred when the target tissue is not amenable to culture or manipulation outside of the body. It can also be used to efficiently target multiple tissue types, allowing for its therapeutic use in a wider range of diseases.¹⁸ However, the viruses that can be used as vectors are sometimes limited in their affinity for multiple tissue types, and while they are non-pathogenic, the amount of virus necessary for use in therapeutic genome editing may induce an immune response.¹⁸

CLINICAL APPLICATIONS OF GENOME EDITING

The most immediate uses of genome editing have been in biomedical research settings. The relative ease of using the CRISPR-Cas9 system, as well as other programmable nucleases, has triggered the modeling of human disease and proof-of-concept studies in a number of species and in human cell lines.²¹ A few experimental uses have progressed to early clinical trial stages in humans. Selected examples that are most promising for gene therapy are discussed in this section.

Monogenic Disorders

Nearly 8,000 diseases are monogenic, i.e., caused by mutations in single genes.³ Many of these diseases are candidates for gene editing because, simplistically speaking, the modification needed is only in one gene. At this time, successful genome editing for several monogenic diseases has been achieved in model organisms. For example, in a mouse model of Duchenne muscular dystrophy (DMD), which mimics the human form of DMD with a mutation in the *dystrophin* gene, a viral vector was used to deliver Cas9 *in vivo* to mouse muscle cells.²²⁻²⁵ The Cas9 was engineered to cut the *dystrophin* gene in two places flanking the mutation, thereby removing the mutation from the cells’ genomic DNA, then the cut ends of *dystrophin* were repaired by the NHEJ mechanism.²²⁻²⁵ The technique only partially restored Dystrophin protein function, but it was enough to restore partial muscle function in the mice. Particularly exciting was the finding that gene editing occurred in satellite cells, stem cells that are present in muscle, implying that the satellite cells could populate the muscles with cells carrying the partially repaired *dystrophin* gene.²⁵

Preclinical studies using genome editing to correct the mutations that cause cystic fibrosis have also been promising. Organoids are small amounts of functional tissue derived from human stem cells. In intestinal organoid tissue derived from patients carrying mutations in the *CFTR* gene, which causes cystic fibrosis, the CRISPR-Cas9 system was used to correct the mutations through the HR mechanism.²⁶ The corrected *CFTR* was fully functional and was able to “rescue” the cystic fibrosis phenotype in the organoids.²⁶ Together with other experiments showing that cultured intestinal organoids can be transplanted into and become functional in the colons of mice,²⁷ this provides a potential strategy for gene therapy in patients with cystic fibrosis.

Other studies demonstrated successful proof-of-concept results using genome editing for the treatment of many other monogenic diseases, including hemophilia B, hereditary tyrosinemia, ADA-caused SCID, sickle cell disease, and β -thalassemia.^{3,18,19} The biotechnology company Editas has stated that it will begin a clinical trial in 2017 using CRISPR-Cas9 as a gene therapy mechanism to correct mutations causing Leber congenital amaurosis.²⁸

Cancers

With more than 1.5 million cases of cancer diagnosed and half a million deaths from cancer each year,²⁹ the prospect of treating cancer using genome editing-based technologies is appealing. However, it is widely thought that direct repair of acquired or inherited mutations in cancer cells would not be effective.¹⁸ Mutations in cancer cells give them a fitness advantage over non-cancerous cells, i.e., they divide quickly and do not respond to the cells' signals to halt growth or self-destruct. Even the most efficient genome editing could not repair every cancer cell present in a tissue or throughout the body, so cancer cells with repaired mutations would quickly be outcompeted by their non-repaired counterparts, rendering the therapy ineffective.¹⁸

Despite the inability to directly correct mutations in cancer cells, research has shown exciting results using engineered T-cells to harness the immune system's ability to fight cancer. T-cells are harvested from patients with certain types of cancer, engineered to express receptors that have specific and strong affinity for tumor antigens, and then infused back into patients, where they attack tumor cells.^{30,31} This technique has been the most successful in trials for melanomas and leukemias and lymphomas of B-cell origin.³¹

Genome editing is now being explored as a technique to engineer T-cells that more stably and permanently express the receptors that target them to cancer cells. In June 2016, the National Institutes of Health approved a proposal to use the CRISPR-Cas9 system to edit T-cells from patients with one of three cancer types: multiple myeloma, sarcoma, or melanoma.³² The genome editing will include inserting a gene that helps the T-cells better recognize cancer cells, inactivating a gene that interferes with the recognition process, and inactivating a gene that allows cancer cells to prevent T-cell attacks.³² Recruitment could begin late in 2016, once FDA and institutional review board approval are granted.³³ Another trial using genome-edited T-cells is set to begin this year in China in patients who have metastatic non-small cell lung cancer and for whom chemotherapy, radiation therapy, and other treatments have failed. In that trial, CRISPR-Cas9 will be used to inactivate the gene that encodes PD-1, which normally acts as a check on the cell's capacity to launch an immune response.³⁴

Non-Genetic Disorders

In addition to the use of genome editing to correct diseases caused by genetic mutations, it also is being investigated for use in treating infectious diseases and a variety of other health conditions. For example, the discovery that patients who carry mutations disabling the HIV receptor CCR5 are nearly completely resistant to HIV infection provided the basis for a genome editing-based clinical trial for treating HIV. A small, early-phase clinical trial removed T-cells from patients with HIV, used an engineered nuclease to mutate the *CCR5* gene, and then transplanted the edited T-cells back into the patients.^{3,18,35} Preliminary results showed that in the majority of patients receiving the edited T-cells, HIV DNA levels in the blood decreased, and in one patient, HIV was undetectable.³⁵ Unlike the fitness disadvantage that directly edited cancer cells have when compared to their non-edited counterparts, T-cells with the edited *CCR5* gene have a fitness advantage over the non-edited T-cells; in the trial, the edited T-cell population had lower rates of cell death than did non-edited T-cells, suggesting that they are more stable.³⁵ Complete removal of the virus will be challenging, however, and will depend on extremely efficient delivery and editing strategies;¹⁸ phase II trials are now ongoing to test such strategies. Similar genome editing mechanisms have also shown promising results in treating hepatitis B virus infection.^{36,37}

Genome editing also is being explored as a therapy to reduce cardiovascular disease risk. The gene *PCSK9* was recently discovered as a modulator of LDL cholesterol function. People carrying

dominant gain-of-function mutations in *PCSK9* have highly elevated LDL level and premature coronary heart disease, and those carrying homozygous loss-of-function mutations have a nearly 80 percent reduction in LDL level with no apparent adverse clinical consequences.^{38,39} *PCSK9*-targeting monoclonal antibodies are currently being tested in clinical trials as LDL-lowering therapies.⁴⁰ Genome editing of *PCSK9* has been tested in the pre-clinical setting. A viral vector was used for *in vivo* delivery of Cas9, engineered to introduce mutations in the *PCSK9* gene using the NHEJ mechanism, to liver cells of mice.⁴¹ Editing occurred in more than half of the liver cells, and resulted in a 35-40 percent reduction in total cholesterol and reduced LDL plasma fractions.⁴¹ This study has contributed to the notion that the future of cholesterol management may first be a bi-weekly or monthly intervention using *PCSK9*-inhibitor antibody drugs, then eventually become a one-time intervention that permanently and selectively modifies the genome to inactivate *PCSK9* and thereby reduce cholesterol.⁴²

CONSIDERATIONS BEFORE CLINICAL USE

The pace of exploration of genome editing as a potential tool for gene therapy has been rapid in recent years. However, translation of applications to the clinic will require the careful consideration of a number of factors, including the safety of the technology, its possible use in editing the germline, and high costs that could result in access problems and health disparities.

Safety

The specificity of engineered nucleases, i.e., their ability to cut DNA at precisely targeted positions and avoid cutting at non-targeted locations, will be a key factor in the translation of this mechanism of gene therapy into clinical practice. Genetic modifications resulting from genome editing are permanent, so off-target modifications could create cells with functional impairment or even oncogenic potential. CRISPR-Cas9 genome editing appears to result in only rare instances of off-target modification; one study estimated that one error in 300 trillion base pairs could occur, and given that the human genome is only 3 billion base pairs, that equates to one off-target modification per 100,000 cells.⁴³ However, more sophisticated methods are needed for evaluating the likelihood of off-target modification for each potential clinical use, and studies are ongoing to develop ways of preventing off-target modification.^{44,45} Clinical use of genome modification would not be appropriate without mechanisms to ensure that off-target modifications are extremely rare and result in negligible clinical consequence.^{18,46}

Another safety concern lies with using viral vectors as delivery mechanisms. Adeno-associated virus (AAV) vectors are approved for clinical use,⁴⁷ and have high delivery efficacy for a number of tissue types. But AAV vectors pose some challenges. In some cases, nucleases packaged within AAV vectors are constitutively active, increasing the chances of off-target modification.¹⁸ Also, many people who have been naturally exposed to AAV have developed immunity to it, so it may not be an appropriate delivery mechanism for them.¹⁸ Immunotoxicity also may occur upon exposure to certain engineered nucleases, including Cas9, since they are microbially derived.⁴⁸ Alternative delivery systems, including lipids and nanoparticles, are being explored to avoid the potential for immunotoxicity.^{49,50}

Germline Editing

The most ethically-fraught conversations about genome editing center on the use of the technology to modify the genome of germline cells (eggs and sperm) or early-stage embryos. Such editing would result in permanent modifications to the individual arising from the germline cells or embryo, and would permanently change the gene pool since those modifications would be passed

on to future generations. Conversations about these issues took on new urgency when researchers in China demonstrated that CRISPR-Cas9 could be successfully used to edit the genome of early-stage human embryos.⁵¹ The embryos used in the study were genetically incapable of maturing into viable zygotes, and important limitations in the efficiency of CRISPR-Cas9 in human embryos were discovered, but the study nonetheless illustrated the application of genome editing to human embryos before ethical standards for its use have been widely promulgated. Further evidence that genome editing is close to being used in human embryos comes from a study that used CRISPR-Cas9 to induce genome modifications in one-cell stage embryos of cynomolgus monkeys, resulting in live births.⁵² Cynomolgus monkeys are so genetically close to humans that they are often used to model human disease. The genome-edited animals are now being studied to determine the efficiency of the editing and potential health consequences stemming from it.⁵²

Several organizations, including the National Academies of Sciences, Engineering, and Medicine (NASEM) and the American Society of Human Genetics (ASHG), have convened expert working groups to study the issue and define principles by which germline editing should or should not occur. Discussions center on the use of genome editing to treat or cure diseases for which no other equally effective therapy exists, and what types of disorders are sufficiently debilitating that extreme measures like genome editing are needed. The case for germline editing is most compelling when both parents are homozygous for a disease-related gene variant; however, that is a rare occurrence.⁵³ Another question that arises is whether genome editing has any value over preimplantation genetic diagnosis, which allows prospective parents who carry heritable disease-causing genes to select embryos lacking those genes.⁵⁴ Genome editing for complex polygenic diseases is likely not possible because those genes usually have very weak effects on their own and are often involved in a variety of physiological functions, some of which may be beneficial.^{53,54} Discussions also focus on the potential for non-medical use of germline editing, such as for selecting desirable traits, and the autonomy of parents to make genetic modifications in their offspring, who themselves are not able to consent.⁵³

NASEM, along with the Royal Academy and the Chinese Academy of Sciences, held a summit late in 2015 during which a committee of scientific and ethics experts discussed genome editing and developed conclusions about its use.⁵⁵ The consensus conclusions support preclinical research on genome editing, as well as its use in somatic gene therapy concordant with regulatory law. However, the committee does not support clinical use of germline editing until “(i) the relevant safety and efficacy issues have been resolved, based on appropriate understanding and balancing of risks, potential benefits, and alternatives, and (ii) there is broad societal consensus about the appropriateness of the proposed application.”⁵⁵ The committee will complete a comprehensive study of the scientific underpinnings of human genome editing technologies, their potential use in biomedical research and medicine, including human germline editing, and the clinical, ethical, legal, and social implications of their use by late 2016.⁵⁶

Similarly, ASHG has convened a Workgroup on the Implications of Genome Editing to craft policy on genome editing; in addition to ASHG, the Canadian Association of Genetic Counselors, International Genetic Epidemiology Society, National Society of Genetic Counselors, and Association of Genetic Nurses and Counselors (United Kingdom and Ireland) participated in the Workgroup.⁵⁷ It developed a draft policy outline that supports research into the use of germline editing as long as it does not culminate in a human pregnancy, and believes that clinical application should not proceed unless, at a minimum, there is “a) a compelling medical rationale, b) an evidence base that supports its clinical use, c) an ethical justification, and d) a transparent public process to solicit and incorporate stakeholder input.”⁵⁷ ASHG has solicited member comments on the draft policy and will finalize it in the coming months.

The AMA Code of Medical Ethics contains similar sentiments regarding gene therapy and genetic engineering. Opinion 7.3.6, “Research in Gene Therapy & Genetic Engineering,” states that genetic manipulation should be reserved for therapeutic purposes, and that efforts to enhance “desirable” characteristics are contrary to the ethical tradition of medicine. It sets out a number of conditions that should be met before physicians engage in research involving gene therapy or genetic engineering, including evidence that the intervention will be safe and effective, that no other suitable or effective therapies are available, and that it is restricted to somatic cells. The full opinion is in the Appendix. The Council believes that the principles set forth in Opinion 7.3.6 should guide AMA policy on genome editing.

Costs and Health Disparities

As is the case for many expensive therapies, access problems are likely to occur if genome editing-based gene therapies become viable clinical options. Use of the first gene therapy product approved by the EMA, Glybera, has been limited to only one patient because it carries a price tag of more than \$1 million. It was covered by the patient’s insurance company, but only after her physician worked intensely to obtain authorization.¹⁶ It is not known what the cost of the newly EMA-approved gene therapy Strimvelis will be, but its manufacturer, GlaxoSmithKline, has stated that it will be “significantly less” than the \$1 million mark.¹⁶ According to the manufacturer of Glybera, UniQure, the high cost of gene therapy drugs is based on the substantial development costs, the fact that the market for the rare diseases they treat is exceptionally small, and in Glybera’s case, that it is administered only once, rather than repeatedly over a period of time.⁵⁸ Compared to the \$250,000 per year average cost of other orphan drugs that treat rare diseases, a one-time dose of a \$1 million drug could be considered cost-saving. However, that cost is so high that it is unlikely patients who need the therapies could afford them, or that insurance companies would authorize payment. This undoubtedly would create health disparities issues, in which only the wealthiest patients, or those fortunate enough to have coverage through insurers who will approve the therapy, could have access to it. Although Glybera and Strimvelis are based on transgene expression rather than permanent genome modification, it is reasonable to assume that genome editing-based gene therapies would have similarly expensive development processes, leading to high costs for patients.

CONCLUSIONS

The last few years have seen unprecedented progress in the development of genome editing mechanisms and their potential applications for gene therapy. While most research is at the preclinical stages, a small number of clinical trials in humans have begun, with others planned for the near future. Much work remains to ensure the safety and effectiveness of genome editing, and questions remain about the appropriate use of germline editing. The Council supports continued research into the clinical applications of genome editing, but urges caution and thoughtful consideration before clinical germline editing is undertaken. The Council also urges continued work to develop international consensus standards for permissible therapeutic uses of germline editing.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and the remainder of the report be filed.

1. That our American Medical Association (AMA) encourage continued research into the therapeutic use of genome editing. (New HOD Policy)

- 1 2. That our AMA urge continued development of consensus international principles, grounded in
- 2 science and ethics, to determine permissible therapeutic applications of germline genome
- 3 editing. (New HOD Policy)

Fiscal Note: Less than \$1000

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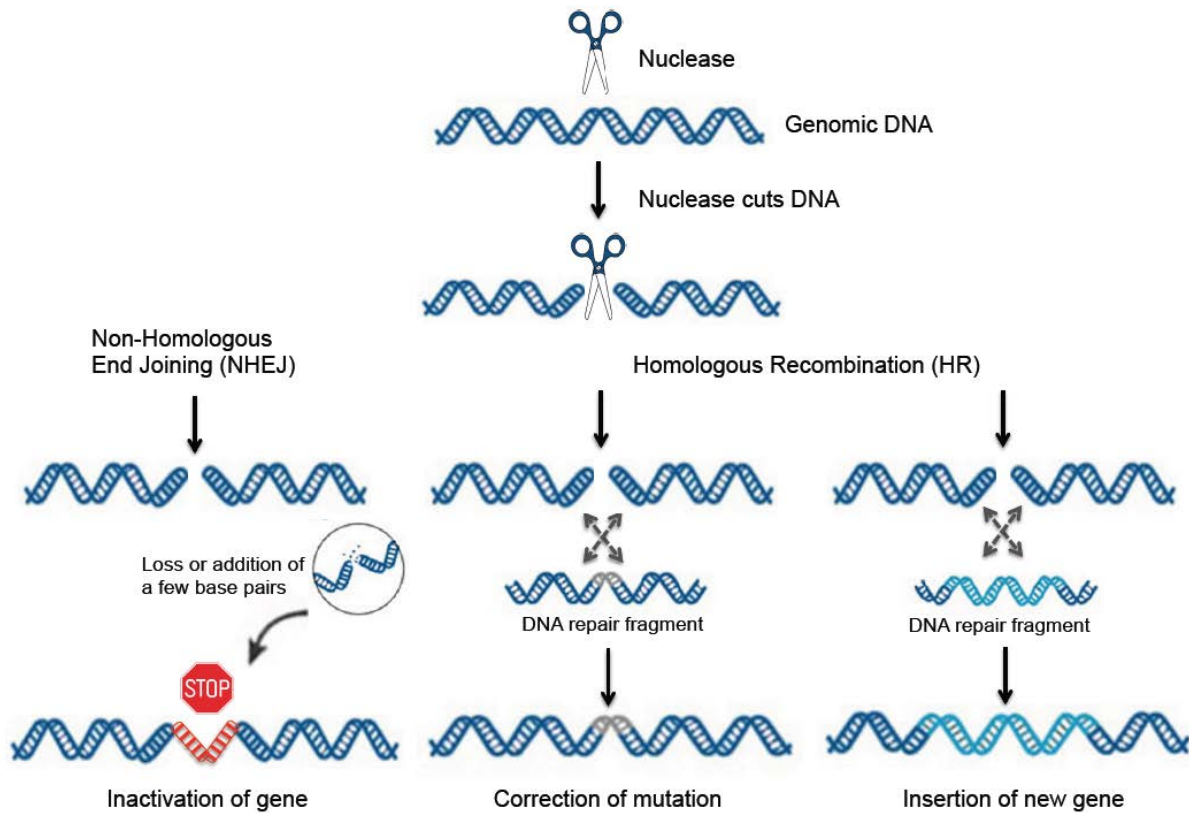
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Figure. The genome editing process.



A nuclease engineered to cleave genomic DNA at a precise location is inserted into the cell. Once the DNA is cut, the cell uses either non-homologous end-joining (NHEJ) or homologous recombination (HR) to repair the cut. In NHEJ, the two ends of the DNA strand that have been cut are directly rejoined, but this process results in the insertion or deletion of a small number of nucleotides, disrupting normal gene function. In HR, an exogenous DNA fragment containing a new gene or a corrected sequence of nucleotides, along with sequences that match those surrounding the site of the DNA cut, is inserted into the cell. The cell uses the exogenous DNA fragment as a template to repair the cut, incorporating the sequence present into the genomic DNA, correcting a mutation or inserting a functional gene. (Figure adapted from <http://www.calyxt.com/technology/targeted-genome-editing/>.)

Appendix. AMA Code of Medical Ethics, 7.3.6, Research in Gene Therapy & Genetic Engineering

Gene therapy involves the replacement or modification of a genetic variant to restore or enhance cellular function or the improve response to nongenetic therapies. Genetic engineering involves the use of recombinant DNA techniques to introduce new characteristics or traits. In medicine, the goal of gene therapy and genetic engineering is to alleviate human suffering and disease. As with all therapies, this goal should be pursued only within the ethical traditions of the profession, which gives primacy to the welfare of the patient.

In general, genetic manipulation should be reserved for therapeutic purposes. Efforts to enhance “desirable” characteristics or to “improve” complex human traits are contrary to the ethical tradition of medicine. Because of the potential for abuse, genetic manipulation of nondisease traits or the eugenic development of offspring may never be justifiable.

Moreover, genetic manipulation can carry risks to both the individuals into whom modified genetic material is introduced and to future generations. Somatic cell gene therapy targets nongerm cells and thus does not carry risk to future generations. Germ-line therapy, in which a genetic modification is introduced into the genome of human gametes or their precursors, is intended to result in the expression of the modified gene in the recipient’s offspring and subsequent generations. Germ-line therapy thus may be associated with increased risk and the possibility of unpredictable and irreversible results that adversely affect the welfare of subsequent generations.

Thus in addition to fundamental ethical requirements for the appropriate conduct of research with human participants, research in gene therapy or genetic engineering must put in place additional safeguards to vigorously protect the safety and well-being of participants and future generations.

Physicians should not engage in research involving gene therapy or genetic engineering with human participants unless the following conditions are met:

- (a) Experience with animal studies is sufficient to assure that the experimental intervention will be safe and effective and its results predictable.
- (b) No other suitable, effective therapies are available.
- (c) Gene therapy is restricted to somatic cell interventions, in light of the far-reaching implications of germ-line interventions.
- (d) Evaluation of the effectiveness of the intervention includes determination of the natural history of the disease or condition under study and follow-up examination of the participants’ descendants.
- (e) The research minimizes risks to participants, including those from any viral vectors used.
- (f) Special attention is paid to the informed consent process to ensure that the prospective participant (or legally authorized representative) is fully informed about the distinctive risks of the research, including use of viral vectors to deliver the modified genetic material, possible implications for the participant’s descendants, and the need for follow-up assessments.

Physicians should be aware that gene therapy or genetic engineering interventions may require additional scientific and ethical review, and regulatory oversight, before they are introduced into clinical practice.

REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-16)
Hormone Therapies: Off-Label Uses and Unapproved Formulations
(Resolution 512-A-15)
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. To develop a report, update recommendations, and inform physicians about the use of off-label and unapproved uses of hormones, especially compounded hormone therapies (bioidentical hormones).

Methods. English-language articles were selected from a search of the PubMed database through August 2016 using the search terms “off-label hormone therapy,” “bioidentical hormone,” and “off-label” with the terms “estrogen,” “progesterone,” “thyroid hormone,” “dehydroepiandrosterone,” “testosterone,” “growth hormone,” and “hCG.” Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society websites were conducted to identify clinical guidelines and position statements. Additionally, Internet searches were conducted for “wellness clinics.”

Results. Females, males, children, transgender individuals, and athletes are all recipients of hormone therapies. The use of the therapies can be categorized as FDA-approved, off-label use supported by scientific evidence; off-label use in the absence of scientific evidence, and use of non-FDA-approved products. A number of FDA-approved hormone products exist and are being used for labeled indications as well as for off-label uses, both with and without support of scientific evidence. In addition, many hormones being prescribed for both medical and non-medical indications are not FDA-approved products, including dietary supplements and compounded products. Even though compounded hormone therapies are not FDA-approved, they do require a prescription. Little scientific evidence exists to support specific claims of efficacy of compounded hormone therapy preparations; a literature review produced no adequate randomized placebo-controlled trials to support their use.

Conclusion. Current AMA policy supports the clinical decision-making authority of a physician to use an FDA-approved product off-label when such use is based upon sound scientific evidence or sound medical opinion; however, to date the use of compounded hormone therapies is not supported by such evidence. Additionally, traditional compounding is recognized as a legal and important therapeutic approach when an FDA-approved drug product is not available or does not meet the clinical needs of individual patients. However, in the case of many of the uses for compounded hormones, comparable FDA-approved therapies are available. Further concern is prompted by the fact that compounding pharmacies are exempt from including specific and important safety information on labeled instructions. That lack of information may put some patients at risk.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-I-16

Subject: Hormone Therapies: Off-Label Uses and Unapproved Formulations
(Resolution 512-A-15)

Presented by: Bobby Mukkamala, MD, Chair

Referred to: Reference Committee K
(Paul A. Friedrichs,, MD, Chair)

INTRODUCTION

Resolution 512-A-15, “Off-Label Use of Hormone Therapy,” introduced by the Women Physicians Section and referred by the House of Delegates asked:

That our American Medical Association work with national health care organizations to advocate on behalf of the public and our patients on the appropriate evaluation and treatment of hormone deficiencies, as well as the side effects from use of hormone therapy without objective evidence to guide treatment, especially when given to promote weight loss or a general feeling of well-being.

Hormone therapy is the treatment of diseases or conditions with hormones that are derived from endocrine glands or substances that simulate or modulate hormonal effects.¹ The most common uses of U.S. Food and Drug Administration (FDA) approved hormone therapies include replacement during menopause, oncology therapies, and for endocrine or genetic disorders. Although oral contraceptives are a common use of hormones, their primary use for the prevention of pregnancy is not considered a therapy. Over the past several years there has been a large expansion in the use of hormones for off-label uses such as “well-being,” anti-aging, low libido and sexual dysfunction and other conditions in the absence of an evidence base to guide treatment (e.g., human chorionic gonadotropin (hCG) for weight loss).² Clinicians prescribing hormone therapies off-label are found in primary care clinics or practices, hospital settings, specialty practices, and “commercial wellness clinics.” Products being prescribed include both FDA-approved pharmaceuticals and unapproved hormones, including compounded preparations.

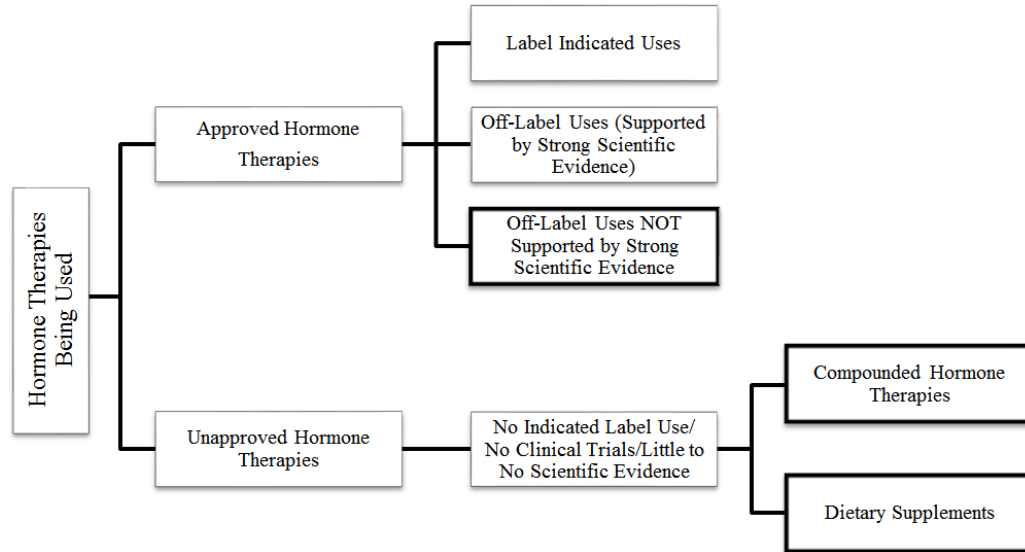
Recently, the pursuit of individual health and well-being has been put in the spotlight and become an evolving trend. The global wellness industry is now a \$3.4 trillion market, more than 3-fold larger than the worldwide pharmaceutical industry.³ In the U.S., the sale of compounded hormone therapies is estimated at \$1.5 billion, with continued growth projected over the next several years.⁴

Females, males, children, transgender individuals, and athletes are all recipients of hormone therapies. These therapies can be categorized as follows (see Figure 1):

- Use of approved drugs according to a labeled indication
- Off-label use of FDA-approved hormone therapies supported by scientific evidence
- Off-label use of FDA-approved hormone therapies in the absence of scientific evidence

- Widespread use of unapproved hormone therapies, including compounded hormone therapies. While subject to some FDA regulation, hormone-containing dietary supplements can also be considered in this category.

Figure 1. Flow chart of hormone therapy uses (bold boxes indicate the focus of this report).



CURRENT AMA POLICY

Current AMA Policy H-120.988, “Patient Access to Treatments Prescribed by Their Physicians,” supports the decision-making authority of a physician and the lawful use of FDA-approved drug products for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion. Policy D-120.969, “FDA Oversight of Bioidentical Hormone (BH) Preparations,” is a set of directives urging stronger FDA oversight over bioidentical hormones; this report will update this policy. Policy H-100.962, “The Use of Hormones for Anti-Aging: A Review of Efficacy and Safety,” based on a previous Council report, states that proponents of anti-aging therapies have the responsibility to prove claims of a positive risk/benefit profile through well-designed, randomized, placebo-controlled clinical trials. The goal of Policy H-460.907, “Encouraging Research Into the Impact of Long-Term Administration of Hormone Replacement Therapy in Transgender Patients,” is reflected in the title of the policy. Finally, Policy D-140.957, “Ethical Physician Conduct in the Media,” seeks to establish guidelines for physician endorsement and dissemination of medical information in the media.

METHODS

English-language articles were selected from a search of the PubMed database through August 2016 using the search terms “off-label hormone therapy,” “bioidentical hormone,” and “off-label” with the terms “estrogen,” “progesterone,” “thyroid hormone,” “dehydroepiandrosterone,” “testosterone,” “growth hormone,” and “hCG.” Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society websites were conducted to identify clinical guidelines and position statements. Additionally, Internet searches were conducted for “wellness clinics.”

BACKGROUND

Women's Health Initiative

The findings of the Women's Health Initiative (WHI) are an important backdrop to the marketing of off-label hormone therapies. The initial results of the WHI were summarized in CSAPH Report 5-A-09.⁵ Briefly, following publication and analysis of the results of the WHI, the U.S. Preventive Services Task Force (USPSTF) recommended against the routine use of combined hormone therapy (estrogen plus progestin) for the prevention of chronic conditions in postmenopausal women and the routine use of estrogen alone for the prevention of chronic conditions in postmenopausal women who have had a hysterectomy. Subsequently, the FDA also required estrogen/progestin or estrogen-only products to contain a black box warning on the potential serious adverse events associated with long-term administration.⁵ A reanalysis of the WHI data suggests that combined hormone therapy may be appropriate for younger, low-risk women who are seeking short-term relief from menopause symptoms, but the USPSTF continues to recommend against the use of combined hormone therapy for disease prevention or long-term health improvement.⁶

Off-Label Prescribing

When the FDA approves a drug or device and its product labeling, it does so for a specific use or indication. When a physician prescribes a drug for an indication that is not included in the product labeling, or at a dosage outside the recommended range, or uses a different route of administration, or for a patient from a population excluded from the label recommendation (e.g., pediatric), such uses are termed "unlabeled" or "off-label." Off-label prescribing is not illegal because the FDA does not regulate the practice of medicine (21 U.S.C. § 396). Once a drug product has been approved for marketing, physicians may prescribe it for uses or in treatment regimens or patient populations that are not included in the approved product labeling. AMA Policy H-120.988 strongly supports the option of off-label prescribing "when such use is based upon sound scientific evidence or sound medical opinion."

The prevalence and clinical importance of off-label prescribing in routine patient care are substantial. In general, off-label prescribing ranges from 10-20%, but is much higher in certain medical specialties (e.g., oncology) and patient populations (e.g., pediatrics, patients with rare diseases).⁷⁻¹² Accordingly, the spectrum of off-label uses is wide. They can be a source of innovation and new practices, represent primary therapy or the standard of care, or they may represent the only available therapy or be a therapy of last resort. Concerns include a lack of substantial evidence supporting safety and efficacy for many off-label uses and the potential for increased costs when newer branded drugs are used in this manner. Recently, the lack of strong scientific evidence to support many common off-label uses, and an increased frequency of adverse events leading to discontinuation of therapy, have led to calls for more scrutiny of such practices.^{10,13,14}

In one study of hormone prescribing in primary care clinics, more than 20,000 new prescriptions were issued between 2005 and 2009; 5.2% of them were for off-label uses.¹⁵ Additionally, a recent survey of the activity of compounding pharmacies estimated that 26 to 33 million hormone therapy prescriptions are compounded annually for 2 to 3 million individuals.^{4,16} All compounded preparations are by definition not FDA-approved, even if they include FDA-approved drugs. Limited pathways exist for non-FDA-approved drugs to be compounded and supplied to patients.

APPROVED HORMONE THERAPIES

A number of FDA-approved hormone products exist. These include, but are not limited to, steroidal hormones, aromatase inhibitors, gonadotropin releasing hormones (GnRHs), GnRH analogs, GnRH antagonists, selective estrogen receptor modulators (SERMs), antiandrogens, somatostatin analogs, growth hormone (hGH), hGH secretagogues, human chorionic gonadotropin (hCG), and thyroid hormones. There are several labeled uses for these hormone therapies; Table 1 provides class examples of FDA-approved hormones and examples of indicated uses for the class. Table 1 also notes some off-label uses of hormone therapies, most of which lack supporting scientific evidence.

UNAPPROVED HORMONE THERAPIES

Beyond the pattern of FDA-approved medications being used off-label without support of scientific evidence, many hormones being prescribed for both medical and non-medical indications are not FDA-approved products. These include dietary supplements and compounded products.

Dietary Supplements

Dietary supplements are regulated by the Dietary Supplement Health and Education Act of 1994 (DSHEA).¹⁷ Under DSHEA, dietary supplements are not regulated as drugs. Manufacturers, not the FDA, are responsible for evaluating the safety and labeling of products before marketing to ensure that they meet all legal requirements. Thyroid hormone and dehydroepiandrosterone (DHEA) are two common hormones found in commercially available dietary supplements. Recent studies have revealed that one in three older adults are using five or more prescription medications and approximately half regularly use over-the-counter dietary supplements and medications.¹⁸ In addition to concerns with dietary supplement quality and contamination,¹⁹ there is a high risk of adverse events associated with the use of multiple medications and dietary supplements. Half of all potential major drug-drug interactions identified in outpatients involved over-the-counter products.¹⁸

Compounded Hormone Therapies (Bioidentical Hormones)

Bioidentical hormones are semi-synthetic hormones that are chemically synthesized from a natural starting material, most commonly a plant sterol sourced from soybeans or the Mexican yam.²⁰ Bioidentical hormones are structurally identical to hormones produced in the body. Some are commercially available products approved by the FDA (e.g., micronized estradiol), and many are compounded preparations that are not FDA-approved. Compounded bioidentical hormones have become popular because of direct-to-consumer marketing by compounding pharmacies, commercial wellness clinics, and some individuals outside of the medical community along with media depiction as safer, natural, and more effective alternatives to prescription hormone therapies. Although compounded bioidentical hormones are not FDA-approved, they do require a prescription. The term bioidentical hormones does not include over-the-counter herbal preparations or plant-based products with estrogenic activity.

The term “bioidentical hormone” does not have a standardized definition, which adds to the confusion regarding the identity, use, and safety of the products. Depending on the context in which it is used, the term can imply natural (not synthetic), compounded, plant derived, or structurally identical to human hormones.²¹ The term “bioidentical hormone therapy” has been recognized by the FDA and The Endocrine Society as a marketing term and not a description based on scientific evidence.^{20,22-24} Therefore “compounded hormone therapy” (CHT) will be used to

1 describe these preparations throughout this report. Furthermore, CHT often not only refers to
2 compounded hormone preparations, but may be inclusive of the initial diagnostic testing and
3 monitoring that is repeated over time on a patient.

4
5 Regulation. CHTs are prepared in compounding pharmacies and are regulated under sections 503A
6 and 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Section 503A applies to
7 traditional compounding pharmacies and §503B applies to compounding outsourcing facilities
8 which produce bulk amounts of products (e.g., for hospitals or in the event of drug shortages). The
9 vast majority of the products that are the focus of this report are compounded in traditional
10 compounding pharmacies and are therefore regulated under §503A. Compounded drugs are not
11 subject to the same rigorous evaluation and approval process as prescription drugs that are FDA-
12 approved. Section 503A describes that compounded drug products are exempt from three sections
13 of the FD&C Act including those concerning current good manufacturing practice (cGMP); the
14 labeling of drugs with adequate directions for use, standardized labels, or product inserts (including
15 any black box warnings); and the approval of the drugs under new drug applications (NDAs) or
16 abbreviated new drug applications (ANDAs).²⁵ Additionally, the statute puts restrictions on the
17 compounding of products that are essentially copies of drugs that are commercially available.²⁶
18 Previously, §503A also included restrictions on advertising or promotion of the compounding of
19 drugs or drug classes or the solicitation of prescriptions for compounded drugs, but these
20 provisions were deemed unconstitutional by the U.S. Supreme Court in 2002.²⁷ Traditional
21 compounding pharmacies are not required to register with the FDA, investigate or report adverse
22 events, or report sales under §503A. Currently, individual state boards of pharmacy maintain
23 oversight of traditional compounding pharmacies under §503A while the FDA maintains a risk-
24 based enforcement approach with respect to violations of the FD&C Act.

25
26 Evidence Base. Little scientific evidence exists to support specific claims of efficacy of CHT
27 preparations. A literature review produced no adequate randomized placebo-controlled trials.
28 Authors of a literature review of randomized controlled trials of CHT progesterone cream for the
29 relief of menopause-related vasomotor symptoms found three studies.²⁸ None of the trials applied
30 FDA methodology for evaluating symptom relief and the search authors determined in their review
31 that the data presented do not support the use of CHT progesterone cream for the relief of
32 menopause-related vasomotor symptoms.

33
34 Two observational studies were found evaluating menopausal symptom relief for 3-6 months in
35 patients receiving CHT preparations from a wellness clinic which offer low-level evidence that
36 CHT improves menopausal symptoms. The first study involved 296 women receiving various CHT
37 treatments, doses, and routes of administration and showed a statistically significant improvement
38 in emotional symptoms such as irritability and anxiety.²⁹ The second study involved 200 women
39 receiving estrogen, progesterone, testosterone, or some combination of the three hormones either
40 via topical or sublingual administration. The results of this study showed that topical CHT was not
41 as effective as sublingual CHT at reducing vasomotor, mood, and quality-of-life symptoms.³⁰

42
43 CHT preparations can be inconsistent in dose and purity. After reports of quality control problems
44 associated with CHT, the FDA conducted two surveys to evaluate compounded drugs. In 2001, the
45 FDA evaluated 29 compounded drugs from 12 different compounding pharmacies and reported
46 that while none of the samples failed identity testing, 10 (34%) of the samples failed standard
47 quality testing, including potency testing.³¹ In another survey in 2006, the FDA collected 198
48 samples from compounding pharmacies; 73 were finished compounded drug products; 33% of
49 these products did not conform to information on the label.³² Other reports of both subpotent
50 products and products containing excessive amounts of active ingredient(s) exist.²² One
51 preliminary pharmacokinetic study in which plasma estradiol levels achieved with CHT doses

commonly thought to be bioequivalent to FDA-approved products were compared to the FDA-approved estradiol patch. The plasma levels achieved with all doses of the CHTs were significantly lower than with the estradiol patch.³³

The Endocrine Society, The American Association of Clinical Endocrinologists, American Congress of Obstetricians and Gynecologists, American Society for Reproductive Medicine, The North American Menopause Society, and The Women's Health Practice and Research Network of the American College of Clinical Pharmacy have issued position statements outlining their concerns regarding CHT, specifically mentioning patient safety because of the lack of evidence-based research regarding clinical effectiveness and inherent risks associated with hormone compounding.^{1,23,34-37} Policy D-120.969, "FDA Oversight of Bioidentical Hormone (BH) Preparations," urges the FDA to take several actions regarding bioidentical hormones.

CHT Marketing and Conflicts of Interest. There have been some ethical and conflict of interest issues associated with commercial wellness clinics and compounding pharmacies that prescribe and dispense CHT. Some compounding pharmacies that sell CHT also market the products to the public by providing listings of their offerings and offer referrals to providers who can prescribe the CHT. Some proprietors of commercial wellness clinics have published peer-reviewed journal articles that have been viewed as misleading³⁸ and questionable rhetorical approaches may be used to appeal to those lacking scientific literacy, for example, failing to distinguish between "cutting edge medicine" and "untested or unproven therapies."³⁹

CHT proponents often use the WHI trial results as part of a marketing approach to promote CHT as safer than traditional hormone therapies, emphasizing that CHT is different from the hormones used in the WHI study, and either implying or directly claiming that CHT is safer than FDA-approved preparations, despite a lack of evidence to substantiate this claim.^{39,40} In addition, the FDA requires that patient package inserts and class labeling black box warnings reflective of the findings of the WHI be included with all FDA-approved estrogen and progesterone products. Because CHTs are not FDA-approved products, they are exempt from FDA labeling and warning requirements, and patient package inserts and the black box warnings are not included.²² The lack of warnings may lead some patients to conclude CHTs are safer.¹

Additional claims often employed as marketing tactics by CHT prescribers and compounders also cannot be substantiated.^{21,41} For example, the claim that CHT has improved delivery compared to FDA-approved hormone therapies has not been evaluated in clinical trials.²¹ Some clinicians also advocate for saliva testing as a way to provide customized therapy for patients, an approach that lacks scientific validity (see below).³⁵

Patient Perspective. Surveys indicate that approximately one in three individuals who use hormone therapy rely on CHT and believe it is "natural."¹⁶ Using terms such as "bioidentical" and "natural," health care providers are able to market and prescribe CHT as distinctly different treatments from traditional hormone replacement therapies and as alternatives to prescription drugs. CHT appeals to consumers who seek more holistic healthcare approaches and tend to reject synthetic, manufactured pharmaceutical drugs.⁴² Surveys indicate that patients who seek CHT do so because of a lack of satisfaction with their primary care physicians. Wellness practitioners are perceived as better listeners, and as validating their symptoms and willing to find solutions.⁴² There is abundant promotion from celebrities who have published popular books and magazine articles discussing hormone therapies.^{39,43-46}

Among patients receiving hormone replacement therapies, only 14% of respondents knew that CHT was not FDA-approved.⁴⁷ Additionally, those patients view the fact that compounding of

1 CHT is not under FDA purview as part of the appeal. Furthermore, they view the customization as
 2 less dangerous even though opponents view this as one of the biggest risks of CHT.⁴² Even when it
 3 is pointed out that a lack of safety data and product information does not mean CHT is safe,
 4 patients continue to believe CHTs are safer than FDA-approved hormone therapies.⁴⁸

5
 6 Hormone Customization. A major appeal of CHT is that the treatment is marketed as customized to
 7 each individual patient, compared to mass-produced FDA-approved pharmaceuticals. Most
 8 compounding pharmacies have the capability to prepare hormone therapies for various routes of
 9 administration including oral, sublingual, percutaneous, implant, injectable, or suppository. The
 10 pharmacokinetic properties are unknown for the majority of these compounded hormone
 11 preparations.

12
 13 To achieve “individualized” hormone therapy for each patient, many CHT clinicians recommend
 14 saliva (and occasionally blood, serum, or urine) hormone testing. The implication is that the results
 15 of the saliva hormone test will aid in the determination of the type, dosage, and route of
 16 administration of hormone therapy prescribed for the patient.³⁴ However, actual hormone
 17 customization is very difficult to achieve because of hormone pharmacokinetics and physiologic
 18 variation. There is no evidence that hormonal concentrations in saliva are biologically meaningful,
 19 can be used to customize hormone therapies, or predict therapeutic effect.³⁷ Furthermore, saliva
 20 hormone assays do not have independent quality control programs, lack an accepted reference
 21 range³⁶ and the FDA has stated that no scientific evidence supports the use of saliva testing to
 22 titrate hormone dosages or monitor hormone levels.³⁵

23
 24 Commonly Prescribed CHTs. Two of the most commonly prescribed CHTs in the United States are
 25 bi-est (two estrogens) and tri-est (three estrogens).²¹ Bi-est is a formulation of 20% 17 β -estradiol
 26 and 80% estriol and tri-est is a formulation of 10% estrone, 10% 17 β -estradiol, and 80% estriol
 27 (see Table 2). These percentages are calculated on a milligram-per-milligram basis and not
 28 estrogenic potency or concentration. Because these formulations are not FDA-approved, the actual
 29 milligram amounts can vary depending on the specific prescription that is written for each patient.
 30 No placebo-controlled clinical trials evaluating the safety or effectiveness of bi-est or tri-est
 31 preparations have been conducted. Also of note is that there is no form of estriol that is an FDA-
 32 approved product; however, estriol can be legally compounded because a USP monograph on
 33 estriol exists.

34
 35 The Wiley Protocol is a commonly prescribed, patented⁴⁹ CHT that uses high amounts of estradiol
 36 and progesterone in a “cyclical and rhythmic pattern” as opposed to “static dosing” to mimic the
 37 hormone levels of a 20 year-old female. Since the development of the first protocol, additional
 38 protocols have been developed utilizing testosterone (for women), testosterone and DHEA (for
 39 men), thyroid hormones, and cortisol (see Table 2).⁵⁰ One study examined the standardization of
 40 Wiley Protocol CHT preparation concentrations from a selection of the compounding pharmacies
 41 approved to distribute the product. Despite the use of standardized instructions and compounding
 42 materials distributed with the Wiley Protocol products, not all pharmacies passed quality control
 43 measures for the CHTs tested.⁵¹ This study did not evaluate the clinical effectiveness of the Wiley
 44 Protocol but made the claim that clinical studies are currently underway evaluating its effectiveness
 45 in pre- and post-menopausal women and in patients with cancer, osteoporosis, and multiple
 46 sclerosis. No evidence of such trials could be located in PubMed, clinicaltrials.gov, or the
 47 Cochrane Register of Controlled Clinical Trials.⁵¹

48
 49 TX-001HR is solubilized 17 β -estradiol and natural progesterone combined in a single gelatin
 50 capsule for the treatment of vasomotor symptoms in postmenopausal women.⁵² It is currently being
 51 evaluated in a phase 3 placebo-controlled clinical trial (REPLENISH) for the treatment of

menopause-related moderate to severe vasomotor symptoms. If it is approved, TX-001HR would become the first FDA-approved hormone therapy that combines 17 β -estradiol and natural progesterone in a single treatment similar to CHT.⁵²

SPECIFIC CONDITIONS

Below are some disorders and conditions for which CHT and off-label therapies are commonly prescribed.

Aging

Hormone therapy for anti-aging was reviewed in CSAPH Report 5-A-09.⁵ The decline of endogenous hormones is common with aging and the off-label use of hormone therapies to reverse the effects of aging is wide-spread. Large scale, randomized, placebo-controlled studies are still lacking to support the use of any hormone therapies for anti-aging purposes. Studies evaluating their long-term effects and risks when used off-label are also lacking.⁵³

Female Sexual Dysfunction, Low Libido, and Sexual Desire

The most common sexual dysfunction in women is known as female sexual interest/arousal disorder (FSAD) in *DSM-5* (previously hypoactive sexual desire disorder (HSDD) in *DSM-IV-TR*).⁵⁴ Treatment options include non-pharmacologic approaches such as education, counseling, and psychotherapy. There is currently one FDA-approved product, flibanserin, for FSAD.⁵⁵ It is a non-hormone, mixed function serotonin agonist/antagonist. In addition to flibanserin, several hormone therapies have been used off-label to treat FSAD. Randomized controlled trials using testosterone for sexual dysfunction in women had mixed results and efficacy is unclear. Testosterone may benefit secondary outcomes such as well-being and vitality, but these are difficult to distinguish from the combined effects of testosterone and estrogen.³⁶ The American Congress of Obstetricians and Gynecologists reaffirmed their Practice Bulletin in 2015 summarizing clinical management guidelines for female sexual dysfunction. These guidelines support the use of transdermal testosterone as an effective short-term treatment of FSAD (≤ 6 mos), with little evidence to support longer use.⁵⁶ Other possible off-label hormone therapies for this condition include conjugated estrogens, the SERM ospemifene, and DHEA, but evidence to support their use is limited or inconsistent.^{1,57,58} CHT has become an option because the limited number of FDA-approved products containing testosterone does not meet the needs of all women and the ability to customize a hormone therapy is readily available.¹ However, the inconsistencies in CHT dose and purity remain a concern.

Perimenopause/Menopause

Currently, numerous FDA-approved hormone replacement therapies are available to treat menopausal symptoms and to prevent osteoporosis including estrogen-only therapies, progestin-only therapies, combination estrogen/progestin therapies, and combination estrogen/SERM therapy.⁵⁹ These formulations vary in dosage, route of administration, and source (i.e., some are considered bioidentical, others are synthetic, and some are derived from animals). Non-oral estrogen formulations may be associated with reduced risk of venous thromboembolism and stroke.³⁶ Women who still have a uterus and are taking estrogen therapy for the relief of menopausal symptoms are advised to also take progestin therapy; evidence shows that progestins inhibit estrogen-induced endometrial stimulation and reduce the risk of endometrial hyperplasia and cancer.⁶⁰ Topical progesterone is not adequate for endometrial protection, and there are case reports of endometrial cancer associated with its use.⁶¹⁻⁶⁴

Many women have turned to CHTs as a treatment for menopausal symptoms despite the limited data to support improved safety or efficacy with these therapies.¹ In one comparative pharmacokinetic study, plasma estradiol levels achieved with CHTs (commonly thought to be bioequivalent to FDA-approved products) were significantly lower than with the estradiol patch. Even higher doses of the compounded product resulted in lower levels of estradiol than the patch. Also of note were the variable patterns of estrogen absorption observed with some of the compounded formulations.³³ There is no evidence to support the use of CHTs with unpredictable pharmacokinetics in place of several FDA-approved and tested choices for hormone replacement therapy.

Male Hypogonadism and Infertility

Although the term hypogonadism commonly refers to low testosterone levels, by definition, it describes impaired spermatogenesis and low hormonal production. Testosterone supplementation in hypogonadic men further decreases sperm production and many of these patients seek alternative treatments for increasing testosterone in order to maintain (or restore) spermatogenesis and fertility. The goal in these patients is typically to inhibit the negative feedback on the hypothalamic-pituitary axis, promote endogenous testosterone production, and increase the production of the gonadotropins LH and FSH. The hormone therapies used for male hypogonadism and fertility include hCG injections, hCG and human menopausal gonadotropin (hMG) injections, the SERM clomiphene citrate, hCG injections with testosterone, or aromatase inhibitors such as anastrozole. All of these therapies are off-label except for the hCG injections.^{65,66} Evidence is lacking to support the routine use of aromatase inhibitors for this condition.^{65,67,68}

Gender Re-affirming

Several hormone therapies are used in transition therapy for transgender individuals. All of the treatments for gender re-affirming therapy are off-label. No randomized clinical trials have been conducted to determine the optimal dosages and treatment paradigms for gender re-affirming hormone therapies, but specific treatment guidelines have been recommended.⁶⁹⁻⁷¹

The treatment goal for transgender men (female to male patients) is to induce virilization, including the cessation of menses and the development of male-pattern hair growth and physique.⁶⁹ Hormone therapies recommended in The Endocrine Society's Clinical Practice Guideline include testosterone cypionate, enanthate, and undecanoate injections, transdermal testosterone gels, and testosterone patches.⁷⁰ Other therapies being used include implantable testosterone pellets, medroxyprogesterone or lynestrenol (for cessation of menses), and finasteride (for treatment of male pattern baldness that may occur with testosterone treatments).^{69,72}

The treatment goals for transgender females (male to female patients) are to induce breast formation, obtain a more female distribution of fat, and reduce male-pattern hair growth. To accomplish these goals, endogenous action of androgens must be stopped.⁶⁹ Hormone therapies recommended in The Endocrine Society's Clinical Practice Guideline include estradiol valerate or cypionate injections, transdermal estradiol patches, oral estradiol tablets, the antiandrogens spironolactone and cyproterone acetate (which is not an approved drug in the U.S.), and GnRH agonists (such as goserelin). Other therapies, not considered first-line, that are used include the antiandrogens flutamide, nilutamide, or bicalutamide, and 5 α -reductase inhibitors finasteride, and dutasteride.^{69,72} Some clinics that provide services for transgender individuals recommend CHT preparations made by compounding pharmacies such as topical testosterone and estradiol creams for cost saving purposes, since many of the necessary drug therapies are not covered by

insurance.⁷² There is no evidence that custom CHTs are safer or more effective than FDA-approved therapies.

Adverse effects are a concern with the use of any hormone therapy. However, serious short-term complications appear to be uncommon, or at least have yet to be reported in literature, for transition therapy; long-term effects have not been characterized. Policy H-460.907 encourages research into the long-term administration of hormone replacement therapy in transgender patients.

SPECIFIC HORMONE THERAPIES

Some FDA-approved drugs and individual CHTs are used as stand-alone therapies for several medical (and non-medical) conditions, and are prescribed by clinicians in various settings.

Testosterone

Testosterone is FDA-approved only for men who have low testosterone levels (≤ 300 ng/dL) in conjunction with an associated medical condition such as cancer chemotherapy or a genetic or endocrine disorder.⁷³ Replacement therapy for idiopathic low levels or low testosterone due to aging are off-label uses for the drug.⁷⁴ A significant proportion of men receiving testosterone therapies lack adequate testosterone serum measurements prior to receiving prescriptions.^{74,75} The most common diagnoses for testosterone therapy include hypogonadism, fatigue, erectile dysfunction, and psychosexual dysfunction.⁷⁶ The FDA warns about a potential link between exogenous testosterone and the risk of heart attacks and strokes⁷⁷ and is requiring manufacturers of testosterone products to conduct a clinical trial to determine the effects of testosterone replacement therapy on cardiovascular outcomes.^{74,78} The American Association of Clinical Endocrinologists and the American College of Endocrinology conclude in a position statement, that there is no convincing evidence of an increase or decrease in cardiovascular risk related to testosterone therapy and randomized controlled trials are needed.⁷⁹ If physicians choose to prescribe testosterone off-label, they should be well-informed about any potential risks, especially the cardiovascular outcomes.⁷⁵

Androgen deficiency syndrome in women is a controversial concept. For women, testosterone has been used for the treatment of diminished libido, decreased well-being, dysphoric mood, and unexplained fatigue. However, there are no FDA-approved testosterone therapies for women.³⁶ Patients are increasingly utilizing compounding pharmacies for these therapies, at times in combination with estrogen and progestin. The use of CHT can result in excessive doses and adverse effects.⁷⁵

Dehydroepiandrosterone, Dehydroepiandrosterone Sulphate, and Androstenedione

DHEA and dehydroepiandrosterone sulphate (DHEAS), the sulphate ester of DHEA, are converted to androstenedione and then to estrone or testosterone and further to estradiol or estriol. Studies have associated low DHEA and DHEAS with a myriad of conditions affecting both sexes including depression and reduced cognition, as well as decreased bone mineral density, arthritis, systemic lupus erythematosus and decreased libido and sexual dysfunction in women, and congestive heart failure and increased mortality in men. High levels have been associated with postmenopausal breast cancer and decreased sense of well-being in women.^{36,58} Currently, DHEA and DHEAS are not FDA-approved; no pharmaceutical grade DHEA or DHEAS is available in the U.S.; and there are no indications for their use. Nonpharmaceutical grade DHEA and DHEAS are available in over-the-counter dietary supplement products and from compounding pharmacies, but DHEA and

DHEAS content can vary significantly.^{36,42} Evidence that DHEA or DHEAS is beneficial for any condition is lacking.

Androstenedione was previously available over-the-counter as a prohormone in dietary supplements. The Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act, classified androstenedione as a Schedule III controlled substance, and it was removed from the market.⁸⁰

Human Chorionic Gonadotropin (hCG)

Human chorionic gonadotropin (hCG) is a hormone produced by the human placenta. Injectable hCG is an FDA-approved prescription hormone therapy for treating some forms of female infertility and male hypogonadism. First described in 1954, the “hCG diet” has reemerged as a fad where injectable and/or oral forms of hCG have been prescribed by physicians or distributed by commercial wellness clinics, and a modified version of the diet has been promoted on television.^{81,82} Homeopathic hCG-containing products also are sold via the Internet and over-the-counter for weight loss.⁸³

Patients on this diet are typically restricted to approximately 500 calories per day and receive hCG doses of approximately 200 international units daily. The hCG diet has been repeatedly refuted in studies and meta-analyses. Experts agree that it is inappropriate and that any weight loss is due to the severe caloric restriction.^{2,84-86}

FDA-approved hCG preparations are injections while many of the purported hCG products being sold on the Internet are oral and nasal formulations. There is no evidence to support absorption of hCG via oral or nasal routes of administration. The FDA has received reports of serious adverse events associated with hCG use for weight loss, and there have been recent reports of adverse events and risks associated with the hCG diet in the literature.^{2,85} The FDA requires the following warning statement on approved hCG products:

HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or ‘normal’ distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.

hCG is also used as a doping agent by athletes to stimulate endogenous production of testosterone or to prevent testicular atrophy during prolonged administration of other anabolic substances. It also stimulates the endogenous production of epitestosterone which means that the ratio of testosterone to epitestosterone (T/E ratio), a common parameter in antidoping testing, stays within a normal range and increases the chances of evading detection.⁸⁷ There have been, however, analytical tests developed to directly detect doping with hCG.⁸⁸

Human Growth Hormone (hGH)

Human growth hormone (hGH) is an FDA-approved hormone therapy available since the late 1980s for short stature caused by specific diseases or syndromes. In 2003, it was approved despite controversy for the treatment of idiopathic short stature in children. The American Association of Clinical Endocrinologists and the Pediatric Endocrine Society, in position statements^{89,90} concluded that information on the safety and effectiveness of hGH for idiopathic short stature was limited and its use should be individualized and carefully monitored.

hGH also is commonly used off-label for its purported anti-aging effects and ability to increase performance, endurance, lean muscle mass, and exercise capacity. Although studies have evaluated hGH for performance enhancement, none of them have produced evidence to support use by athletes for this purpose.⁹¹ There also is insufficient evidence to support the use of hGH as an anti-aging medicine.⁵³

Thyroid Hormone

Thyroid hormone has been used for weight loss and depression in euthyroid individuals despite a lack of evidence for these indications.^{92,93} In some cases, thyroid hormone has been found in commercial dietary supplements in doses equal to or greater than those used as replacement therapy in patients with hypothyroidism.⁹⁴ These products can cause serious adverse events, including thyrotoxicosis.

FDA-approved formulations of the endogenous thyroid hormones, levothyroxine (LT4) and liothyronine (LT3), are highly effective and safe therapies for the treatment of hypothyroidism. LT4 monotherapy is the recommended first-line hormone therapy. LT4 and LT3 can be administered in a combination therapy with a LT4/LT3 ratio of approximately 14:1 to mimic the ratio secreted by the thyroid gland.^{36,95}

“Natural” desiccated, non-synthetic thyroid products of porcine or bovine origin also are available. Compounding pharmacies can use any of the available thyroid medications to create preparations containing various ratios or concentrations according to the prescription request.

CONCLUSIONS

Off-label use of hormone therapies that is not supported by scientific evidence and the use of unapproved hormone therapies (Figure 1, bold) have been the focus of this report. Patients receiving off-label therapies not backed by scientific evidence are more likely to experience adverse drug events.^{13,15} Patients are relying on media information to educate themselves about their medical conditions—whether accurate or not.⁹⁶ Marketing veiled as educational material and promotion by celebrities has made CHT appear as panacea for many ailments.

Policy H-120.988 supports the clinical decision-making authority of a physician to use an FDA-approved product off-label when such use is based upon sound scientific evidence or sound medical opinion; however, to date the use of compounded hormone therapies is not supported by such evidence. Additionally, traditional compounding is recognized as a legal and important therapeutic when an FDA-approved drug product is not available or does not meet the clinical needs of individual patients. However, in the case of many of the uses for compounded hormones, comparable FDA-approved therapies are available. Further concern is prompted by the fact that compounding pharmacies are exempt from including specific and important safety information on labeled instructions. That lack of information may put patients at risk.

RECOMMENDATIONS

The Council on Science and Public Health recommends the following recommendations be adopted in lieu of Resolution 512-A-15 and the remainder of the report be filed:

1. That Policy D-120.969 be amended by addition and deletion to read as follows:

D-120.969 ~~FDA Oversight of Bioidentical~~ Compounded Hormone ~~(BH)~~ Therapy Preparations

- 1 Our AMA will: (1) recognizes the term “bioidentical hormone” as a marketing term not
2 grounded in science; use of the term “compounded hormone therapy” is
3 preferred; (42) will urge that renewed attention be devoted to the ~~of the Food and Drug~~
4 ~~Administration (FDA) to conduct surveys for purity and potency dosage accuracy~~
5 of all compounded hormone therapy “bioidentical hormone” formulations; (23) will
6 urge continued attention to the FDA to require mandatory reporting by drug manufacturers,
7 including compounding pharmacies, of adverse events related to the use of compounded
8 hormone therapies “bioidentical hormones”; (3) urge the FDA to create a registry of adverse
9 events related to the use of compounded “bioidentical hormone” preparations; (4) recommends
10 that physicians and other prescribers fully inform patients of the potential side effects and risks
11 of the use of compounded hormone replacement therapy; and (5) will request that when drug
12 ingredients with black box warnings are used in compounded products, patients should be
13 informed about the ~~FDA require the inclusion of uniform patient information, such as warnings~~
14 and precautions associated with the use of such drug ingredients, in packaging of compounded
15 “bioidentical hormone” products; and (5) urge the FDA to prohibit the use of the term
16 “bioidentical hormones” unless the preparation has been approved by the FDA. (Res. 706, I-06)
17 (Modify HOD Policy)
18
19 2. Our AMA supports that patients be informed that compounded products are not FDA-approved
20 (New HOD Policy)
21
22 3. That our AMA urge the United States Pharmacopeia to re-examine the validity of the current
23 estriol monograph. (Directive to Take Action)

Fiscal Note: Less than \$500

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Table 1. Examples of FDA approved hormones.

Class	Class Examples	Examples of Indicated Uses (for Class)	Examples of Off-Label Use (for Class)
Steroidal Hormones	Estradiol Progesterone Testosterone	HRT Breast, endometrial, prostate cancer Male hypogonadism	Gender re-affirming therapy ^a FSAD Low Testosterone, ED, fatigue ^a
Aromatase Inhibitors	Letrozole Anastrozole	Breast cancer treatment; endocrine disorders	Sports doping ^a
GnRH Analogs	Leuprolide Goserelin	Prostate cancer	Gender re-affirming therapy ^a
SERMs	Raloxifene Fulvestrant	Chemoprevention of breast cancer; metastatic breast cancer	FSAD ^a Male hypogonadism
Antiandrogens	Flutamide Bicalutamide	Prostate cancer	Gender re-affirming therapy ^a
Somatostatin Analogues	Octreotide	Acromegaly, gigantism, thyrotropinoma, carcinoid syndrome, VIPomas	Sports doping ^a
Growth Hormone	hGH	hGH deficiency; cachexia from AIDS; SHOX deficiency; Turner syndrome; chronic renal failure; Prader-Willi syndrome; children of short stature because of intrauterine growth retardation; idiopathic short stature	Antiaging ^a ; sports doping ^a
hGH secretagogues	Tesamorelin	HIV-associated lipodystrophy	Sports doping ^a ; anti-aging ^a
GnRHs	LH FSH	Infertility therapy; reversal of anovulation	Sports doping ^a
GnRH antagonists	Ganirelix Abarelix	Infertility therapy; prostate cancer	
Human Chorionic Gonadotropin	hCG	Infertility therapy	Weight loss ^a
Thyroid Hormone	Levothyroxine Liothyronine	Hypothyroidism	Weight loss ^a ; Sports doping ^a

HRT = hormone replacement therapy; ED = Erectile dysfunction; FSAD = female sexual interest/arousal disorder; GnRH = gonadotropin releasing hormone; SERMs = selective estrogen receptor modulator; VIPomas = vasoactive intestinal peptide-secreting tumors; hGH = human growth hormone; SHOX = Short stature homeobox gene; LH = luteinizing hormone; FSH = Follicle stimulating hormone; HCG = Human chorionic gonadotropin

^aLacks scientific evidence

Table 2. Common Compounded Hormone Preparations^a

Compounded Formulation	Ingredients	Dose	Route of Administration
Bi-est	20% estradiol 80% estriol ^c	1.25-2.5 mg/d ^b	Oral, transdermal, sublingual, or vaginal
Tri-est	10% estradiol 10% estrone 80% estriol ^c	1.25-2.5 mg/d ^b	Oral, transdermal, sublingual, or vaginal
Estriol	Estriol ^c	2.0-8.0 mg/d ^b	Oral, transdermal, sublingual, or vaginal
Progesterone	Progesterone	100-200 mg/d ^b	Oral, transdermal, sublingual, vaginal, or injectable
Wiley Protocol Original ^{TM49}	Estradiol and Progesterone	Multi-phasic rhythmic dosing (amounts vary throughout a 28 day cycle) ⁴⁹	Topical
Wiley Protocol for Men TM	DHEA and Testosterone	Multi-phasic rhythmic dosing	Topical
Wiley Protocol Thyroid TM		Multi-phasic rhythmic dosing	Topical
Wiley Protocol Testosterone TM for Women	Testosterone	Multi-phasic rhythmic dosing	Topical
Wiley Protocol Sparc TM Therapy	Cortisol	Multi-phasic rhythmic dosing	Topical

^aData was compiled from several Internet sources and Files et al.²¹^bmg amounts can vary depending on the compounding pharmacy^cNot an FDA approved drug

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 901
(I-16)

Introduced by: Virginia, American College of Radiology, Alabama, Georgia, Kentucky,
District of Columbia, Mississippi, West Virginia, South Carolina

Subject: Disclosure of Screening Test Risk and Benefits, Performed Without a
Doctor's Order

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, Numerous companies have launched health and wellness programs marketed directly
2 to patients; and
3

4 Whereas, These programs often include health screenings and tests that are conducted outside
5 of the normal physician-patient encounter; and
6

7 Whereas, Patients are often uninformed or misinformed and indeed may be confused or misled
8 about the value of these tests; and
9

10 Whereas, Patients may often be enticed to pay for unnecessary services that offer little or no
11 medical value and may cause harm in some cases; and
12

13 Whereas, These programs drive up medical costs for patients who do not need the tests or
14 receive false positive results and then request additional testing from their physician; and
15

16 Whereas, There is currently very little oversight regulating how these entities conduct business
17 and their impact on patients and overall healthcare costs; therefore be it
18

19 RESOLVED, That our American Medical Association advocate that if a screening test is being
20 marketed as having a medical benefit and is offered and performed by a wellness program
21 vendor without a specific order by the individual's physician or other licensed provider, they
22 must provide the patient with the test specific evidence based guidance that supports the utility
23 of the test (Directive to Take Action); and be it further
24

25 RESOLVED, That our AMA advocate that if the procedure is not supported by specific evidence
26 based guidance as a screening test for that patient and the patient still would like the screening
27 test, the Wellness Program Vendor must offer the patient the opportunity to discuss the risks,
28 benefits, and alternatives with a physician licensed to practice medicine in the state in which the
29 test is being performed (New HOD Policy); and be it further
30

31 RESOLVED, That our AMA engage with federal regulators on whether vendors of health and
32 wellness programs are in compliance with regulations applicable to marketing to patients in view
33 of the impact of such programs on patients (Directive to Take Action); and be it further
34

35 RESOLVED, That, where possible, our AMA continue to work with state medical societies,
36 interested medical specialty societies and state agencies to provide public education regarding
37 appropriate use of vendor wellness programs. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/14/16

RELEVANT AMA POLICY

9.6.8 Direct-to-Consumer Diagnostic Imaging Tests

Diagnostic imaging tests are sometimes marketed directly to consumers before they have been scientifically validated. This can help consumers prevent disease and promote health, but may also expose patients to risk without benefit, create conflicts of interests for physicians, and be abused for profits.

Individually, physicians who offer diagnostic imaging services that have not been scientifically validated and for which a patient has not been referred by another physician have an ethical obligation to:

- (a) Perform a requested diagnostic imaging test only when, in the physician's judgment, the possible benefits of the service outweigh its risks.
- (b) Recognizing that in agreeing to perform diagnostic imaging on request, the physician:
 - (i) establishes a patient-physician relationship, with all the ethical and professional obligations such relationship entails;
 - (ii) assumes responsibility for relevant clinical evaluation, including pre- and post-test counseling about the test, its results, and indicated follow-up. Physicians may choose to refer the patient for post-test counseling to an appropriate physician who accepts the patient.
- (c) Obtain the patient's informed consent. In addition to the usual elements of informed consent, the physician should disclose:
 - (i) that the diagnostic imaging test has not been validated scientifically;
 - (ii) the inaccuracies inherent in the proposed test;
 - (iii) the possibility of inconclusive results;
 - (iv) the likelihood of false positive and false negative results;
 - (v) circumstances that may require further assessments and additional cost.
- (d) Ensure that the patient's interests are primary and place patient welfare above physician interests when the physician has a financial interest in the imaging facility.
- (e) Ensure that any advertisements for the services are truthful and not misleading or deceptive, in keeping with ethical guidelines and applicable law.

Collectively, physicians should:

- (f) Advocate for the conduct of appropriate trials aimed at determining the predictive power of diagnostic imaging tests and their sensitivity and specificity for target populations.
- (g) Develop suitable guidelines for specific diagnostic imaging tests when adequate scientific data become available.

AMA Principles of Medical Ethics: I, II, V, VIII

H-160.921 Store-Based Health Clinics

1. It is AMA policy that any individual, company, or other entity that establishes and/or operates store-based health clinics should adhere to the following principles: a. Store-based health clinics must have a well-defined and limited scope of clinical services, consistent with state scope of practice laws. b. Store-based health clinics must use standardized medical protocols derived

from evidence-based practice guidelines to insure patient safety and quality of care. c. Store-based health clinics must establish arrangements by which their health care practitioners have direct access to and supervision by MD/DOs, as consistent with state laws. d. Store-based health clinics must establish protocols for ensuring continuity of care with practicing physicians within the local community. e. Store-based health clinics must establish a referral system with physician practices or other facilities for appropriate treatment if the patient's conditions or symptoms are beyond the scope of services provided by the clinic. f. Store-based health clinics must clearly inform patients in advance of the qualifications of the health care practitioners who are providing care, as well as the limitation in the types of illnesses that can be diagnosed and treated. g. Store-based health clinics must establish appropriate sanitation and hygienic guidelines and facilities to insure the safety of patients. h. Store-based health clinics should be encouraged to use electronic health records as a means of communicating patient information and facilitating continuity of care. i. Store-based health clinics should encourage patients to establish care with a primary care physician to ensure continuity of care. 2. Our AMA will continue to monitor the effects of store-based health clinics on the health care marketplace, and report back to the House of Delegates. 3. Health insurers and other third-party payers should be prohibited from waiving and/or lowering co-payments only for patients that receive services at store-based health clinics. (CMS Rep. 7, A-06; CMS Rep. 5, A-07; Reaffirmed: CSAPH Rep. 4, I-14)

H-180.948 Opposition to Incentives for Care in Non-Physician Clinics

Our AMA will communicate with large insurance companies that providing incentives to patients toward non-physician clinics outside the primary care physician relationship can lead to decisions made on limited information, duplication of testing and procedures, ultimately higher health care costs and a reduction in the quality of health care for the patients of America. (Res. 708, A-11)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 902
(I-16)

Introduced by: Medical Student Section

Subject: Removing Restrictions on Federal Public Health Crisis Research

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Instances in which government funding for scientific research on public health crises issues, such as tobacco, the HIV/AIDS epidemic, contraception, and gun violence, has been restricted for purposes of influencing political discourse are numerous;^{1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17} and

Whereas, In each of these instances, the AMA has had to respond by drafting individual new policies, which delays the organization's official response to emerging public health challenges, potentially at critical points in the discourse (ex. H-75.998, H-120.947, H-145.976, H-145.984, H-495.978, H-495.988, H-460.982, H-460.930 etc.); and

Whereas, The National Science Foundation (NSF) continues to battle concerted efforts by Congress to dictate funding within the agency and selectively defund social science research;¹⁸ and

¹ Corless, I.B., and Lindeman, M.P. AIDS: Principles, Practices, & Politics. Hemisphere Publishing Corporation. 1989. p496

² Johnson, JA. CRS Report for Congress: AIDS Funding for Federal Government Programs: FY1981-FY2009. Congressional Research Service. 2008. Available at <http://fpc.state.gov/documents/organization/104280.pdf>

³ Plante, H. "Reagan's Legacy." San Francisco AIDS Foundation. 2011. Available at <http://sfaf.org/hiv-info/hot-topics/from-the-experts/2011-02-reagans-legacy.html>

⁴ Francis, D.P. Commentary: Deadly AIDS policy failure by the highest levels of the US government: A personal look back 30 years later for lessons to respond better to future epidemics. J Public Health Policy. 2012;33(3):290-300

⁵ Drucker E. Failed drug policies in the United States and the future of AIDS: a perfect storm. J Public Health Policy. 2012;33(3):309-16.

⁶ Helms, J. S.AMDT.963 to H.R.3058: Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 1988. 100th Congress of the United States of America. Available at <https://www.congress.gov/amendment/100th-congress/senate-amendment/963>

⁷ Helms, J. S.AMDT.1992 to S.1220: AIDS Federal Policy Act of 1988. 100th Congress of the United States of America. Available at <https://www.congress.gov/amendment/100th-congress/senate-amendment/1992>

⁸ Muggli, M.E. et al. The tobacco industry's political efforts to derail the EPA report on ETS. Am J Prev Med. 2004 Feb;26(2):167-77.

⁹ Hirschhorn, N. Evolution of the tobacco industry's positions on addiction to nicotine: a report prepared for the Tobacco Free Initiative, World Health Organization. WHO. 2008. Available at:

http://apps.who.int/iris/bitstream/10665/43988/1/9789241597265_eng.pdf

¹⁰ Reilly, P. R. Eugenics and Involuntary Sterilization: 1907-2015. Annu Rev Genomics Hum Genet. 2015;16:351-68.

¹¹ Asetoyer, C, Luluquisen, M, and Millis, N. Indigenous Women's Reproductive Justice Roundtable Report on the Availability of Plan B® and Emergency Contraceptives Within Indian Health Service. Native American Community Board. 2009. Available at: <http://www.nativeshop.org/images/stories/media/pdfs/ RoundtableofEC PlanBintheHISER2009.pdf>

¹² Harris, G. Surgeon General Sees 4-Year Term as Compromised. New York Times. 2007 July 11.

¹³ Carmona, R. The Trauma of Politics: a surgeon general's perspective. Am J Prev Med. 2013;45(6):742-744.

¹⁴ Jamieson, C. Gun violence research: history of the federal funding freeze. Psychological Science Agenda. 2013 Feb. Available at <http://www.apa.org/science/about/psa/2013/02/gun-violence.aspx>

¹⁵ Kellermann, A.L. and Rivara, F.P. Silencing the Science on Gun Research. JAMA. 2013;309(6):549-550.

¹⁶ Florida House of Representatives. CS/CS/HB 155: Privacy of Firearm Owners. 2011. Available at

<https://www.flsenate.gov/Session/Bill/2011/0155/?Tab=BillText>

¹⁷ Missouri State Senate. Bill 656 Modifies provisions relating to firearms and corporate security advisors. 2014. Available at <http://www.senate.mo.gov/14info/pdf-bill/tat/SB656.pdf>

¹⁸ Mervis, J. House budget plan would rearrange and restrict federal research portfolio. Science. 2016. Available at <http://www.sciencemag.org/news/2016/03/house-budget-plan-would-rearrange-and-restrict-federal-research-portfolio>

Whereas, Multiple former US Surgeons General have confirmed under oath that they were pressured against addressing public health issues during their terms, had scientifically sound but politically-charged topics removed from their speeches, and had reports delayed until after they had left office to prevent the issues from entering public discussion;^{19,20,21} and

Whereas, Medical practitioners and researchers are likely to encounter non-scientifically-founded opposition to federal funding for many topics in public health research and medical practice in the future; therefore be it

RESOLVED, That our American Medical Association recognize the importance of timely research and open discourse in combatting public health crises (New HOD Policy); and be it further

RESOLVED, That our AMA oppose efforts to restrict funding or suppress the findings of biomedical and public health research for the purpose of influencing political discourse. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.

Received: 08/29/16

RELEVANT AMA POLICY

Availability of Professionals for Research H-460.982

(1) In its determination of personnel and training needs, major public and private research foundations, including the Institute of Medicine of the National Academy of Sciences, should consider the future research opportunities in the biomedical sciences as well as the marketplace demand for new researchers. (2) The number of physicians in research training programs should be increased by expanding research opportunities during medical school, through the use of short-term training grants and through the establishment of a cooperative network of research clerkships for students attending less research-intensive schools. Participation in research training programs should be increased by providing financial incentives for research centers, academic physicians, and medical students. (3) The current annual production of PhDs trained in the biomedical sciences should be maintained. (4) The numbers of nurses, dentists, and other health professionals in research training programs should be increased. (5) Members of the industrial community should increase their philanthropic financial support to the nation's biomedical research enterprise. Concentration of support on the training of young investigators should be a major thrust of increased funding. The pharmaceutical and medical device industries should increase substantially their intramural and extramural commitments to meeting postdoctoral training needs. A system of matching grants should be encouraged in which private industry would supplement the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration sponsored Career Development Awards, the National Research Service Awards and other sources of support. (6) Philanthropic foundations and voluntary health agencies should continue their work in the area of training and funding new investigators. Private foundations and other private organizations should increase their funding for clinical research faculty positions. (7) The National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration should modify the renewal grant application system by lengthening the funding period for grants that have received high priority scores through peer review. (8) The support of clinical research faculty from the National Institutes of Health Biomedical Research

¹⁹ Harris, G. Surgeon General Sees 4-Year Term as Compromised. New York Times. 2007 July 11.

²⁰ Carmona, R. The Trauma of Politics: a surgeon general's perspective. Am J Prev Med. 2013;45(6):742-744.

²¹ Kennedy, E. Letter to Department of Health and Human Services Secretary Michael Leavitt. August 30, 2007. Available at http://www.help.senate.gov/imo/media/doc/2007_08_30.pdf

Support Grants (institutional grants) should be increased from its current one percent. (9) The academic medical center, which provides the multidisciplinary research environment for the basic and clinical research faculty, should be regarded as a vital medical resource and be assured adequate funding in recognition of the research costs incurred.

Citation: (BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CSA Rep. 13, I-99; Reaffirmed: CME Rep. 4, I-08; Modified: Res. 305, A-12; Modified: CME Rep. 2, A-12)

A Declaration of Professional Responsibility H-140.900

Our AMA adopts the Declaration of Professional Responsibility

DECLARATION OF PROFESSIONAL RESPONSIBILITY: MEDICINE's SOCIAL CONTRACT WITH HUMANITY

Preamble

Never in the history of human civilization has the well being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. Wars and acts of terrorism enlist innocents as combatants and mark civilians as targets. Advances in medical science and genetics, while promising to do great good, may also be harnessed as agents of evil. The unprecedented scope and immediacy of these universal challenges demand concerted action and response by all. As physicians, we are bound in our response by a common heritage of caring for the sick and the suffering. Through the centuries, individual physicians have fulfilled this obligation by applying their skills and knowledge competently, selflessly and at times heroically. Today, our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient.

Declaration

We, the members of the world community of physicians, solemnly commit ourselves to: (1)

Respect human life and the dignity of every individual.

(2) Refrain from supporting or committing crimes against humanity and condemn any such acts.

(3) Treat the sick and injured with competence and compassion and without prejudice.

(4) Apply our knowledge and skills when needed, though doing so may put us at risk.

(5) Protect the privacy and confidentiality of those for whom we care and breach that confidence only when keeping it would seriously threaten their health and safety or that of others.

(6) Work freely with colleagues to discover, develop, and promote advances in medicine and public health that ameliorate suffering and contribute to human well-being.

(7) Educate the public and polity about present and future threats to the health of humanity.

(8) Advocate for social, economic, educational, and political changes that ameliorate suffering and contribute to human well-being.

(9) Teach and mentor those who follow us for they are the future of our caring profession.

We make these promises solemnly, freely, and upon our personal and professional honor.

Citation: (CEJA Rep. 5, I-01; Reaffirmation A-07)

Support for Public Health D-440.997

1. Our AMA House of Delegates request the Board of Trustees to include in their long range plans, goals, and strategic objectives to support the future of public health in order "to fulfill society's interest in assuring the conditions in which people can be healthy." This shall be accomplished by AMA representation of the needs of its members? patients in public health-related areas, the promotion of the necessary funding and promulgation of appropriate legislation which will bring this to pass.

2. Our AMA: (A) will work with Congress and the Administration to prevent further cuts in the funds dedicated under the Patient Protection and Affordable Care Act to preserve state and local public health functions and activities to prevent disease; (B) recognizes a crisis of inadequate public health funding, most intense at the local and state health jurisdiction levels,

and encourage all medical societies to work toward restoration of adequate local and state public health functions and resources; and (C) in concert with state and local medical societies, will continue to support the work of the Centers for Disease Control and Prevention, and the efforts of state and local health departments working to improve community health status, lower the risk of disease and protect the nation against epidemics and other catastrophes.

Citation: (Res. 409, A-99; Modified CLRPD Rep. 1, A-03; Reaffirmed: CSAPH Rep. 1, A-13;

Appended: Res. 206, A-13; Reaffirmation A-15)

Health Court Principles H-435.951

AMA PRINCIPLES FOR HEALTH COURTS

- These principles are intended to serve as legislative guidelines for state medical associations and can be amended on an as needed basis.
- Health courts should be structured to create a fair and expeditious system for the resolution of medical liability claims - with a goal of resolving all claims within one year from the filing date.
- Health court judges should have specialized training in the delivery of medical care that qualifies them for serving on a health court.
- Negligence should be the minimum threshold for compensation to award damages.
- Health court judgments should not limit the recovery of economic damages, but non-economic damages should be based on a schedule.
- Qualified experts should be utilized to assist a health court in reaching a judgment.
- Health court pilot projects should have a sunset mechanism in place to ensure that participating physicians, hospitals, and insurers do not experience a drastic financial impact based on the new judicial format.

I. Health Court Structure

Jurisdiction

- Health courts should only be established at the state or local level.
- If a health court is established on a statewide or local basis, then it should be established within the state's trial court of general jurisdiction. Using the already established system would lessen the financial and administrative burden.
- To capture all medical liability cases, a health court that is established as a statewide or local program should have exclusive jurisdiction over any lawsuit (contract or tort) which involves an injury arising from the alleged negligence of a health care provider.
- Appeals should be handled within the health court system as well.
- The jurisdiction's discovery rules should be modified to be consistent with the timeline for resolving a case before a health court.
- Eventually, health courts should have expanded jurisdiction over the validity of advance directives, managed care independent review decisions, and other health law issues.

Trial Format

- One option for a health court is to have a bench trial before a specially trained judge.
- Another option is for a health court to have a jury trial under the authority of a specially trained judge.
- Health courts utilizing a jury should provide juries with a specialized educational session on the basics of medical care delivery and the distinction between negligence and adverse outcomes as well as appropriate guidelines on the purpose of awarding non-economic damages.

Administrative Option

- An administrative system (e.g. established by a hospital or insurer) should include many of the same requirements that the AMA supports for a health court established within a jurisdiction's standard judicial system.
- Health court pilot programs established through an insurer or hospital should have jurisdiction over patients who choose to opt in to the system.

II. Health Court Judges

Selection of Health Court Judges

- Health court judges should be appointed by a health court task force.
- The health court task force should be comprised of four physicians, four lawyers, and four laypersons.
- The majority and minority leaders in each of the state's legislative chambers should pick one member from each category (i.e., house majority leader would pick one physician, one lawyer, and one layperson for the task force. The house minority leader, the senate majority leader, and the senate minority leader would do the same.)
- The health court task force chairmanship should rotate on an annual basis.
- The majority and minority leaders in each legislative chamber should ask the state medical association for a list of health court task force candidates before making an appointment.
- Governmental entities should adjust the term of a health court judge based on the length of terms in their state for other special courts.

Training for Health Court Judges

- Health court judges should complete a judicial training program which provides an overview of medical and legal issues that often arise in medical liability cases.
- The curriculum should be established by the health court task force.
- The medical portion of the training program should include both in-classroom clinical training and an internship whereby the judge "shadows" a physician in different health care settings.
- States and other government bodies with an existing judicial training program should have this office administer the special training program for judges assigned to the health court.

III. Health Court Procedure

Threshold for Patient Compensation

- Negligence must be proven for a patient to recover in a health court proceeding.

Damages

- Economic damages should not be limited. Injured parties should be fully compensated for their economic losses.
- Non-economic damage awards should be established by a schedule. Consistent injuries should result in consistent non-economic damage awards based on the schedule. The health court task force should establish the schedule.
- One option for the schedule is to base it on type/severity of the injury. Another option is to have the schedule link non-economic damages awards to the amount of economic damages included in the judgment.
- Punitive damages, if allowed, should not be awarded unless the party alleging such damages meets the burden of producing clear and convincing evidence of oppression, fraud, malice, or the opposing party's intent to do harm.
- Health court judges should give jury instructions that provide clear delineations between the purposes of economic damages (for economic loss), non-economic damages (for pain and suffering), and punitive damages (for punishment to prevent future bad behavior). The instructions should also distinguish the different burden of proof needed for punitive damages.
- Future damages should be paid on a periodic basis as authorized by a health court.

Other Procedural Issues

- Health courts should be designed to resolve claims within one year from the filing date.
- Health courts should limit attorney's fees to maximize the award to the patient.
- Collateral payment sources should be admissible as evidence in a health court proceeding.
- Health court damage awards should include mandatory offsets for collateral payments for the same injury.
- An affidavit/certificate of merit should be a prerequisite to filing a medical liability case before a health court.
- A pre-trial screening panel should be utilized prior to the start of a trial before a health court.
- The statute of limitations in a health court should be two years from the act or omission.
- The period for suspending the application of state statutes of limitations for minors should be no more than six years after birth. The statute should include a three-year statute of repose from

manifestation as well for minors.

- In a health court proceeding, statements of sympathy, apology or regret made by a health care provider or their staff to an alleged victim or family of the victim relating to the discomfort, pain, suffering, injury, or death resulting from an unanticipated outcome of medical care should be inadmissible as evidence of an admission of liability or as evidence of an admission against interest.

IV. Medical Error Reporting

Medical Error Reporting

- The AMA continually strives to advance efforts to improve patient safety through educational activities and all other available means to discover and promote "best practices" in the delivery of health care services. Toward this end, a health court system should encourage the reporting of medical errors.
- The reporting system should be non-punitive, and it should be confidential and not subject to discovery in legal proceedings.
- The medical error reporting system should collaborate with the Patient Safety Organization (PSO) (which will be established pursuant to the federal Patient Safety and Quality Improvement Act of 2005) in its state or region to encourage the efficient reporting and analysis of the data.

V. Experts

Court Appointed Medical Experts

- The health court task force should maintain a list of qualified medical experts from which a judge may select to help clarify or interpret medical testimony given in legal proceedings.
- A health court judge should use and rely on the testimony of a court appointed medical expert.
- A court appointed medical expert must, at a minimum, meet the same qualifications as the medical experts who testify on behalf of a party in the presiding lawsuit.

Party Expert Witnesses

- Health courts should only allow medical expert witnesses to testify if the expert witness is licensed as a doctor of medicine or osteopathy.
- An expert witness should be trained and experienced in the same field as the defendant or has specialty expertise in the disease process or procedure performed in the case.
- An expert witness should be certified by a board recognized by the American Board of Medical Specialties or the American Osteopathic Association, or by a board with equivalent standards.
- An expert witness should, within five years of the date of the alleged occurrence or omission giving rise to the claim, be in active medical practice in the same field as the defendant, or have devoted a substantial portion of his time teaching at an accredited medical school, or in university-based research in relation to the medical care and type of treatment at issue.
- A person who testifies as an expert witness in a health court should be deemed to have a temporary license to practice medicine in the state for the purpose of providing such testimony and should be subject to the jurisdiction of the state medical board.

VI. Review and Sunset

Review

- The health court task force should be charged with reviewing the health court program on an ongoing basis. They should issue quarterly reports, open to the public, on claims filed, decisions rendered, claims paid, and claims resulting in no payment.

Sunset

- The health court task force may recommend to the governor and the legislative leaders that the health court system should be sunset if it is not financially viable or does not result in a more balanced and fair process.
- Given that the costs are unknown and could potentially be charged to physicians, a health court system should include appropriate funding from government or foundation sources to protect participants from significant financial losses based on their participation under a health

court format rather than the traditional medical liability system.
Citation: (BOT Rep. 15, A-07)

Abuse of Medicine for Political Purposes H-65.993

The AMA opposes the use of the practice of medicine to suppress political dissent wherever it may occur.

Citation: (Res. 127, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CEJA Rep. 2, A-05; Reaffirmed: CEJA Rep. 5, A-15)

Government Interference in Patient Counseling H-373.995

1. Our AMA vigorously and actively defends the physician-patient-family relationship and actively opposes state and/or federal efforts to interfere in the content of communication in clinical care delivery between clinicians and patients.
2. Our AMA strongly condemns any interference by government or other third parties that compromise a physician's ability to use his or her medical judgment as to the information or treatment that is in the best interest of their patients.
3. Our AMA supports litigation that may be necessary to block the implementation of newly enacted state and/or federal laws that restrict the privacy of physician-patient-family relationships and/or that violate the First Amendment rights of physicians in their practice of the art and science of medicine.
4. Our AMA opposes any government regulation or legislative action on the content of the individual clinical encounter between a patient and physician without a compelling and evidence-based benefit to the patient, a substantial public health justification, or both.
5. Our AMA will educate lawmakers and industry experts on the following principles endorsed by the American College of Physicians which should be considered when creating new health care policy that may impact the patient-physician relationship or what occurs during the patient-physician encounter:
 - A. Is the content and information or care consistent with the best available medical evidence on clinical effectiveness and appropriateness and professional standards of care?
 - B. Is the proposed law or regulation necessary to achieve public health objectives that directly affect the health of the individual patient, as well as population health, as supported by scientific evidence, and if so, are there no other reasonable ways to achieve the same objectives'
 - C. Could the presumed basis for a governmental role be better addressed through advisory clinical guidelines developed by professional societies'
 - D. Does the content and information or care allow for flexibility based on individual patient circumstances and on the most appropriate time, setting and means of delivering such information or care?
 - E. Is the proposed law or regulation required to achieve a public policy goal ? such as protecting public health or encouraging access to needed medical care ? without preventing physicians from addressing the healthcare needs of individual patients during specific clinical encounters based on the patient's own circumstances, and with minimal interference to patient-physician relationships'
 - F. Does the content and information to be provided facilitate shared decision-making between patients and their physicians, based on the best medical evidence, the physician's knowledge and clinical judgment, and patient values (beliefs and preferences), or would it undermine shared decision-making by specifying content that is forced upon patients and physicians without regard to the best medical evidence, the physician's clinical judgment and the patient's wishes'
 - G. Is there a process for appeal to accommodate individual patients' circumstances'
6. Our AMA strongly opposes any attempt by local, state, or federal government to interfere with a physician's right to free speech as a means to improve the health and wellness of patients across the United States.

Citation: (Res. 201, A-11; Reaffirmation: I-12; Appended: Res. 717, A-13; Reaffirmed in lieu of Res. 5, I-13; Appended: Res. 234, A-15)

Council on Scientific Affairs Conference: "Clinical Research: Assessing the Future in a Changing Environment" H-460.930

(1) Given the profound importance of clinical research as the transition between basic science discoveries and standard medical practice of the future, the AMA will a) be the principal advocate for clinical research; b) promote the importance of this science and of well-trained researchers to conduct it; and c) facilitate communication among different organizations and groups, including managed care organizations, that are essential for broad-based support of clinical research.

(2) Our AMA continues to advocate vigorously for a stable, continuing base of funding and support for all aspects of clinical research within the research programs of all relevant federal agencies, including the National Institutes of Health, the Agency for Health Care Policy and Research, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs and the Department of Defense.

(3) Traditional sources of financial support for clinical research and for academic health centers are diminishing significantly in the evolving health care environment of the 1990s. All endeavors that depend upon development of new knowledge and technologies for their continued success recognize the need to devote a proportion of revenue for research and development. The AMA believes it is an inherent obligation of capitation programs and managed care organizations to invest in broad-based clinical research (as well as in health care delivery and outcomes research) to assure continued transition of new developments from the research bench to medical practice. The AMA strongly encourages these groups to make significant financial contributions to support such research.

(4) Our AMA continues to encourage medical schools a) to support clinical research; b) to train and develop clinical researchers; c) to recognize the contribution of clinical researchers to academic medicine; d) to assure the highest quality of clinical research; and e) to explore innovative ways in which clinical researchers in academic health centers can actively involve practicing physicians in clinical research.

(5) Our AMA believes that one obligation of organized medicine and physicians is to support clinical research, as the basis of advances in medicine. To facilitate this, the AMA should explore ways physicians and physician organizations can encourage and assist in educating the public about the importance of clinical research such as through educational materials and programs for children and schools.

(6) Our AMA encourages and supports development of community and practice-based clinical research networks.

Citation: (CSA Rep. 2, I-96; Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: CME Rep. 4, I-08)

HIV/AIDS Research H-20.905

(1) Information on the HIV Epidemic

Our AMA:

a) Vigorously supports the need for adequate government funding for research, both basic and clinical, in relation to HIV/AIDS epidemic. Research on HIV should be prioritized, funded, and implemented in an expeditious manner consistent with appropriate scientific rigor, and the results of research should form the basis for future programs of prevention and treatment;

b) Requests the Secretary of the Department of Health and Human Services to make available information on HIV expenditures, services, programs, projects, and research of agencies under his/her jurisdiction and, to the extent possible, of all other federal agencies for purposes of study, analysis, and comment. The compilation should be sufficiently detailed that the nature of the expenditures can be readily determined;

- c) Supports ongoing efforts of the Centers for Disease Control and Prevention to periodically monitor the incidence and prevalence of HIV infection in the U.S. population as a whole, as well as in groups of special interest such as adolescents and minorities;
- d) Encourages federal and state agencies, in cooperation with medical societies and other interested organizations, to study and report means to increase access to quality care for women and children who are HIV-infected;
- e) Encourages further research to assess the risk of HIV transmission in specific surgical techniques and how any such risk may be decreased;
- f) Supports exploring ways to increase public awareness of the benefits of animal studies in HIV/AIDS research.

(2) Lookback Studies

Our AMA encourages the cooperation of the medical community and patients in scientifically sound look-back studies designed to further define the risk of HIV transmission from an infected physician to a patient and to determine if there is any scientific basis for the development of a list of exposure-prone procedures. A panel of experts should be assembled to translate available look-back information into a meaningful statement on the estimated true risk of transmission and the need, if any, for additional studies.

(3) Community Research Initiatives

Our AMA supports the objectives of community-based research to reduce HIV disease and encourages periodic review of progress toward these objectives.

Citation: (CSA Rep. 4, A-03; Reaffirmed: Res. 725, I-03; Reaffirmed: Res. 907, I-08)

HIV/AIDS Education and Training H-20.904

(1) Public Information and Awareness Campaigns

Our AMA:

- a) Supports development and implementation of HIV/AIDS health education programs in the United States by encouraging federal and state governments through policy statements and recommendations to take a stronger leadership role in ensuring interagency cooperation, private sector involvement, and the dispensing of funds based on real and measurable needs. This includes development and implementation of language- and culture-specific education programs and materials to inform minorities of risk behaviors associated with HIV infection.
- b) Our AMA urges the communications industry, government officials, and the health care communities together to design and direct efforts for more effective and better targeted public awareness and information programs about HIV disease prevention through various public media, especially for those persons at increased risk of HIV infection;
- c) Encourages education of patients and the public about the limited risks of iatrogenic HIV transmission. Such education should include information about the route of transmission, the effectiveness of universal precautions, and the efforts of organized medicine to ensure that patient risk remains immeasurably small. This program should include public and health care worker education as appropriate and methods to manage patient concern about HIV transmission in medical settings. Statements on HIV disease, including efficacy of experimental therapies, should be based only on current scientific and medical studies;
- d) Encourages and will assist physicians in providing accurate and current information on the prevention and treatment of HIV infection for their patients and communities;
- e) Encourages religious organizations and social service organizations to implement HIV/AIDS education programs for those they serve.

(2) HIV/AIDS Education in Schools

Our AMA:

- a) Endorses the education of elementary, secondary, and college students regarding basic knowledge of HIV infection, modes of transmission, and recommended risk reduction strategies;

b) Supports efforts to obtain adequate funding from local, state, and national sources for the development and implementation of HIV educational programs as part of comprehensive health education in the schools.

(3) Education and Training Initiatives for Practicing Physicians and Other Health Care Workers
Our AMA supports continued efforts to work with other medical organizations, public health officials, universities, and others to foster the development and/or enhancement of programs to provide comprehensive information and training for primary care physicians, other front-line health workers (specifically including those in addiction treatment and community health centers and correctional facilities), and auxiliaries focusing on basic knowledge of HIV infection, modes of transmission, and recommended risk reduction strategies.

Citation: CSA Rep. 4, A-03; Appended: Res. 516, A-06; Modified: CSAPH 01, A-16

Proper FDA Authority to Regulate Tobacco H-495.978

Our AMA will continue to support federal legislation that would give the Food and Drug Administration strong regulatory authority over tobacco products.

Citation: (Res. 440, A-07; Reaffirmed: BOT Rep. 8, A-08; Reaffirmation A-15)

FDA Regulation of Tobacco Products H-495.988

1. Our AMA: (A) reaffirms its position that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (C) reaffirms its position that the Food and Drug Administration (FDA) does have, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (D) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (E) urges Congress to pass legislation to phase in the production of less hazardous and less toxic tobacco, and to authorize the FDA have broad-based powers to regulate tobacco products; (F) encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; and (G) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco products.

2. Our AMA: (A) supports the US Food and Drug Administration (FDA) as it takes an important first step in establishing basic regulations of all tobacco products; (B) strongly opposes any FDA rule that exempts any tobacco or nicotine-containing product, including all cigars, from FDA regulation; and (C) will join with physician and public health organizations in submitting comments on FDA proposed rule to regulate all tobacco products.

Citation: (CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12;

Reaffirmation A-13; Modified: Res. 402, A-13; Modified: Speakers Rep., A-14; Appended: Res. 420, A-14; Reaffirmation A-15)

Use of Tobacco Industry-Sponsored Cessation and Prevention Materials D-490.977

Our AMA urges (1) that when physicians and health organizations provide information or materials on tobacco to patients and consumers, such information and materials should come from credible and trustworthy sources with expertise in tobacco control; and (2) physicians and health organizations to avoid providing to patients and consumers information or materials on tobacco that come from tobacco companies or other groups aligned with the tobacco industry.

Citation: (Res. 411, A-07)

Family Planning Clinic Funds H-75.992

Our AMA supports the concept of adequate funding for family planning programs.

Res. 102, A-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10 Reaffirmed: Res. 227, A-11

Media Advertising and Public Service Announcements Regarding Contraception and Safe Sexual Practices H-75.996

The AMA urges the print and broadcast media to permit advertising and public service announcements regarding contraception and safe sexual practices as a matter of public health awareness.

Citation: Res. 114, I-86; Reaffirmed: Sunset Report, I-96; Reaffirmed: CSAPH Rep. 3, A-06; Reaffirmed: CSAPH Rep. 01, A-16

Opposition to HHS Regulations on Contraceptive Services for Minors H-75.998

(1) Our AMA continues to oppose regulations that require parental notification when prescription contraceptives are provided to minors through federally funded programs, since they create a breach of confidentiality in the physician-patient relationship. (2) The Association encourages physicians to provide comparable services on a confidential basis where legally permissible.

Sub. Res. 65, I-82 Reaffirmed: CLRPD Rep. A, I-92 Reaffirmed: BOT Rep. 28, A-03 Reaffirmed: Res. 825, I-04 Reaffirmed: CMS Rep. 1, A-14

Injury Prevention H-10.982

Our AMA (1) supports the CDC's efforts to (a) conduct research, (b) develop a national program of surveillance and focused interventions to prevent injuries, and (c) evaluate the effectiveness of interventions, implementation strategies, and injury prevention programs; (2) supports a Public Health Service public information campaign to inform the public and its policymakers of the injury problem and the potential for effective intervention; (3) supports the development of a National Center for Injury Control at the CDC; and (4) encourages state and local medical societies to support, in conjunction with state and local health departments, efforts to make injury control a priority, and advise the leadership of the United States Congress of this unqualified support; and the AMA remains open to working with all interested parties in efforts to deal with and lessen the effects of violence in our society.

Citation: (Res. 410, A-92; Reaffirmed by BOT Rep. 19 - I-94; Reaffirmed by BOT Rep. 34, A-95; Modified and Reaffirmed by BOT Rep. 52, I-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 3, A-15)

Firearms as a Public Health Problem in the United States - Injuries and Death H-145.997

Our AMA recognizes that uncontrolled ownership and use of firearms, especially handguns, is a serious threat to the public's health inasmuch as the weapons are one of the main causes of intentional and unintentional injuries and deaths. Therefore, the AMA: (1) encourages and endorses the development and presentation of safety education programs that will engender more responsible use and storage of firearms;

(2) urges that government agencies, the CDC in particular, enlarge their efforts in the study of firearm-related injuries and in the development of ways and means of reducing such injuries and deaths;

(3) urges Congress to enact needed legislation to regulate more effectively the importation and interstate traffic of all handguns;

(4) urges the Congress to support recent legislative efforts to ban the manufacture and importation of nonmetallic, not readily detectable weapons, which also resemble toy guns; (5) encourages the improvement or modification of firearms so as to make them as safe as humanly possible;

(6) encourages nongovernmental organizations to develop and test new, less hazardous designs for firearms;

(7) urges that a significant portion of any funds recovered from firearms manufacturers and dealers through legal proceedings be used for gun safety education and gun-violence prevention; and

(8) strongly urges US legislators to fund further research into the epidemiology of risks related to gun violence on a national level.

Citation: (CSA Rep. A, I-87; Reaffirmed: BOT Rep. I-93-50; Appended: Res. 403, I-99; Reaffirmation A-07; Reaffirmation A-13; Appended: Res. 921, I-13)

Firearm Safety Counseling in Physician-Led Health Care Teams H-145.976

Our AMA: (1) will oppose any restrictions on physicians' and other members of the physician-led health care team's ability to inquire and talk about firearm safety issues and risks with their patients; (2) will oppose any law restricting physicians' and other members of the physician-led health care team's discussions with patients and their families about firearms as an intrusion into medical privacy; and (3) encourages dissemination of educational materials related to firearm safety to be used in undergraduate medical education.

Citation: (Res. 219, I-11; Reaffirmation A-13; Modified: Res. 903, I-13)

Data on Firearm Deaths and Injuries H-145.984

The AMA supports legislation or regulatory action that: (1) requires questions in the National Health Interview Survey about firearm related injury as was done prior to 1972; (2) mandates that the Centers for Disease Control and Prevention develop a national firearm fatality reporting system; and (3) expands activities to begin tracking by the National Electronic Injury Surveillance System.

Citation: (Res. 811, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmation A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 903
(I-16)

Introduced by: Medical Student Section

Subject: Prevention of Newborn Falls in Hospitals

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, The few published statistics of in-hospital fall rates suggest that 600 to 1,600 newborn falls occur annually;¹ and

Whereas, Newborn falls most commonly occur when a newborn falls out of the arms of a parent who fell asleep while holding him or her;² and

Whereas, Situations leading to newborn falls are preventable;² and

Whereas, Newborn falls are likely underreported due to parental guilt or fear and lack of no-blame culture, risk factor awareness amongst healthcare providers, parental education on seriousness of the condition, and risk management;³ and

Whereas, Newborn injuries resulting from falls can range from no obvious injuries to skull fractures and severe head injuries;³ and

Whereas, Fall prevention programs implemented across the U.S. have included increased monitoring of mothers and newborns, patient safety contracts, equipment safety protocols, post-fall procedures, and education of healthcare providers and parents;^{4,5} therefore be it

RESOLVED, That our American Medical Association support implementation of newborn fall prevention plans and post-fall procedures through clinically proven, high-quality, and cost-effective approaches. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 08/29/16

¹ Mattleson, T, Henderson-Williams A, Nelson J. Preventing in-hospital newborn falls: a literature review. MCN Am J Matern Child Nurs 2013 Nov-Dec;38(6):359-66.

² Gaffey AD. Fall prevention in our healthiest patients: Assessing risk and preventing injury for moms and babies. J Healthc Risk Manag. 2015;34(3):37-40. doi: 10.1002/jhrm.21163 [doi].

³ Teuten P, Bolger S, Paul SP. Need for improved recognition of in-hospital newborn falls. Aust Nurs Midwifery J. 2015;23(1):28-31.

⁴ Helsley L, McDonald JV, Stewart VT. Addressing in-hospital "falls" of newborn infants. Jt Comm J Qual Patient Saf. 2010;36(7):327-333.

⁵ Ainsworth RM, Maetzold L, Mog C, Summerlin-Long S. Protecting our littlest patients: A newborn falls prevention strategy. Journal of Obstetric, Gynecologic, & Neonatal Nursing. 2013;42:S76.

RELEVANT AMA POLICY**Treatment Decisions for Seriously Ill Newborns H-245.984**

Physicians should play an active role in advocating for changes in the Child Abuse Prevention Act as well as state laws that require physicians to violate the ethical guidelines stated in E-2.215

(Treatment Decisions for Seriously Ill Newborns).

Citation: (CEJA Rep. I, A-92; Modified and Reaffirmed: CEJA Rep. 1, A-03; Reaffirmed: CEJA Rep. 4, A-13)

Physician-Hospital Relationships H-225.997

1. Physicians and hospital authorities have a mutual responsibility to cooperate and work together in effectively maintaining patient care.
2. Although final authority for granting, denial, termination, or limitation of hospital staff privileges is vested in the governing board of the hospital, it is expected that the judgment of the organized medical staff will be relied upon in the evaluation of the professional competence, education, experience, and qualifications of all physicians, including the hospital-associated medical specialists.
3. Physicians having contractual or financial arrangements with hospitals should be members of the organized medical staff and responsible to it. They should be subject to the bylaws of the medical staff and conduct their professional activities according to the standards, rules and regulations adopted by it.
4. Hospital-associated medical specialists, as well as all members of the medical staff, are expected to contribute a reasonable amount of their time, without compensation, to participation in hospital staff committee activities for the purpose of improving patient care; providing continuing education for the benefit of the medical staff; and assisting in the training of physicians and allied health personnel. Physicians who provide teaching or other services in excess of those ordinarily expected of members of the attending staff are entitled to reasonable compensation therefore.
5. Hospitals are entitled to recover their reimbursable expenses, determined in accordance with recognized standard hospital cost-accounting principles, from the operation of departments in which hospital-associated medical specialists perform personally or supervise or direct the services provided patients.
6. The form of the contractual or financial arrangement between hospitals and hospital-associated physicians depends upon the facts and practical considerations existing in each situation. No single form of contractual or financial arrangement can be feasible for all of the arrangements that may be entered into between hospitals and hospital-associated physicians. The essential consideration is that whatever the arrangement, it is fair to the parties, promotes the interests of patients and supports the provision of high quality care and services. Arrangements should be avoided that are unrelated to the professional services, or time expended or to the skill, education, and professional expertise of the physician, and that result in disproportionate earnings.
7. Hospital-associated medical specialists are entitled to charge (a) for the services they provide in accordance with the same standards of equity and fairness that apply to the charges of other physicians, and (b) for supervision of personnel under their direction.
8. There should be no duplication of charges to the patient where services are not actually provided by both the physician and the hospital. Each party should receive the compensation reasonably and equitably owing for services for which each is primarily responsible. Only one of the parties is entitled to the reasonable costs of assuring the accuracy and reliability of the procedures performed in such departments.
9. Both hospitals and hospital-associated medical specialists have an obligation to serve the needs of patients and the medical staff. The primary responsibility for determining the services needed adequately to care for the needs of individual patients should be that of the attending physician subject to review by his peers.

Citation: (BOT Rep. R, A-77; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmation A-05; Reaffirmed: CMS Rep. 1, A-15)

Standardization of Newborn Screening Programs H-245.973

Our AMA: (1) recognizes the need for uniform minimum newborn screening (NBS) recommendations; and (2) encourages continued research and discussions on the potential benefits and harms of NBS for certain diseases.

Citation: (CSAPH Rep. 9, A-06; Reaffirmed in lieu of Res. 502, A-09)

Standardization of Newborn Screening Programs D-245.996

Our AMA will monitor developments in the effort to implement a uniform minimum newborn screening panel, including status of the pending Health Resources and Services Administration report entitled *Newborn Screening: Toward a Uniform Screening Panel and System*, and the ongoing expansion of required tests by each state.

Citation: CSAPH Rep. 9, A-06; Rescinded: CSAPH Rep. 01, A-16

Medical Care for Indigent and Culturally Displaced Obstetrical Patients and Their Newborns H-420.995

Our AMA (1) reaffirms its long-standing position regarding the major importance of high-quality obstetrical and newborn care by qualified obstetricians, family physicians, and pediatricians and the need to make such care available to all women and newborns in the United States; (2) favors educating the public to the long-term benefit of antepartum care and hospital birth, as well as the hazards of inadequate care; and (3) favors continuing discussion of means for improving maternal and child health services for the medically indigent and the culturally displaced.

Citation: (CSA Rep. C, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: CSAPH Rep. 1, A-10)

Centralized Community and Regionalized Perinatal Intensive Care H-245.999

Our AMA (1) urges development on the local level of centralized community or regionalized newborn intensive care units; and (2) encourages (a) training programs necessary to staff regional facilities, (b) allocation of facilities and equipment within communities and development of guidelines, (c) continuing research into etiologic factors responsible for the high-risk infant, and (d) continuing evaluation.

Citation: (BOT Rep. J, A-71; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10)

Sudden Infant Death Syndrome H-245.977

1. The AMA encourages the education of parents, physicians and all other health care professionals involved in newborn care regarding methods to eliminate known Sudden Infant Death Syndrome (SIDS) risk factors, such as prone sleeping, soft bedding and parental smoking.

2. Our AMA will advocate for the appropriate labeling of all infant sleep products, not in compliance with the Safe Infant Sleeping Environment Guidelines, as adopted by the AAP, to adequately warn consumers of the risks of product use and prevent sudden unexpected infant death.

3. Our AMA encourages consumers to avoid commercial devices marketed to reduce the risk of SIDS, including: wedges, positioners, special mattresses, and special sleep surfaces.

4. Our AMA encourages media and manufacturers to follow safe-sleep guidelines in their messaging and advertising.

Citation: Res. 414, A-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15;
Appended: Res. 429, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 904
(I-16)

Introduced by: Medical Student Section

Subject: Improving Mental Health at Colleges and Universities for Undergraduates

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, According to the Association for University and College Counseling Directors (2014), 94% of surveyed college counseling center directors said that the number of students with significant psychological problems is a growing concern;¹ and

Whereas, According to the National College Health Assessment II in 2013, one-third of 20.2 million college students had difficulty functioning due to depression, 50% or more struggled with anxiety, 20% had seriously considered suicide in their lifetime and 5.8% said they had attempted suicide;² and

Whereas, Barriers to seeking counseling include skepticism about the efficacy of counseling services, a lack of time for counseling services, lack of money for services and worry about others' perceptions of one's participation in therapy;³ and

Whereas, Identifying and presenting the benefits of counseling services in improving mental health and social outcomes has been shown to be critical in culturing positive beliefs about the efficacy of mental health services;^{4,5} and

Whereas, Early intervention programs in California public and community colleges increased the percentage of students receiving help by 10%;⁶ and

Whereas, California and Virginia have introduced legislation to expand the scope of services to students by including local community health centers as resources for care and by increasing grant funds for mental health resources in public and community colleges in the state;^{7,8} and

¹ National Survey of College Counseling Centers. 2014. The International Association of Counseling Services, Inc.

² American College Health Association. 2013. American College Health Association-National College Health Assessment II: Reference Group Executive Summary Spring 2013. Hanover, MD: American College Health Association.

³ Mowbray C. T., Mandiberg J. M., Stein C. H., Kopels S., Curlin C., Megivern D., Lett R. Campus mental health services: Recommendations for change. *American Journal of Orthopsychiatry*. 2006;(2):226–237.

⁴ Vidourek RA, King KA, Nabors LA, Merianos AL. Students' benefits and barriers to mental health help-seeking. *Health Psychology and Behavioral Medicine*. 2014;2(1):1009-1022. doi:10.1080/21642850.2014.963586.

⁵ Hoge, C. W., Auchterlonie, J. L., & Milliken, C. S. (2006). Mental health problems, use of mental health services, and attrition from military service after returning from deployment to Iraq or Afghanistan. *JAMA*, 295(9), 1023-1032.

⁶ Gruttadaro D., and Crudo, D. College Students Speak: A Survey Report on Mental Health. 2012. National Alliance on Mental Health.

⁷ AB-2017, as amended, McCarty (2016). College Mental Health Services Program. Available at: http://www.leginfo.ca.gov/pub/15-16/bill/asm/ab_2001-2050/ab_2017_cfa_20160620_134234_sen_comm.html

⁸ HB-206 (2015). A bill to amend and reenact § 23-9.2:8 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 1 of Title 23 a section numbered 23-9.2:13, relating to four-year public institutions of higher education; mental health resources, online module, and online assessment. Available at: <http://lis.virginia.gov/cgi-bin/legp604.exe?141+ful+HB206+pdf>.

1 Whereas, Current AMA policy recognizes the importance of mental health to students in
2 pre-K-12 (D-345.994), medical students (in an opt-out program), residents, and physicians (H-
3 345.973), mentally-ill displaced persons (H-160.978), and diverse at-risk communities
4 (H-345.974); therefore be it

5
6 RESOLVED, That our American Medical Association support accessibility and de-stigmatization
7 as strategies in mental health measures implemented by colleges and universities, in order to
8 improve the provision of care and increase its use by those in need (New HOD Policy); and be it
9 further

10
11 RESOLVED, That our AMA support colleges and universities in publicizing the importance of
12 mental health resources, with an emphasis on the availability and efficacy of such resources
13 (New HOD Policy); and be it further

14
15 RESOLVED, That our AMA support collaborations of university mental health specialists and
16 local health centers in order to provide a larger pool of resources, such that any student be able
17 to access care in a timely and affordable manner. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 08/29/16

RELEVANT AMA POLICY

Increasing Detection of Mental Illness and Encouraging Education D-345.994

1. Our AMA will work with: (A) mental health organizations, state, specialty, and local medical societies and public health groups to encourage patients to discuss mental health concerns with their physicians; and (B) the Department of Education and state education boards and encourage them to adopt basic mental health education designed specifically for preschool through high school students, as well as for their parents, caregivers and teachers.
2. Our AMA will encourage the National Institute of Mental Health and local health departments to examine national and regional variations in psychiatric illnesses among immigrant, minority, and refugee populations in order to increase access to care and appropriate treatment.

Citation: (Res. 412, A-06; Appended: Res. 907, I-12)

Mental Health Services for Medical Students and Resident and Fellow Physicians H-345.973

Our AMA promotes confidential, accessible, and affordable mental health services for medical students and resident and fellow physicians.

Citation: (Res. 915, I-15)

Expansion of Student Health Services H-295.872

1. It is AMA policy that medical students should have timely access to needed preventive and therapeutic medical and mental health services at sites in reasonable proximity to where their education is occurring.
2. Our AMA will encourage the Liaison Committee on Medical Education to develop an annotation to its standard on medical student access to preventive and therapeutic health services that includes a specification of the following:
 - a. Medical students should have timely access to needed preventive and therapeutic medical and mental health services at sites in reasonable proximity to where their education is occurring.
 - b. Medical students should have information about where and how to access health services at all locations where training occurs.
 - c. Medical schools should have policies that permit students to be excused from class or clinical activities to seek needed care.

Citation: (CME Rep. 10, A-07)

Statement of Principles on Mental Health H-345.999

(1) Tremendous strides have already been made in improving the care and treatment of the emotionally disturbed, but much remains to be done. The mental health field is vast and includes a network of factors involving the life of the individual, the community and the nation. Any program designed to combat mental illness and promote mental health must, by the nature of the problems to be solved, be both ambitious and comprehensive.

(2) The AMA recognizes the important stake every physician, regardless of type of practice, has in improving our mental health knowledge and resources. The physician participates in the mental health field on two levels, as an individual of science and as a citizen. The physician has much to gain from a knowledge of modern psychiatric principles and techniques, and much to contribute to the prevention, handling and management of emotional disturbances. Furthermore, as a natural community leader, the physician is in an excellent position to work for and guide effective mental health programs.

(3) The AMA will be more active in encouraging physicians to become leaders in community planning for mental health.

(4) The AMA has a deep interest in fostering a general attitude within the profession and among the lay public more conducive to solving the many problems existing in the mental health field.

Citation: (A-62; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation A-99; Reaffirmed: CSAPH Rep. 1, A-09)

Maintaining Mental Health Services by States H-345.975

Our AMA:

1. supports maintaining essential mental health services at the state level, to include maintaining state inpatient and outpatient mental hospitals, community mental health centers, addiction treatment centers, and other state-supported psychiatric services;

2. supports state responsibility to develop programs that rapidly identify and refer individuals with significant mental illness for treatment, to avoid repeated psychiatric hospitalizations and repeated interactions with the law, primarily as a result of untreated mental conditions;

3. supports increased funding for state Mobile Crisis Teams to locate and treat homeless individuals with mental illness;

4. supports enforcement of the Mental Health Parity Act at the federal and state level; and

5. will take these resolves into consideration when developing policy on essential benefit services.

Citation: (Res. 116, A-12; Reaffirmation A-15)

Access to Mental Health Services H-345.981

Our AMA advocates the following steps to remove barriers that keep Americans from seeking and obtaining treatment for mental illness:

(1) reducing the stigma of mental illness by dispelling myths and providing accurate knowledge to ensure a more informed public;

(2) improving public awareness of effective treatment for mental illness;

(3) ensuring the supply of psychiatrists and other well trained mental health professionals, especially in rural areas and those serving children and adolescents;

(4) tailoring diagnosis and treatment of mental illness to age, gender, race, culture and other characteristics that shape a person's identity;

(5) facilitating entry into treatment by first-line contacts recognizing mental illness, and making proper referrals and/or to addressing problems effectively themselves; and

(6) reducing financial barriers to treatment.

Citation: (CMS Rep. 9, A-01; Reaffirmation A-11; Reaffirmed: CMS Rep. 7, A-11; Reaffirmed: BOT action in response to referred for decision Res. 403, A-12; Reaffirmed in lieu of Res. 804, I-13; Reaffirmed in lieu of Res. 808, I-14)

Awareness, Diagnosis and Treatment of Depression and other Mental Illnesses H-345.984

Awareness, Diagnosis and Treatment of Depression and Other Mental Illnesses: (1) Our AMA encourages: (a) medical schools, primary care residencies, and other training programs as appropriate to include the appropriate knowledge and skills to enable graduates to recognize, diagnose, and treat depression and other mental illnesses, either as the chief complaint or with another general medical condition; (b) all physicians providing clinical care to acquire the same knowledge and skills; and (c) additional research into the course and outcomes of patients with depression and other mental illnesses who are seen in general medical settings and into the development of clinical and systems approaches designed to improve patient outcomes.

Furthermore, any approaches designed to manage care by reduction in the demand for services should be based on scientifically sound outcomes research findings. (2) Our AMA will work with the National Institute on Mental Health and appropriate medical specialty and mental health advocacy groups to increase public awareness about depression and other mental illnesses, to reduce the stigma associated with depression and other mental illnesses, and to increase patient access to quality care for depression and other mental illnesses.

Citation: (Res. 502, I-96; Reaffirm & Appended: CSA Rep. 7, I-97; Reaffirmation A-00; Modified: CSAPH Rep. 1, A-10; Modified: Res. 301, A-12)

Educating Physicians About Physician Health Programs D-405.990

1) Our AMA will work closely with the Federation of State Physician Health Programs (FSPHP) to educate our members as to the availability and services of state physician health programs to continue to create opportunities to help ensure physicians and medical students are fully knowledgeable about the purpose of physician health programs and the relationship that exists between the physician health program and the licensing authority in their state or territory; 2) Our AMA will continue to collaborate with relevant organizations on activities that address physician health and wellness; 3) Our AMA will, in conjunction with the FSPHP, develop state legislative guidelines addressing the design and implementation of physician health programs; and 4) Our AMA will work with FSPHP to develop messaging for all Federation members to consider regarding elimination of stigmatization of mental illness and illness in general in physicians and physicians in training.

Citation: (Res. 402, A-09; Modified: CSAPH Rep. 2, A-11; Reaffirmed in lieu of Res. 412, A-12; Appended: BOT action in response to referred for decision Res. 403, A-12)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 905
(I-16)

Introduced by: Resident and Fellow Section

Subject: Chronic Traumatic Encephalopathy (CTE) Awareness

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, In 1928, a pathologist by the name of Harrison Stanford Martland first introduced the concept of chronic traumatic encephalopathy (CTE), as a collection of symptoms of tremors, slowed movements, and confusion typical of prize boxers who experienced repeated sublethal blows to the head;¹ and

Whereas, CTE was brought to national attention with the paper, "Chronic Traumatic Encephalopathy in a National Football League (NFL) Player"², detailing the potential long-term neurodegeneration in retired NFL players with a history of repetitive head trauma; and

Whereas, CTE is now being recognized as a distinct entity requiring dedicated centers for care, such as the Boston University CTE center, which uses the definition of a progressive degenerative disease of the brain found in athletes (and others) with a history of repetitive brain trauma, in those with both symptomatic concussions and those with asymptomatic sub-concussive hits to the head;³ and

Whereas, There is a high burden of risk of CTE in the United States, with an estimated 1.6 to 3.8 million concussions occurring per year, especially in those who participate in high impact sports such as football, soccer and basketball;⁴ with an estimated 250,000 children (<19 years) treated in U.S. emergency departments for sports and recreation-related injuries causing concussions;⁵ and

Whereas, Since the Global War on Terrorism began, nearly 2 million American military service men and women have been deployed to war zones, with an estimated 5% to 35% having sustained a concussion during their deployment, most of which are secondary to blast exposures;⁶ and

Whereas, The symptoms of CTE are insidious, occurring over 8-10 years of the inciting event or events. Initial symptoms are usually nonspecific and include worsening attention, concentration, and memory, but can progress to include poor judgment, dementia, and Parkinsonism;⁷ and

Whereas, The most effective way to prevent CTE is to reduce the frequency and extent of concussions, or mild traumatic brain injuries, and to ensure there is timely recognition and ample time to rest and recover when concussions do occur; and

¹ Harrison MS. Punch Drunk. JAMA. 1928;91(15):1103-1107. doi:10.1001/jama.1928.02700150029009.

² Omalu, BI, et al. Chronic Traumatic Encephalopathy in a National Football League Player. [Neurosurgery](#). 2005 Jul;57(1):128-34; discussion 128-34.

³ <http://www.bu.edu/cte/about/what-is-cte/>

⁴ Yi, JY, et al. Chronic traumatic encephalopathy. Head, Neck and Spine. 2013; 12 (1). 28-32.

⁵ Centers for Disease Control and Prevention. Nonfatal Traumatic Brain Injuries Related to Sports and Recreation Activities Among Persons Aged ≤19 Years — United States, 2001–2009. MMWR 2011; 60(39):1337–1342.

⁶ Rigg JL, Mooney SR. Concussions and the military: issues specific to service members. [PM R](#). 2011 Oct;3(10 Suppl 2):S380-6.

⁷ Corsellis JA, Burton CJ, Freeman-Browne D. The aftermath of boxing. Psychol Med 1973;3:270-303.

Whereas, AMA policies H-470.954 and H-470.959 support efforts to prevent and treat concussions but do not currently contain language regarding physician or public education about detecting and treating CTE; and

Whereas, There is no legislation or regulation of the development of CTE in major sports leagues; therefore be it

RESOLVED, That our American Medical Association amend part one of Policy H-470.954 by addition and deletion to read as follows:

Reduction of Sports-Related Injury and Concussion

1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; ~~and~~ (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged consequences; and (c) promote education for physicians and the public on the detection, treatment and prognosis of chronic traumatic encephalopathy (CTE). (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA work with interested agencies and organizations to advocate for further research into the causes of and treatments for chronic traumatic encephalopathy (CTE). (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/12/16

RELEVANT AMA POLICY

Reduction of Sports-Related Injury and Concussion H-470.954

1. Our AMA will: (a) work with appropriate agencies and organizations to promote awareness of programs to reduce concussion and other sports-related injuries across the lifespan; and (b) promote awareness that even mild cases of traumatic brain injury may have serious and prolonged consequences.

2. Our AMA supports the adoption of evidence-based, age-specific guidelines on the evaluation and management of concussion in all athletes for use by physicians, other health professionals, and athletic organizations.

3. Our AMA will work with appropriate state and specialty medical societies to enhance opportunities for continuing education regarding professional guidelines and other clinical resources to enhance the ability of physicians to prevent, diagnose, and manage concussions and other sports-related injuries.

4. Our AMA urges appropriate agencies and organizations to support research to: (a) assess the short- and long-term cognitive, emotional, behavioral, neurobiological, and neuropathological consequences of concussions and repetitive head impacts over the life span; (b) identify determinants of concussion and other sports-related injuries in pediatric and adult athletes, including how injury thresholds are modified by the number of and time interval between head impacts and concussions; (c) develop and evaluate effective risk reduction measures to prevent or reduce sports-related injuries and concussions and their sequelae across the lifespan; and (d) develop objective biomarkers to improve the identification, management, and prognosis of athletes suffering from concussion to reduce the dependence on self-reporting and inform evidence-based, age-specific guidelines for these patients. (CSAPH Rep. 3, A-15)

Reducing the Risk of Concussion and Other Injuries in Youth Sports H-470.959

- 1 . Our American Medical Association promotes the adoption of requirements that athletes participating in school or other organized youth sports and who are suspected by a coach, trainer, administrator, or other individual responsible for the health and well-being of athletes of having sustained a concussion be removed immediately from the activity in which they are engaged and not return to competitive play, practice, or other sports-related activity without the written approval of a physician (MD or DO) or a designated member of the physician-led care team who has been properly trained in the evaluation and management of concussion. When evaluating individuals for return-to-play, physicians (MD or DO) or the designated member of the physician-led care team should be mindful of the potential for other occult injuries.
2. Our AMA encourages physicians to: (a) assess the developmental readiness and medical suitability of children and adolescents to participate in organized sports and assist in matching a child's physical, social, and cognitive maturity with appropriate sports activities; (b) counsel young patients and their parents or caregivers about the risks and potential consequences of sports-related injuries, including concussion and recurrent concussions; (c) assist in state and local efforts to evaluate, implement, and promote measures to prevent or reduce the consequences of concussions, repetitive head impacts, and other injuries in youth sports; and (d) support preseason testing to collect baseline data for each individual.
3. Our AMA will work with interested agencies and organizations to: (a) identify harmful practices in the sports training of children and adolescents; (b) support the establishment of appropriate health standards for sports training of children and adolescents; and (c) promote educational efforts to improve knowledge and understanding of concussion and other sport injuries among youth athletes, their parents, coaches, sports officials, school personnel, health professionals, and athletic trainers. (Res. 910, I-10; Reaffirmed: BOT Rep. 9, A-14; Modified: CSAPH Rep. 3, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 906
(I-16)

Introduced by: Resident and Fellow Section

Subject: Universal Color Scheme for Respiratory Inhalers

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, In the medical management of many respiratory conditions, such as asthma and
2 chronic obstructive pulmonary disease, inhaled medications such as corticosteroids, beta-2
3 agonists, and anti-cholinergic agents are commonly administered through respiratory inhalers;
4 and
5

6 Whereas, International practice codifies standard colors for classes of inhaled drugs, for
7 example, in the United Kingdom blue is universally a “rescue” medication or beta-2 agonist and
8 brown is universally a “prevention” medication; and
9

10 Whereas, Universal color schemes allow for easy medication reconciliation in emergency
11 rooms, streamlined universal patient education, and appropriate medication use; and
12

13 Whereas, In the United States, the color of respiratory inhalers is chosen by the pharmaceutical
14 company for brand recognition and marketing, including in the manufacture of generic drugs,
15 without regard to class of drug; and
16

17 Whereas, Respiratory inhalers in the United States are usually prescribed based on in-network
18 insurance formularies, regardless of patients’ recognition of brand names or marketing; and
19

20 Whereas, The interchangeability of colors for classes of drugs leads to several problems,
21 including confusion for patients during self-management, increased risk of adverse events such
22 as beta-2 agonist overdose or undertreating an asthma attack, inaccurate patient education,
23 and incorrect medication reconciliation or prescribing by healthcare providers; and
24

25 Whereas, A universal color scheme for “rescue” inhalers would allow simplified patient
26 education, synchronous dialogue between care provider and patient, reduced confusion, and
27 improved compliance and safety; therefore be it
28

29 RESOLVED, That our American Medical Association work with leading respiratory inhaler
30 manufacturing companies and health agencies such as the Federal Drug Administration and the
31 American Pharmacists Association to develop consensus of a universal color scheme for short-
32 acting beta-2 agonist respiratory inhalers that are used as “rescue inhalers” in the United States
33 (Directive to Take Action); and be it further
34

35 RESOLVED, That our AMA work with leading respiratory inhaler manufacturing companies to
36 ensure the universal color scheme for respiratory inhalers would allow for the least disruption
37 possible to current inhaler colors, taking into account distribution of each brand and impact on
38 current users if color were to change (Directive to Take Action); and be it further

- 1 RESOLVED, That our AMA work with leading respiratory inhaler manufacturing companies to
- 2 ensure that universal color scheme for respiratory inhalers be designed for adherence and
- 3 sustainability, including governance for future companies entering the respiratory inhaler
- 4 market, and reserving colors for possible new drug classes in the future. (Directive to Take
- 5 Action)

Fiscal Note: Estimate cost of \$22,000 to implement resolution.

Received: 09/12/16

References:

"Types of Asthma Inhalers: Which asthma inhaler does what?." <https://www.dred.com/uk/asthma-inhalers.html>
 "GlaxoSmithKline revises colour and labelling of Relvar Ellipta inhaler." *The Pharm J.*, 20/27 December 2014, Vol 293, No 7841/2, <http://www.pharmaceutical-journal.com/news-and-analysis/news/glaxosmithkline-revises-colour-and-labelling-of-relvar-ellipta-inhaler/20067357.article>.
 Jayakrishnan, B. "Asthma inhalers and colour coding: universal dots." *Br J Gen Pract*; 2010; 60(578): 690–691. (1 September.) <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2930224/>
 Partridge M. "Minerva." *BMJ* 1992; 305: 890. (10 October.)
 Horn CR, Cochrane GM. Colour Coding for Bronchodilator Inhalers." *Lancet* 1986; 1(8473): 165. (18 January.)

RELEVANT AMA POLICY

Over-the-Counter Inhalers in Asthma H-115.972

Our AMA: (1) supports strengthening the product labeling for over-the-counter (OTC) epinephrine inhalers to better educate users about patterns of inappropriate use; to include clear statements that the use of OTC inhalers can be dangerous; to urge users to seek medical care if symptoms do not improve or if they meet criteria for the presence of persistent disease; and to encourage explicit discussions with physicians about dosage when these products are used; (2) encourages the FDA to reexamine whether OTC epinephrine inhalers should be removed from the market; and (3) In the event that these products continue to be marketed OTC, further information should be obtained to determine whether OTC availability is a risk factor for asthma morbidity and mortality. (CSA Rep. 2, A-99; Reaffirmed: CSAPH Rep. 1, A-09)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 907
(I-16)

Introduced by: Resident and Fellow Section

Subject: Clinical Implications and Policy Considerations of Cannabis Use

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Medicinal marijuana is currently legal in 23 states within the U.S. including Washington D.C. and recreational use has now been legalized in four states: Colorado, Washington, Oregon and Alaska;¹ and

Whereas, The “Adult Use of Marijuana Act” is a ballot referendum for November, 2016 calling for full decriminalization of the possession and sale of marijuana for individuals over the age of 21 in California;^{2,3} and

Whereas, Without regulation, this growing, multi-billion dollar industry of “Big Marijuana” is on track to becoming a 2.0 version of the entity so many public health advocates have spent decades fighting: Big Tobacco; and

Whereas, AMA support for research and education of cannabis use is strong, the AMA overtly opposes legalization of marijuana and endorses warnings emphasizing its dangers for abuse and misuse (AMA Policies D-95.976 and H-95.995); and

Whereas, One of the more comprehensive analyses on marijuana legalization was completed by the AMA Council on Science and Public Health (CSAPH) in a 2013 report titled “A Contemporary View of National Drug Control Policy” which was adopted at the AMA House of Delegates 2013 Interim meeting; and

Whereas, The CSAPH took a strong stance opposing marijuana legalization until “the findings of comprehensive research into the potential effects, both positive and adverse, of relaxing existing drug prohibitions and controls can be adequately assessed” (H-95.954); and

Whereas, There are in excess of 60 pharmacologically active cannabinoids⁴ and, although clinical responses to cannabinoids vary, potential positive outcomes include reduction in pain sensation, antispasticity, increased appetite, and antiemesis;⁵ and

Whereas, The US Food and Drug Administration has approved dronabinol and nabilone for chemotherapeutic induced nausea and vomiting and cancer or HIV induced anorexia;^{6,7} and

¹ State Marijuana Laws Map. <http://www.governing.com/gov-data/state-marijuana-laws-map-medical-recreational.html>

² <https://www.mpp.org/states/california/>

³ <https://www.regulatecalifornia.com/about/>

⁴ Pertwee RG. Cannabinoid pharmacology: the first 66 years. Br J Pharmacol. 2006;147(suppl 1): S163-S171.

⁵ Koppel BS, Brust JC, Fife T, et al. Systematic review: efficacy and safety of medical marijuana in selected neurologic disorders: report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2014; 82(17):1556-1563.

⁶ Marinol [product information]. Marietta, GA: Solvay Pharmaceuticals; 2008.

⁷ Cesamet [product information]. Aliso Viejo, CA: Valeant Pharmaceuticals, 2008.

Whereas, Statistically significant evidence now exists supporting cannabis use in patients with neuropathic pain and chronic pain with additional data and professional opinion endorsing its use in multiple sclerosis associated spasticity;⁸ and

Whereas, Medicinal marijuana has become a commonly prescribed medication in states where it is legal and cannabis represents an alternative to opioid therapies, which are plagued with addiction, overdoses and deaths; and

Whereas, There were 12.4 million arrests within the US in 2011 with 1.5 million related to drugs⁹ and nearly 80% of these arrests associated with drug possession and approximately 50% connected to marijuana; and

Whereas, The economic burden of drug related issues within the prison system surmounted \$80 billion in 2010 alone with an annual, anticipated cost of the "War on Drugs" totaling about \$50 billion (CSAPH); and

Whereas, CSAPH Report 2-I-13 provides a detailed description of legalization vs decriminalization as follows:

Legalization is defined as "the complete removal of sanctions, making a certain behavior legal and applying no criminal or administrative penalties."
Decriminalization means to "eliminate criminal penalties for or remove legal restrictions." To decriminalize does not mean that consequences are entirely lacking for a certain act or behavior.; and

Whereas, Penalties in states that have decriminalized marijuana currently range from citations and fines to loss of driving privileges; and

Whereas, The majority of Americans are in favor of marijuana legalization, with some polls citing numbers as high as 50-60%;^{10,11} and

Whereas, Medicinal marijuana has garnered support as high as 85+% while an even larger percentage oppose incarceration for marijuana possession;^{12,13} therefore be it

RESOLVED, That our American Medical Association amend Policy H-95.998 by deletion to read as follows:

H-95.998, AMA Policy Statement on Cannabis

Our AMA believes that (1) cannabis is a dangerous drug and as such is a public health concern; (2) ~~sale of cannabis should not be legalized;~~ (3) public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use; and (4) (3) additional research should be encouraged. (Modify Current HOD Policy); and be it further

⁸ Hill KP. Medical Marijuana for Treatment of Chronic Pain and Other Medical and Psychiatric Problems: A Clinical Review. JAMA. 2015 Jun 23;313(24):247483. doi: 10.1001/jama.2015.6199. Review. PubMed PMID: 26103031.

⁹ Carson EA, Sabol WJ. Prisoners in 2011. Washington U.S. Department of Justice, Bureau of Justice Statistics, 2012.

¹⁰ Gallup Poll. Record-High 50% of Americans Favor Legalizing Marijuana Use. October 17, 2011

¹¹ Pew Research Center. Majority now supports legalizing marijuana. April 4, 2013.

¹² Fox News Poll among random national sample of 1,010 registered voters. May 1, 2013.

¹³ Quinnipiac University National Poll. December 5, 2012 <http://www.quinnipiac.edu/institutes-and-centers/polling-institute/national/release-detail?ReleaseID=1820>.

1 RESOLVED, That our AMA amend Policy D-95.976 by deletion to read as follows:

2
3 D-95.976, Cannabis - Expanded AMA Advocacy

4 1. Our AMA will educate the media and legislators as to the health effects of cannabis use
5 as elucidated in CSAPH Report 2, I-13, A Contemporary View of National Drug Control
6 Policy, and CSAPH Report 3, I-09, Use of Cannabis for Medicinal Purposes, and as
7 additional scientific evidence becomes available.

8 2. Our AMA urges legislatures to delay initiating full legalization of any cannabis product
9 until further research is completed on the public health, medical, economic and social
10 consequences of use of cannabis and, instead, support the expansion of such research.

11 3. Our AMA will also increase its efforts to educate the press, legislators and the public
12 regarding its policy position that stresses a "public health", as contrasted with a "criminal,"
13 approach to cannabis.

14 4. Our AMA shall encourage model legislation that would require placing the following
15 warning on all cannabis products not approved by the U.S. Food and Drug Administration:
16 "Marijuana has a high potential for abuse. ~~It has no scientifically proven, currently accepted~~
17 ~~medical use for preventing or treating any disease process in the United States.~~" (Modify
18 Current HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/12/16

RELEVANT AMA POLICY

Alcohol and Drug Abuse Education H-170.992

Our AMA: (1) supports continued encouragement for increased educational programs relating to use and abuse of alcohol, marijuana and controlled substances; (2) supports the implementation of alcohol and marijuana education in comprehensive health education curricula, kindergarten through grade twelve; and (3) encourages state medical societies to work with the appropriate agencies to develop a state-funded educational campaign to counteract pressures on young people to use alcohol. (Sub. Res. 63, I-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmation and Reaffirmed: Sunset Report, I-00; Appended: Res. 415, I-01; Reaffirmed: CSAPH Rep. 1, A-11)

Cannabis Warnings for Pregnant and Breastfeeding Women H-95.936

Our AMA advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding wherever these products are sold or distributed. (Res. 922, I-15)

Immunity from Federal Prosecution for Physicians Recommending Cannabis H-95.938

Our American Medical Association supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws. (Res. 233, A-15)

AMA Policy Statement on Cannabis H-95.998

Our AMA believes that (1) cannabis is a dangerous drug and as such is a public health concern; (2) sale of cannabis should not be legalized; (3) public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use; and (4) additional research should be encouraged. (BOT Rep. K, I-69; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmed in lieu of Res. 202, I-12; Modified: CSAPH Rep. 2, I-13)

Cannabis - Expanded AMA Advocacy D-95.976

1. Our AMA will educate the media and legislators as to the health effects of cannabis use as elucidated in CSAPH Report 2, I-13, A Contemporary View of National Drug Control Policy, and CSAPH Report 3, I-09, Use of Cannabis for Medicinal Purposes, and as additional scientific evidence becomes available.

2. Our AMA urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic and social consequences of use of cannabis and, instead, support the expansion of such research.

3. Our AMA will also increase its efforts to educate the press, legislators and the public regarding its policy position that stresses a "public health", as contrasted with a "criminal," approach to cannabis.

4. Our AMA shall encourage model legislation that would require placing the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States." (Res. 213, I-14)

Cannabis for Medicinal Use H-95.952

(1) Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease. (2) Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product. (3) Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support. (4) Our AMA believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions. (CSA Rep. 10, I-97; Modified: CSA Rep. 6, A-01; Modified: CSAPH Rep. 3, I-09; Modified in lieu of Res. 902, I-10; Reaffirmed in lieu of Res. 523, A-11; Reaffirmed in lieu of Res. 202, I-12; Reaffirmed: CSAPH Rep. 2, I-13)

Cannabis Use H-95.995

Our AMA (1) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk situations; (2) supports the determination of the consequences of long-term cannabis use through concentrated research, especially among youth and adolescents; and (3) supports the modification of state and federal laws to emphasize public health based strategies to address and reduce cannabis use. (CSA Rep. D, I-77; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 2, I-13)

Cannabis Intoxication as a Criminal Defense H-95.997

Our AMA believes a plea of cannabis intoxication not be a defense in any criminal proceedings. BOT Rep. J, A-72 Reaffirmed: CLRPD Rep. C, A-89 Reaffirmed: Sunset Report, A-00 Reaffirmed: CSAPH Rep. 1, A-10 Modified: CSAPH Rep. 2, I-13

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 908
(I-16)

Introduced by: International Medical Graduates Section

Subject: Faith and Mental Health

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Mental health is the foundation for thinking, resilience, self-esteem, well-being, relationships and contribution to society; and

Whereas, Mental illness is a health condition that causes changes in thinking, emotion and behavior; and

Whereas, Nearly one in 5 (20%) of U.S. adults have some form of mental illness in a given year; 1 in 24 (4.2%) has serious mental illness; one in 12 (8.3%) has a substance abuse disorder; and

Whereas, There is a mental health and substance abuse crisis in the United States, there are not enough psychiatrists or mental health providers or services; or there are individuals not seeking treatment; and

Whereas, For a large segment of our population, religion and spirituality often play a vital role in mental health treatment. Spiritual and religious leaders are at times the "first responders," when individuals and families face mental health and substance abuse problems; and

Whereas, Faith community leaders can help reduce the stigma associated with mental illness by educating their congregations and facilitate access to treatment; therefore be it

RESOLVED, That our American Medical Association advocate and support mental health and faith community partnerships that will provide a platform for faith leaders to get educated about psychiatric and substance abuse disorders and mental health providers understand the role of faith in recovery (Directive to Take Action); and be it further

RESOLVED, That our AMA study and support a partnership to foster respectful, collaborative relationships between psychiatrists, other mental health providers and the faith-based community to improve quality care for individuals and families with mental health and substance abuse problems. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/20/16

References:

APA Releases New Resources on Mental Health for Faith Leaders, <http://www.psychiatry.org/newsroom/news-releases/apa-releases-new-resources-on-mental-health-for-faith-leaders>, June 30, 2015

Mental health; A Guide for Faith leaders psychiatry.org/faith

Samsha faith based and community initiative; www.Samsha.gov/faith.

National institute of mental health and substance abuse and Mental health service Administration.

RELEVANT AMA POLICY

Statement of Principles on Mental Health H-345.999

- (1) Tremendous strides have already been made in improving the care and treatment of the emotionally disturbed, but much remains to be done. The mental health field is vast and includes a network of factors involving the life of the individual, the community and the nation. Any program designed to combat mental illness and promote mental health must, by the nature of the problems to be solved, be both ambitious and comprehensive.
- (2) The AMA recognizes the important stake every physician, regardless of type of practice, has in improving our mental health knowledge and resources. The physician participates in the mental health field on two levels, as an individual of science and as a citizen. The physician has much to gain from a knowledge of modern psychiatric principles and techniques, and much to contribute to the prevention, handling and management of emotional disturbances. Furthermore, as a natural community leader, the physician is in an excellent position to work for and guide effective mental health programs.
- (3) The AMA will be more active in encouraging physicians to become leaders in community planning for mental health.
- (4) The AMA has a deep interest in fostering a general attitude within the profession and among the lay public more conducive to solving the many problems existing in the mental health field.
- A-62 Reaffirmed: CLRPD Rep. C, A-88 Reaffirmed: Sunset Report, I-98 Reaffirmation A-99 Reaffirmed: CSAPH Rep. 1, A-09

Increasing Detection of Mental Illness and Encouraging Education D-345.994

1. Our AMA will work with: (A) mental health organizations, state, specialty, and local medical societies and public health groups to encourage patients to discuss mental health concerns with their physicians; and (B) the Department of Education and state education boards and encourage them to adopt basic mental health education designed specifically for preschool through high school students, as well as for their parents, caregivers and teachers.
 2. Our AMA will encourage the National Institute of Mental Health and local health departments to examine national and regional variations in psychiatric illnesses among immigrant, minority, and refugee populations in order to increase access to care and appropriate treatment.
- Res. 412, A-06 Appended: Res. 907, I-12

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 909
(I-16)

Introduced by: American Congress of Obstetricians and Gynecologists

Subject: Promoting Retrospective and Cohort Studies on Pregnant Women and Their Children

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Pregnant women and children are classified as vulnerable populations by Health and Human Services (HHS) 45 Code of Federal Regulations (CFR 46);^{1,2} and

Whereas, Vulnerable populations as outlined in 45 Code of Federal Regulations (CFR) 46 are predominantly excluded from clinical trials;¹ and

Whereas, The majority of pregnant women are prescribed at least one medication during pregnancy;³ and

Whereas, Medications affect pregnant women differently than men and even non-pregnant women;⁴⁻⁶ and

Whereas, Medications taken by pregnant women can lead to adverse health outcomes in their children;⁷⁻⁹ and

Whereas, Although existing AMA policy establishes the inclusion of pregnant women in future studies, it fails to underscore the importance of retrospective analysis of over-the-counter (OTC) medications that have long been assumed safe in pregnancy and would otherwise not warrant such future study; and

Whereas, Medication use during pregnancy can also lead to spontaneous abortion;¹⁰⁻¹² and

Whereas, Acetaminophen is a widely used OTC medication;¹³ and

Whereas, Acetaminophen is recommended for use by pregnant women;¹⁴ and

Whereas, A recent study showed that children born to women who took acetaminophen during pregnancy had as much as a 40% increased risk of developing “behavioral difficulties,” which include “hyperactivity” and “conduct problems;”¹⁵ and

Whereas, The aforementioned study was quickly followed by further research illuminating other potential risks of maternal acetaminophen use;¹⁶⁻¹⁸ and

Whereas, Another recent study concluded that women who took antidepressants during pregnancy were more likely to give birth to children with autism spectrum disorders (ASDs);¹⁹ and

Whereas, Pregnant women were not included in the clinical trials for acetaminophen, antidepressants, or the majority of other commonly used medications;²⁰ and

Whereas, In 2010, the NIH Office of Research on Women's Health supported a workshop to address ethical, regulatory, and scientific issues raised by the enrollment of pregnant women in research studies and found that a "vulnerable population" has a compromised ability to protect its interests and provide informed consent;²¹ and

Whereas, Pregnant women do not, as a group, meet the definition of a "vulnerable population" and have the same capacity for autonomous decision-making as their non-pregnant counterparts, including decisions regarding whether or not to participate in appropriate research studies; therefore be it

RESOLVED, That our American Medical Association recommend to the US Department of Health and Human Services that the Federal Policy for the Protection of Human Subjects, or "Common Rule", be updated to define pregnant women as "scientifically complex" rather than a "vulnerable population" for research purpose (Directive to Take Action); and be it further

RESOLVED, That our AMA urge the federal government to prioritize clinical research and generation and dissemination of data, emphasizing retrospective and cohort studies, on common medications' effects on underlying medical conditions across the entire continuum from pregnancy through lactation and development to better inform prescribing (New HOD Policy); and be it further

RESOLVED, That our AMA support federal legislation to 1) establish an interagency taskforce within the Department of Health and Human Services to improve federal interagency and key stakeholder communication, coordination and collaboration to advance research on medications in pregnancy and breastfeeding, and 2) to require the United States Food and Drug Administration to provide regular reports to Congress tracking the inclusion of pregnant and breastfeeding women in clinical trials. (New HOD Policy)

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- ¹⁴ Feldkamp ML, Meyer RE, Krikov S, Botto LD. Acetaminophen use in pregnancy and risk of birth defects: findings from the National Birth Defects Prevention Study. *Obstetrics & Gynecology*. 2010 Jan 1;115(1):109-15.
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Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/27/16

RELEVANT AMA POLICY

7.1.3 Study Design & Sampling

To be ethically justifiable, biomedical and health research that involves human subjects must uphold fundamental principles of respect for persons, beneficence, and justice. These principles apply not only to the conduct of research, but equally to the selection of research topics and study design.

Well-designed, ethically sound research aligns with the goals of medicine, addresses questions relevant to the population among whom the study will be carried out, balances the potential for benefit against the potential for harm, employs study designs that will yield scientifically valid and significant data, and generates useful knowledge. For example, research to develop biological or chemical weapons is antithetical to the goals of the medical profession, whereas research to develop defenses against such weapons can be ethically justifiable.

Physicians who engage in biomedical or health research with human participants thus have an ethical obligation to ensure that any study with which they are involved:

- (a) Is consistent with the goals and fundamental values of the medical profession.
- (b) Addresses research question(s) that will contribute meaningfully to medical knowledge and practice.
- (c) Is scientifically well designed to yield valid data to answer the research question(s), including using appropriate population and sampling controls, clear and appropriate inclusion/exclusion criteria, a statistically sound plan for data collection and analysis, appropriate controls, and when applicable, criteria for discontinuing the study (stopping rules).
- (d) Minimizes risks to participants, including risks associated with recruitment and data collection activities, without compromising scientific integrity.
- (e) Provides mechanisms to safeguard confidentiality.
- (f) Does not disproportionately recruit participants from historically disadvantaged populations or populations whose ability to provide fully voluntary consent is compromised. Participants who otherwise meet inclusion/exclusion criteria should be recruited without regard to race, ethnicity, gender, or economic status.
- (g) Recruits participants who lack the capacity to give informed consent only when the study stands to benefit that class of participants and participants with capacity would not yield valid results. In this event, assent should be sought from the participant and consent should be obtained from the prospective participant's legally authorized representative, in keeping with ethical guidelines.
- (h) Has been reviewed and approved by appropriate oversight bodies.

AMA Principles of Medical Ethics: I, II, III, V, VII

Inclusion of Women in Clinical Trials H-525.991

Our AMA: (1) encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; (2) supports the National Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and (3) encourages translation of important research results into practice.

Res 183, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 05, A-16

Use of Serotonin Reuptake Inhibitors in Pregnancy D-420.995

1. Our AMA encourages further research into the treatment of depression during pregnancy, including the effects of antidepressant drugs, as well as strategies designed to best protect the health and welfare of both the mother and the child.
 2. Our AMA Council on Science and Public Health will monitor the activities of relevant medical specialty societies on this issue, including development of practice guidelines or policy statements, and assist as needed in educating the physician community.
- CSAPH Rep. 13, A-07

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 910
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire,
Rhode Island, Vermont

Subject: Disparities in Public Education as a Crisis in Public Health
and Civil Rights

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Conditions in the places where people live, learn, work, and play affect a wide range of health risks and outcomes. These conditions are known as social determinants of health (SDOH) <http://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health>; and

Whereas, Some have asserted that the triple aim of better health, improved health care delivery, and reduced cost can be achieved by attending to the social and environmental factors which contribute approximately half of the factors that may affect health (McGinnis JM, Williams-Russo P, Knickman JR. The case for more active policy attention to health promotion. *Health Aff* (Millwood). 2002;21(2):78-93); and

Whereas, There are persistent racial and ethnic disparities in educational attainment: a representative example being reading proficiency at 4th grade level (2013 Data, National Assessment of Educational Progress (NAEP), ED/NCES); and

Whereas, The equal protection clause of the 14th Amendment requires that when a state establishes a public school system, no child living in that state may be denied equal access to schooling (US Supreme Court ruling in *Plyer v Doe*); and

Whereas, Many of social determinants of health, including education, nutrition, housing and neighborhood safety, may fall outside the expertise of the house of medicine, and would be difficult for the AMA to study in a depth that would be adequate to the task, this should not preclude the AMA from taking a thoughtful public policy position that may be used in subsequent advocacy where the opportunity presents itself; therefore be it

RESOLVED That our American Medical Association consider continued educational disparities based on ethnicity, race and economic status a detriment to the health of the nation (New HOD Policy); and be it further

RESOLVED That our AMA issue a call to action to all educational private and public stakeholders to come together to organize and examine, and using any and all available scientific evidence, to propose strategies, regulation and/or legislation to further the access of all children to a quality public education as one of the great unmet health and civil rights challenges of the 21st century. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.
Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 911
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire,
Rhode Island, Vermont

Subject: Importance of Oral Health in Medical Practice

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Good oral health is a crucial part of good health, yet millions of Americans lack access to basic oral health care largely due to its high cost and poor coverage;^{1,2,3,5} and

Whereas, Healthy People 2020 made oral health one of its top nine health indicators, yet only 41.8% of people age two years and older had a dental visit during the past 12 months, and half of the U.S. seniors perceive their dental health as poor or very poor;⁸ and

Whereas, Poor oral hygiene resulting in periodontal and gum disease is strongly associated with multiple medical issues, including heart disease, stroke, diabetes, respiratory disease, and oropharyngeal cancers;^{4,5,10} and

Whereas, According to the 2011 Institute of Medicine report “Advancing Oral Health in America”, if low-income patients are not accessing dental care, visits with their primary care physicians may represent an opportunity to evaluate their oral health,⁴ but such physicians currently rarely have adequate training to recognize oral health problems; and

Whereas, In 2014, the American Academy of Family Physicians and joint partners including the American Academy of Pediatrics, released a report entitled “Interprofessional Study of Oral Health in Primary Care,” that sought to identify elements that lead to successful promotion of oral health services in primary care offices;⁶ and

Whereas, With proper training, non-dental healthcare professionals, such as physicians, nurses, pharmacists, and physician assistants, can screen for oral diseases and deliver preventive care services;^{5,9} therefore be it

RESOLVED, That our American Medical Association recognize the importance of managing oral health as a part of overall patient care (New HOD Policy); and be it further

RESOLVED, That our AMA support efforts to educate physicians on oral condition screening and management, as well as the consequences of poor oral hygiene on mental and physical health (New HOD Policy); and be it further

RESOLVED, That our AMA encourage closer collaboration of physicians with dental providers to provide comprehensive medical care (New HOD Policy); and be it further

RESOLVED, That the AMA support efforts to increase access to oral health services. (New HOD Policy)

References:

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Fiscal Note: Minimal - less than \$1,000.

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RELEVANT AMA POLICY

Coverage of Children's Deformities, Disfigurement and Congenital Defects H-185.967

1. The AMA declares: (a) that treatment of a minor child's congenital or developmental deformity or disorder due to trauma or malignant disease should be covered by all insurers; (b) that such coverage shall include treatment which, in the opinion of the treating physician, is medically necessary to return the patient to a more normal appearance (even if the procedure does not materially affect the function of the body part being treated); and (c) that such insurability should be portable, i.e., not denied as a pre-existing condition if the patient's insurance coverage changes before treatment has been either initiated or completed.

2. Our AMA will advocate for appropriate funding for comprehensive dental coverage (including dental implants) for children with orofacial clefting.

(Sub. Res. 119, I-97; Reaffirmed, A-03; Reaffirmation A-05; Reaffirmation A-08; Appended: Res. 109, A-13)

Non Physicians' Expanded Scope of Practice (Laboratory Testing and Test Interpretation) D-35.999

Our AMA, through appropriate legislative and regulatory efforts, seeks to: (1) ensure that diagnostic laboratory testing should only be performed by those individuals who possess appropriate clinical education and training, under the supervision of licensed physicians (MD/DO); and (2) limit laboratory test ordering and interpretation of test results solely to licensed physicians (MD/DO) and licensed dentists (DDS/DMD).

(Sub. Res. 307, A-00; Reaffirmed: CME Rep. 2, A-10)

Funding for Teaching Health Center Graduate Medical Education Program D-305.955

Our American Medical Association will encourage Congress to reauthorize the Teaching Health Center Graduate Medical Educational Program to its full and ongoing funding needs to continue the training of primary providers in community based health centers in underserved areas to assure a continuing supply of primary providers and dentists for the underserved populations.

(Res. 214, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 912
(I-16)

Introduced by: American Academy of Pain Medicine
Subject: Neuropathic Pain Recognized as a Disease
Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, Neuropathic pain is characterized by neuroplastic changes that cause sensitization of
2 the nervous system. Those changes result in anatomical and physiological changes that affect
3 neurological function, result in long-term potentiation and gene expression changes that then
4 allow the pain to continue with or without any further peripheral input, lower pain threshold, and
5 this dysfunction then also accounts for the epiphenomena associated with the disease, including
6 cognitive, emotional, memory, and motor changes, which then becomes the illness of chronic
7 pain; and

8
9 Whereas, The Institute of Medicine Report “Relieving Pain in America, A Blueprint for
10 Transforming Prevention, Care, Education, and Research,” released June 29, 2011, and the
11 National Pain Strategy, released on March 19, 2016, have suggested chronic (neuropathic) pain
12 as a disease; and

13
14 Whereas, All types of chronic pain has neuropathic pain as part of the illness and our AMA
15 CSAPH has tacitly referred to chronic neuropathic pain as a disease; and

16
17 Whereas, The designation of neuropathic pain as a disease will have significant benefits for
18 research, funding, education, and applications to improve clinical practice, such as reducing the
19 opioid crisis we currently face; and

20
21 Whereas, Our AMA has declared alcoholism, addiction, and obesity as diseases, using similar
22 criteria; therefore be it

23
24 RESOLVED, That our American Medical Association recognize neuropathic pain as a disease
25 state with multiple pathophysiological aspects requiring a range of interventions to advance
26 neuropathic pain treatment and prevention. (New HOD Policy)

References:

1. Institute of Medicine Report Relieving Pain in America, A Blueprint for Transforming Prevention, Care, Education, and Research, released June 29, 2011.
2. iprcc.nih.gov/National_Pain_Strategy/NPS_Main.htm; March 2016.
3. CSAPH Report: Neuropathic Pain (A-06).
4. CSAPH Report: Maladyria: Pathophysiology and Nonpharmacologic Treatment (A-10).

Fiscal Note: Minimal - less than \$1,000.

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 913
(I-16)

Introduced by: Medical Student Section

Subject: Improving Genetic Testing and Counseling Services in Hospitals and Healthcare Systems

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Advances in genetic sequencing and testing technology have made genetic tests increasingly available to physicians and the public and expanded the amount of genetic data available to both patients and providers;¹ and

Whereas, The applications of genetic testing across medicine are expanding, including into such areas as whole-genome sequencing, carrier testing, prenatal testing, preimplantation testing, newborn screening, and predictive testing;^{2,3} and

Whereas, Genetic specialists, such as board-certified genetic counselors and board-certified medical geneticists are trained to assess and counsel patients on the physical, mental, social, and emotional impacts of genetic conditions;^{4,5} and

Whereas, Some physicians feel insufficiently prepared to counsel patients on genetic testing results due to a lack of knowledge and skills; perceived ethical, legal, and social implications; lack of access to genetics services such as consults; and difficulty in understanding the clinical impact of genetic tests;^{4,6,7} and

Whereas, Seventy-five percent of hospital-based primary care physicians in the US in a national survey stated that they have no access to genetics expertise if needed;⁵ and

Whereas, Pursuant to existing AMA Policy H-460.908, the AMA will continue to represent physicians' voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based personalized medicine; therefore be it

RESOLVED, That our American Medical Association support efforts to assess the usage of genetic testing and need for counseling services, physician preparedness in counseling patients or referring them to board-certified genetics specialists (New HOD Policy); and be it further

¹ Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society. (2008) "U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services." 1(192). Available at http://osp.od.nih.gov/sites/default/files/SACGHS_oversight_report.pdf

² UnitedHealth Group. (2012) "Personalized Medicine: Trends and Prospects for the New Science of Genetic Testing and Molecular Diagnostics." Available at <http://www.unitedhealthgroup.com/~media/uhg/pdf/2012/unh-working-paper-7.ashx>

³ National Library of Medicine. (2016) "What Are the Types of Genetic Tests?." Genetics Home Reference. Available at <https://ghr.nlm.nih.gov/primer/testing/uses>

⁴ Shelton CA and Whitcomb DC. (2015) Evolving Roles for Physicians and Genetic Counselors in Managing Complex Genetic Disorders. Clin Trans Gastroenterol, 6, e124. doi:10.1038/ctg.2015.46

⁵ Haga SB, Burke W, and Agans R. (2013) Primary-care physicians' access to genetic specialists: an impediment to the routine use of genomic medicine?. Genetics in Medicine, 15: 513–514. doi:10.1038/gim.2012.168.

⁶ Burke W and Korngiebel DM. (2015) Closing the Gap between Knowledge and Clinical Application: Challenges for Genomic Translation. PLoS Genetics, 11(2), e1004978. <http://doi.org/10.1371/journal.pgen.1004978>

⁷ Mikat-Stevens NA, Larson IA, and Tarini BA. (2015) Primary-care providers' perceived barriers to integration of genetics services: A systematic review of the literature. Genetics in Medicine, 17(3): 169-176

1 RESOLVED, That our AMA encourage efforts to create and disseminate guidelines for best
2 practice standards concerning counseling for genetic test results (New HOD Policy); and be it
3 further
4

5 RESOLVED, That our AMA support further research into and open discourse concerning issues
6 in medical genetics, including the genetic specialist workforce shortage, physician preparedness
7 in the provision of genetic testing and counseling services, and impact of genetic test results
8 and counseling on patient satisfaction. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/29/16

RELEVANT AMA POLICY

Genomic-Based Personalized Medicine H-460.908 - Our AMA: (1) acknowledges the increasingly important role of genomic-based personalized medicine applications in the delivery of care, and will continue to assist in informing physicians about relevant personalized medicine issues; (2) will continue to develop educational resources and point-of-care tools to assist in the clinical implementation of genomic-based personalized medicine applications, and will continue to explore external collaborations and additional funding sources for such projects; and (3) will continue to represent physicians' voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based personalized medicine, such as genetic test regulation, clinical validity and utility evidence development, insurance coverage of genetic services, direct-to-consumer genetic testing, and privacy of genetic information.
CSAPH Rep. 4, A-10

Genomic and Molecular-based Personalized Health Care D-460.976 - Our AMA will: (1) continue to recognize the need for possible adaptation of the US health care system to prospectively prevent the development of disease by ethically using genomics, proteomics, metabolomics, imaging and other advanced diagnostics, along with standardized informatics tools to develop individual risk assessments and personal health plans; (2) support studies aimed at determining the viability of prospective care models and measures that will assist in creating a stronger focus on prospective care in the US health care system; (3) support research and discussion regarding the multidimensional ethical issues related to prospective care models, such as genetic testing; (4) maintain a visible presence in genetics and molecular medicine, including web-based resources and the development of educational materials, to assist in educating physicians about relevant clinical practice issues related to genomics as they develop; and (5) promote the appropriate use of pharmacogenomics in drug development and clinical trials.
CSAPH Rep. 4, A-06 Reaffirmed: CSAPH Rep. 4, A-10

Medical Genetics D-460.996 - Our AMA will join with the American College of Medical Genetics and other professional and lay organizations to: (1) Publicize the resources and services offered by medical genetics professionals to other medical specialties; and (2) advocate for federal funding specifically targeted to the development and stable support of a clinical genetics infrastructure commensurate with the application of new genetic knowledge to the prevention and treatment of human disease.
Res. 527, A-99 Modified and Reaffirmed: CSAPH Rep. 1, A-09

Genetics Testing Legislation H-460.931 - The AMA opposes legislative initiatives on genetic testing that would unduly restrict the ability to use stored tissue for medical research; and will

continue to support existing federal and private accreditation and quality assurance programs designed to ensure the accuracy and reliability of tests, but oppose legislation that could establish redundant or duplicative federal programs of quality assurance in genetic testing.
Sub. Res. 219, I-96 Reaffirmed: CSAPH Rep. 3, A-06 Reaffirmed: CEJA Rep. 6, A-11

Multiplex DNA Testing for Genetic Conditions H-480.966 - Policy of the AMA is that: (1) tests for more than one genetic condition should be ordered only when clinically relevant and after the patient or parent/guardian has had full counseling and has given informed consent; (2) efforts should be made to educate clinicians and society about genetic testing; and (3) before genetic testing, patients should be counseled on the familial implications of genetic test results, including the importance of sharing results in instances where there is a high likelihood that a relative is at risk of serious harm, and where the relative could benefit from early monitoring or from treatment.

CEJA Rep. 1, I-96 Appended: BOT Rep. 16, I-99 Modified: CSA Rep. 3, A-03 Modified: CSAPH Rep. 1, A-13

Genetic Susceptibility Testing for Hereditary Cancers H-55.979 - (1) That physicians who feel unprepared to provide comprehensive genetic test counseling should refer candidates for genetic susceptibility testing to specialized care centers with experience and expertise in hereditary cancers or to investigators for relevant research, where family history can be confirmed and they can be tested if they so choose. (2) That genetic susceptibility testing, including that marketed directly to consumers, should be provided only in the context of fully informed consent and comprehensive pre- and post-test counseling by a qualified health care professional.

CSA Rep. 7, I-96 Reaffirmed: CSAPH Rep. 3, A-06 Modified: BOT Rep. 7, A-08

Direct-to-Consumer Marketing and Availability of Genetic Testing D-480.987 - Our AMA: (1) recommends that genetic testing be carried out under the personal supervision of a qualified health care professional; (2) encourages individuals interested in obtaining genetic testing to contact a qualified healthcare professional for further information; (3) will work with relevant organizations to develop criteria on what constitutes an acceptable advertisement for a direct-to-consumer genetic test; (4) encourages the U.S. Federal Trade Commission, with input from the U.S. Food and Drug Administration and the Centers for Medicare and Medicaid Services, to require that direct-to-consumer advertisements for genetic testing are truthful and not misleading; such advertisements should include all relevant information regarding capabilities and limitations of the tests, and contain a statement referring patients to physicians to obtain further information; (5) will work to educate and inform physicians regarding the types of genetic tests that are available directly to consumers, including information about the lack of scientific validity associated with some direct-to-consumer genetic tests, so that patients can be appropriately counseled on the potential harms.

Res. 502, A-04 Modified: BOT Rep. 7, A-08 Reaffirmed: CSAPH Rep. 4, A-10

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 914
(I-16)

Introduced by: Indiana
Subject: Needle / Syringe Disposal
Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, The abuse of oral opioids has been decreasing because of tighter controls on
2 prescriptions; and
3

4 Whereas, Due to restrictions on oral medications, some drug addicts are switching to
5 intravenous opioids in the form of heroin, fentanyl, etc.; and
6

7 Whereas, These intravenous drug abusers often have difficulty obtaining new needles/syringes,
8 so they resort to reusing needles/syringes; and
9

10 Whereas, These intravenous drug abusers have been known to collect used needles/syringes
11 from sharps containers in hospitals, clinics, medical offices, etc.; IV drug abusers are present in
12 these facilities as patients and visitors, but sometimes enter as unwelcome individuals on the
13 prowl for needles/syringes; and
14

15 Whereas, Reuse of needles/syringes is associated with an increased incidence of HIV, hepatitis
16 C, endocarditis, septic thrombophlebitis, cellulitis, soft tissue abscess, vascular injury, soft tissue
17 injury, etc.; and
18

19 Whereas, Diabetics and IV drug abusers sometimes will dispose of used needles/syringes in
20 public restrooms; therefore be it
21

22 RESOLVED, That our American Medical Association support the requirement that medical
23 facility needle/syringe disposal devices be as theft-proof and tamper-proof as possible; this
24 requirement could be established by rule or by statute (New HOD Policy); and be it further
25

26 RESOLVED, That our AMA support the requirement that stored used needles/syringes be
27 properly secured so as to discourage theft (New HOD Policy); and be it further
28

29 RESOLVED, That our AMA support the requirement that theft and tamper-proof containers be
30 placed in public restrooms for the purpose of needle/syringe disposal; an ideal device would
31 crush the syringe as part of the disposal process; (New HOD Policy) and be it further
32

33 RESOLVED, That our AMA encourage those communities with a significant IV drug abuse
34 population to establish a needle exchange program, since this helps eliminate the demand for
35 used needles/syringes. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/29/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 915
(I-16)

Introduced by: Women Physicians Section

Subject: Women and Alzheimer's Disease

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Women make up two-thirds of the more than 5 million individuals in this country currently suffering from and dying with Alzheimer's disease and related dementias; and

Whereas, Recent data suggest that women with early memory problems worsen significantly faster than men at the same stage of dementia; and

Whereas, An understanding of these sex and gender differences may lead to new diagnostic procedures and experimental treatment targets; and

Whereas, Sex [and gender] differences in the vulnerability to Alzheimer's could have implications on the design of clinical trials of potential treatments; therefore be it

RESOLVED, That our American Medical Association participate in efforts to raise awareness of the noted sex and gender differences in incidence and etiology of Alzheimer's disease and related dementias (Directive to Take Action); and be it further

RESOLVED, That our AMA make readily available to physicians the relevant guidelines for clinical decision making in the diagnosis and treatment of Alzheimer's disease and other dementias (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage physicians to consider performing regular cognitive testing as a part of wellness visit protocols for older adults, especially patients with increased risk of developing Alzheimer's disease and other forms of dementia, including, but not limited to, female sex, genetics, and cardiovascular co-morbidities (New HOD Policy); and be it further

RESOLVED, That our AMA encourage increased enrollment in clinical trials with all appropriate patients with Alzheimer's and related dementias, and their families, to better identify sex-differences in incidence and progression and to advance a treatment and cure of Alzheimer's and related dementia. (New HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

References:

1. Women and Alzheimer's Disease. http://www.alz.org/documents_custom/2014_facts_figures_fact_sheet_women.pdf.

2. Rocca WA, Mielke MM, Vemuri P, and Miller VM. Maturitas. 2014 Oct; 79(2):196-201. Sex and gender differences in the causes of dementia: a narrative review.

Women with Memory Impairment Deteriorate Faster than Men, Alzheimer's Study Shows. <http://www.wsj.com/articles/women-with-memory-impairment-deteriorate-faster-than-men-according-to-alzheimers-study-1437480061>.

RELEVANT AMA POLICY

Alzheimer's Disease H-25.991

The AMA:

- (1) encourages physicians to make appropriate use of guidelines for clinical decision making in the diagnosis and treatment of Alzheimer's disease and other dementias;
- (2) encourages physicians to make available information about community resources to facilitate appropriate and timely referral to supportive caregiver services;
- (3) encourages studies to determine the comparative cost-effectiveness/cost-benefit of assisted in-home care versus nursing home care for patients with Alzheimer's disease and related disorders;
- (4) encourages studies to determine how best to provide stable funding for the long-term care of patients with Alzheimer's disease and other dementing disorders; and
- (5) supports the use of evidence-based cost-effective technologies with prior consent of patients or designated healthcare power of attorney, as a solution to prevent, identify, and rescue missing patients with Alzheimer's disease and other related dementias with the help of appropriate allied specialty organizations.

CSA Rep. 6, I-97 Reaffirmed: CSAPH Rep. 3, A-07 Appended: Res. 503, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 916
(I-16)

Introduced by: Women Physicians Section

Subject: Women and Pre-Exposure Prophylaxis (PrEP)

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, According to the Centers for Disease Control and Prevention (CDC), women accounted for 19% of new HIV infections in the U.S. in 2014¹; and

Whereas, African American women are disproportionately affected, as they comprise 13% of the U.S. female population, but account for 64% of women living with HIV and 62% of new HIV cases among women¹; and

Whereas, Pre-exposure prophylaxis (PrEP) holds significant promise for women, as it does not require a partner's cooperation and instead enables greater control of one's sexual health and reproductive desires; and

Whereas, The CDC estimates that of the one million people in the U.S. who are eligible for PrEP, approximately 468,000 are cisgender (a person whose gender identity corresponds with the sex the person had or was identified as having at birth) women²; and

Whereas, The Office of Population Affairs updated its recommendations to explicitly state that prevention of sexually transmitted infection, including HIV prevention, is a core family planning service³; and

Whereas, Sixty percent of women access primary care through family planning providers⁹; and

Whereas, While a recent survey of family planning providers found that 75% of respondents believed HIV prevention education to be an essential part of family planning visits, 64-75% of these providers also reported great discomfort with educating their patients about PrEP, and even more were uncomfortable prescribing it¹⁰; and

Whereas, Of 340 family planning providers who took the survey, only 4% reported ever prescribing PrEP;¹⁰ therefore, be it

RESOLVED, Our American Medical Association partner with the appropriate organizations to increase community awareness about Pre-exposure prophylaxis (PrEP) by developing a women-focused PrEP education and social marketing campaign aimed at reaching PrEP eligible women in the U.S., particularly women of color (Directive to Take Action); and be it further

RESOLVED, Our AMA make readily available the current guidelines on Pre-exposure prophylaxis (PrEP) to increase knowledge and skills among family planning and other sexual and reproductive health care providers, particularly in areas with high HIV incidence (Directive to Take Action); and be it further

1 RESOLVED, That our AMA encourage residency programs (e.g., Obstetrics and Gynecology,
2 Family Medicine) to train future physicians to offer and administer HIV prevention services,
3 including Pre-exposure prophylaxis (PrEP), and improve providers' ability to respond holistically
4 to women living with and vulnerable to HIV (New HOD Policy); and be it further

6 RESOLVED, That our AMA encourage relevant organizations to develop training for physicians
7 on HIV prevention services, including Pre-exposure prophylaxis (PrEP) (New HOD Policy); and
8 be it further

10 RESOLVED, That our AMA encourage family planning, sexual health, and primary care
11 providers to facilitate the integration of Pre-exposure prophylaxis (PrEP) services within clinics
12 that serve HIV-vulnerable women and communities highly impacted by HIV. (Reaffirm HOD
13 Policy)

References:

1. Centers for Disease Control and Prevention (2016). HIV among women factsheet. Retrieved from www.cdc.gov/hiv/group/gender/women/.
2. Smith D.K., Van Handel M., Wolitski R.J. (2015). Vital signs: Estimated percentages and numbers of adults with indications for preexposure prophylaxis to prevent HIV acquisition - United States, 2015. Morbidity and Mortality Weekly Report, 64(46), 1291-1295. DOI: 10.15585/mmwr.mm6446a4.
3. Centers for Disease Control and Prevention (2014). Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm?s_cid=rr6304a1_w.
4. Baeten J.M., Donnell D., Mugo N.R. (2014). Single-agent tenofovir versus combination emtricitabine plus tenofovir for pre-exposure prophylaxis for HIV-1 acquisition: an update of data from a randomised, double-blind, phase 3 trial. Lancet Infect Diseases, 14(11), 1055-64. DOI:10.1016/S1473-3099(14)70937-5.
5. Mugo N.R., Hong T., Celum C., et al. (2014). Pregnancy incidence and outcomes among women receiving preexposure prophylaxis for HIV prevention a randomized clinical trial. Journal of the American Medical Association, 312(4), 362-371. DOI:10.1001/jama.2014.8735.
6. Foster C., Lyall H., Olmscheid B., et al. (2009). Tenofovir disoproxil fumarate in pregnancy and prevention of mother-to-child transmission of HIV-1: Is it time to move on from zidovudine? HIV Medicine, 10(7), 397-406.
7. Gibb D.M., Kizito H., Russell E.C., et al. (2012). Pregnancy and infant outcomes among HIV-infected women taking long-term ART with and without tenofovir in the DART trial. Plos Med, 9(5), e1001217.
8. Bush S., Magnuson D., Rawlings K.M., et al. (2016). Racial characteristics of FTC/TDF for pre-exposure Prophylaxis (PrEP) users in the US. Abstract 2651. Presented at American Society for Microbiology/ICAAC 2016, 16-20.
9. Kaiser Family Foundation. Women and HIV/AIDS in the United States factsheet, 2014. Retrieved from <http://kff.org/hiv/aids/factsheet/women-and-hiv/aids-in-the-united-states/>.
10. Seidman D., Carlson K., Weber S., Witt J., Kelly P.J. (2016). United States family planning providers' knowledge of and attitudes towards pre-exposure prophylaxis for HIV prevention: A national survey. Contraception, 93(5), 463-469. DOI: 10.1016/j.contraception.2015.12.018.
11. Smith D.K., Mendoza M.C.B., Stryker J.E., Rose C.E. PrEP awareness and attitudes in a national survey of primary care clinicians in the United States, 2009–2015. PLoS ONE, 11(6), e0156592. DOI:10.1371/journal.pone.0156592.

Fiscal Note: Estimated cost of \$40,000 for social media campaign for PrEP Awareness.

Received: 09/30/16

RELEVANT AMA POLICY

Pre-Exposure Prophylaxis for HIV H-20.895

1. Our AMA will educate physicians and the public about the effective use of pre-exposure prophylaxis for HIV and the US PrEP Clinical Practice Guidelines.
2. Our AMA supports the coverage of PrEP in all clinically appropriate circumstances.

Maternal HIV Screening and Treatment to Reduce the Risk of Perinatal HIV Transmission H-20.918

In view of the significance of the finding that treatment of HIV-infected pregnant women with appropriate antiretroviral therapy can reduce the risk of transmission of HIV to their infants, our AMA recommends the following statements:

- (1) Given the prevalence and distribution of HIV infection among women in the United States, the potential for effective early treatment of HIV infection in both women and their infants, and the significant reduction in perinatal HIV transmission with treatment of pregnant women with appropriate antiretroviral

therapy, routine education about HIV infection and testing should be part of a comprehensive health care program for all women. The ideal would be for all women to know their HIV status before considering pregnancy.

(2) Universal HIV testing of all pregnant women, with patient notification of the right of refusal, should be a routine component of perinatal care. Basic counseling on HIV prevention and treatment should also be provided to the patient, consistent with the principles of informed consent.

(3) The final decision about accepting HIV testing is the responsibility of the woman. The decision to consent to or refuse an HIV test should be voluntary. When the choice is to reject testing, the patient's refusal should be recorded. Test results should be confidential within the limits of existing law and the need to provide appropriate medical care for the woman and her infant.

(4) To assure that the intended results are being achieved, the proportion of pregnant women who have accepted or rejected HIV testing and follow-up care should be monitored and reviewed periodically at the appropriate practice, program or institutional level. Programs in which the proportion of women accepting HIV testing is low should evaluate their methods to determine how they can achieve greater success.

(5) Women who are not seen by a health care professional for prenatal care until late in pregnancy or after the onset of labor should be offered HIV testing at the earliest practical time, but not later than during the immediate postpartum period.

(6) When HIV infection is documented in a pregnant woman, proper post-test counseling should be provided. The patient should be given an appropriate medical evaluation of the stage of infection and full information about the recommended management plan for her own health. Information should be provided about the potential for reducing the risk of perinatal transmission of HIV infection to her infant through the use of antiretroviral therapy, and about the potential but unknown long-term risks to herself and her infant from the treatment course. The final decision to accept or reject antiretroviral treatment recommended for herself and her infant is the right and responsibility of the woman. When the woman's serostatus is either unknown or known to be positive, appropriate counseling should also be given regarding the risks associated with breast-feeding for both her own disease progression and disease transmission to the infant.

(7) Appropriate medical treatment for HIV-infected pregnant women should be determined on an individual basis using the latest published Centers for Disease Control and Prevention recommendations. The most appropriate care should be available regardless of the stage of HIV infection or the time during gestation at which the woman presents for prenatal or intrapartum care.

(8) To facilitate optimal medical care for women and their infants, HIV test results (both positive and negative) and associated management information should be available to the physicians taking care of both mother and infant. Ideally, this information will be included in the confidential medical records. Physicians providing care for a woman or her infant should obtain the appropriate consent and should notify the other involved physicians of the HIV status of and management information about the mother and infant, consistent with applicable state law.

(9) Continued research into new interventions is essential to further reduce the perinatal transmission of HIV, particularly the use of rapid HIV testing for women presenting in labor and for women presenting in the prenatal setting who may not return for test results. The long-term effects of antiretroviral therapy during pregnancy and the intrapartum period for both women and their infants also must be evaluated. For both infected and uninfected infants exposed to perinatal antiretroviral treatment, long-term follow-up studies are needed to assess potential complications such as organ system toxicity, neurodevelopmental problems, pubertal development problems, reproductive capacity, and development of neoplasms.

(10) Health care professionals should be educated about the benefits of universal HIV testing, with patient notification of the right of refusal, as a routine component of prenatal care, and barriers that may prevent implementation of universal HIV testing as a routine component of prenatal care should be addressed and removed. Federal funding for efforts to prevent perinatal HIV transmission, including both prenatal testing and appropriate care of HIV-infected women, should be maintained.

CSA Rep. 4, A-03 Reaffirmed: CEJA Rep. 3, A-10

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 917
(I-16)

Introduced by: Women Physicians Section

Subject: Youth Incarceration in Adult Prisons

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, Statistics reveal that thousands of children (some as young as 10 years old) in the
2 U.S. have been prosecuted as adults and sent to adult prisons; and
3

4 Whereas, According to the Prison Project, more than 34,000 youth and children ages 12-17
5 were incarcerated or housed in adult State or Federal prisons in 2016; and
6

7 Whereas, The Human Rights Watch and the American Civil Liberties Union have estimated that
8 the U.S. sends an extraordinary number of children to adult jails and prisons—totaling more
9 than 95,000 in 2011; and
10

11 Whereas, The Federal Bureau of Investigation defines violent crimes as those involving force or
12 threat of force, including murder and non-negligent manslaughter, forcible rape, robbery, and
13 aggravated assault; and
14

15 Whereas, More than 90% of youth incarceration is for non-violent crimes; and
16

17 Whereas, Some children are sentenced to life without parole or a sentence of capital
18 punishment; and
19

20 Whereas, The majority of the 50 states have laws that allow children to be sentenced and sent
21 to adult prisons; and
22

23 Whereas, Children placed in adult prisons, have almost no opportunity for meaningful
24 rehabilitation; and
25

26 Whereas, Due to the level of the emotional and physical development of children, juveniles are
27 vulnerable and ill-prepared to overcome the predatory behaviors prevalent in adult prisons; and
28

29 Whereas, Adult incarceration of children, including life sentencing in this manner does not
30 consider the socioeconomic plight and life journey of the child; and
31

32 Whereas, Children incarcerated in adult prisons are 7.7 times more likely to commit suicide,
33 while children placed in Juvenile Detention Facilities are less likely to commit suicide than their
34 corresponding age in the general population; and
35

36 Whereas, These children are also five times more likely to be sexually assaulted, and in one
37 survey as many as 50% have admitted to physical assault by inmates and guards; and

Whereas, California Senate Bill 260 gives juveniles once sentenced to adult prison, a chance to demonstrate remorse and rehabilitation once incarcerated, and establishes a parole process with different criteria; and

Whereas, The criminalization of children creates a permanent path which subtracts from the individual child and destroys their lives and our society as a whole; therefore be it

RESOLVED, That our American Medical Association oppose incarceration of children (individuals less than 18 years of age) in adult prisons for non-violent crimes (New HOD Policy); and be it further

RESOLVED, That our AMA work with appropriate organizations to address age cutoffs for children (individuals less than 18 years of age) in adult prisons (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for elimination of the incarceration of children (individuals less than 18 years of age) in adult prisons for non-violent crimes (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for the passage of legislation that addresses reform for children (individuals less than 18 years of age) in adult prisons with respect to developing appropriate guidelines for parole, expungement and sealing of records, and solitary confinement (Directive to Take Action); and be it further

RESOLVED, That our AMA support early intervention and rehabilitation for children (individuals 18 years of age or younger) that have been incarcerated in adult prisons. (New HOD Policy)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

References:

1. Equal Justice Initiative, Cruel and Unusual: Sentencing 13- and 14-Year-Old Children to Die in Prison, available at <http://eji.org/sites/default/files/discussion-guide-cruel-and-unusual.pdf>.
2. U.S. Department of Justice Office of Justice Programs Bureau of Justice Statistics 2011.
3. Puzzanchera, C. (2009). Juvenile arrests 2008. Juvenile Justice Bulletin, (Aug. 30, 2010). Retrieved from www.ojp.usdoj.gov.
4. Schiraldi, Vincent and Jason Zeidenberg. (1997) The Risks Juveniles Face When They Are Incarcerated With Adults.
5. Struckman-Johnson, Cindy and David Struckman Johnson. "Sexual Coercion Reported by Men and Women." The Journal of Sex Research, Vol. 33, No. 1, 1996.
6. Justice Policy Institute, http://www.justicepolicy.org/images/upload/97-02_rep_riskjuvenilesface_jj.pdf.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 918
(I-16)

Introduced by: American Society of Clinical Oncology

Subject: Ensuring Cancer Patient Access to Pain Medication

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, An alarming number of people are dying from opioid overdoses or suffering misuse
2 and abuse disorders; and
3

4 Whereas, The escalation of abuse, addiction, and diversion of opioids has led to an “opioid
5 epidemic”; and
6

7 Whereas, Congress, the Administration, multiple federal agencies, and state legislatures are
8 involved in efforts aimed at preventing and responding to opioid misuse and abuse; and
9

10 Whereas, Among cancer patients and cancer treatment survivors, it is widely acknowledged that
11 too much pain goes untreated and that opioids remain an essential part of many cancer and
12 cancer treatment associated pain treatment plans; and
13

14 Whereas, Barriers currently exist for cancer patients and survivors to access necessary pain
15 medications; and
16

17 Whereas, Cancer patients represent a special population given the nature of the disease, its
18 treatment, and potential life-long sequelae, and should be largely exempt from laws and
19 regulations that restrict access or limit doses; and
20

21 Whereas, In the care of patients with cancer, it is primarily one practice team, and in most
22 cases, one physician, who is longitudinally responsible for their care and prescribing; and
23

24 Whereas, There is broad agreement that opioid therapy is generally the first-line approach for
25 moderate to severe chronic pain associated with cancer and anti-cancer therapy; and
26

27 Whereas, Some elements of both state and federal tightening of controls could introduce further
28 barriers to appropriate treatment of pain related to cancer and its treatment, unintentionally
29 harming a vulnerable population; therefore be it

1 RESOLVED, That our American Medical Association Policy D-120.947, A More Uniform
2 Approach to Assessing and Treating Patients with Controlled Substances for Pain Relief, be
3 amended by addition as follows:

4
5 3. Our AMA will work diligently with the Centers for Disease Control and Prevention
6 and other regulatory agencies to provide increased leeway in the interpretation of the
7 new guidelines for appropriate prescription of opioid medications in long-term care
8 facilities and in the care of patients with cancer and cancer survivors, in much the
9 same way as is being done for hospice and palliative care. (Modify Current HOD
10 Policy)
11

12 RESOLVED, That our AMA advocate and support advocacy at the state and federal levels
13 against arbitrary prescription limits that restrict access to medically necessary treatment by
14 limiting the dose, amount or days of the first or subsequent prescription for patients with pain
15 related to a cancer or terminal diagnosis. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

A More Uniform Approach to Assessing and Treating Patients for Controlled Substances for Pain Relief D-120.947

1. Our AMA will consult with relevant Federation partners and consider developing by consensus a set of best practices to help inform the appropriate clinical use of opioid analgesics, including risk assessment and monitoring for substance use disorders, in the management of persistent pain.

2. Our AMA will urge the Centers for Disease Control and Prevention to take the lead in promoting a standard approach to documenting and assessing unintentional poisonings and deaths involving prescription opioids, including obtaining more complete information on other contributing factors in such individuals, in order to develop the most appropriate solutions to prevent these incidents.

3. Our AMA will work diligently with the Centers for Disease Control and Prevention and other regulatory agencies to provide increased leeway in the interpretation of the new guidelines for appropriate prescription of opioid medications in long-term care facilities, in much the same way as is being done for hospice and palliative care.

BOT Rep. 3, I-13 Appended: Res. 522, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 919
(I-16)

Introduced by: Michigan

Subject: Coal-Tar-Based Sealcoat Threat to Human Health and the Environment

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, Coal-tar-based sealcoats, containing a high concentration of polycyclic aromatic
2 hydrocarbons (PAH), are commonly used and applied widely on various forms of pavement and
3 playgrounds as a form of maintenance; and
4

5 Whereas, Application of products containing high PAH concentration comes with adverse health
6 and environmental consequences; and
7

8 Whereas, PAH compounds have been proven to be carcinogenic, mutagenic, and teratogenic to
9 humans according to the International Agency for Research on Cancer; and
10

11 Whereas, Application of these sealcoats to pavements and playgrounds erodes and evaporates
12 over time causing chemicals, and specifically PAH, to leach into the water, soil, and air; and
13

14 Whereas, Alternatives including asphalt, acrylic, or latex sealcoats with low or no PAH exist at a
15 similar cost; some even argue that sealing is not necessary, as it is more cost effective to
16 repave occasionally rather than to sealcoat regularly; and
17

18 Whereas, Individuals with lifelong exposure to coal-tar sealcoat treated pavements and
19 playgrounds have a 38-fold higher risk of cancer; and
20

21 Whereas, Studies show 50-75 percent of PAH found in the Great Lakes sediment originates
22 from coal tar sealcoats, which eventually ends up in the aquatic wildlife including those species
23 consumed by people; and
24

25 Whereas, Washington, DC, Minnesota, Washington, and counties, townships, and
26 municipalities in many other states including Michigan have banned the use of coal-tar
27 sealcoats; therefore be it
28

29 RESOLVED, That our American Medical Association advocate for national legislation to ban the
30 use of pavement sealcoats that contain polycyclic aromatic hydrocarbons (PAH); or at least, use
31 sealcoat products that contain low or no PAH, specifically products where the concentration of
32 PAH is less than 1/1000th the concentration in coal-tar sealcoats. (Directive to Take Action)

References:

1. International Agency for Research on Cancer, 1987. Coal-tar Pitches.
2. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Supplement 7, pp 174-175.
3. Van Metre, Peter C., and Barbara J. Mahler. "Contribution of PAHs from coal-tar pavement sealcoat and other sources to 40 US lakes." *Science of the Total Environment* 409.2 (2010): 334-344.
4. Mahler, Barbara J., et al. "Acute toxicity of runoff from seal coated pavement to *Ceriodaphnia dubia* and *Pimephales promelas*." *Environmental Science & Technology* 49.8 (2015): 5060-5069.
5. Mahler, Barbara J., et al. "Coal-tar-based pavement sealcoat and PAHs: implications for the environment, human health, and stormwater management." *Environmental Science & Technology* 46.6 (2012): 3039-3045.
6. D.C. Code § 8-153.01
7. Washington, Chapter 70.295 RCW Minnesota, 116.202 (2015)
8. Action to Restrict or Discontinue the Use of Coal Tar-Based Sealants in the United States, Minnesota Pollution Control Agency (2014) pca.state.mn.us

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 920
(I-16)

Introduced by: Michigan

Subject: Haptention and Hypersensitivity Disorders Communication

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Chemical and/or metal sensitization (e.g., due to cosmetics, medications, and fumes) is poorly understood and grossly under-recognized by physicians; and

Whereas, Haptention is a known and well documented physiologic process occurring in humans, creating symptoms and disease; therefore be it

RESOLVED, That our American Medical Association re-engage its communication efforts to make physicians aware of the process of haptention and sensitization and their multiple ramifications, as well as to help physicians teach patients methods to avoid exposure to haptens, and to help physicians include chemical sensitivity in the differential diagnosis, take a history focused on exposures to toxins and symptoms related to known toxins and testing.
(Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

RELEVANT AMA POLICY

Modern Chemicals Policies D-135.987

Our AMA: (1) will call upon the United States government to implement a national modern, comprehensive chemicals policy that is in line with current scientific knowledge on human and environmental health, and that requires a full evaluation of the health impacts of both newly developed and industrial chemicals now in use; and (2) encourages the training of medical students, physicians, and other health professionals about the human health effects of toxic chemical exposures.

Citation: (Sub. Res. 404, A-08; Reaffirmation A-10)

Modern Chemicals Policies H-135.942

Our AMA supports: (1) the restructuring of the Toxic Substances Control Act to serve as a vehicle to help federal and state agencies to assess efficiently the human and environmental health hazards of industrial chemicals and reduce the use of those of greatest concern; and (2) the Strategic Approach to International Chemicals (SAICM) process leading to the sound management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that minimize adverse effects on human health and the environment.

Citation: (Sub. Res. 404, A-08; Reaffirmation A-10; Reaffirmed: CSAPH Rep. 5, A-11)

Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976 D-135.976

Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and (3) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).

Citation: (Res. 515, A-12; Modified: Res. 907, I-13; Reaffirmation I-13)

Human and Environmental Health Impacts of Chlorinated Chemicals H-135.956

The AMA: (1) encourages the Environmental Protection Agency to base its evaluations of the potential public health and environmental risks posed by exposure to an individual chlorinated organic compound, other industrial compound, or manufacturing process on reliable data specific to that compound or process; (2) encourages the chemical industry to increase knowledge of the environmental behavior, bioaccumulation potential, and toxicology of their products and by-products; and (3) supports the implementation of risk reduction practices by the chemical and manufacturing industries.

Citation: (Sub. Res. 503, A-94; Reaffirmation I-98; Reaffirmed: CSAPH Rep. 2, A-08)

Green Initiatives and the Health Care Community H-135.939

Our AMA supports: (1) responsible waste management policies, including the promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are non-toxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities.

Citation: CSAPH Rep. 1, I-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 402, A-10; Reaffirmed in lieu of: Res. 504, A-16

Education and Prevention Programs Regarding Air Pollution Impact on Body Organs and Systems H-135.954

The AMA will provide leadership and participate in a major air pollution education and prevention program carried out by the health care community, in cooperation with environmental organizations and business, to inform patients and the public of the negative health effects of indoor and outdoor air pollution on the organs and systems of the body.

Citation: Res. 404, I-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation I-06; Rescinded: CSAPH Rep. 01, A-16;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 921
(I-16)

Introduced by: Michigan

Subject: Raise the Minimum Age of Legal Access to Tobacco to 21 Years

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Over the past 50 years, tobacco control in the United States has led to an estimated eight million fewer premature deaths, and

Whereas, Tobacco use continues to significantly affect public health, and more than 40 million Americans still smoke, and

Whereas, A recent Institute of Medicine report projected a 12 percent decrease in smoking prevalence if the minimum age of legal access to tobacco products was raised to 21 years; therefore be it

RESOLVED: That our American Medical Association reaffirm its support for raising the minimum age of legal access to tobacco products to 21 years. (Reaffirm HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986

H-495.986 Tobacco Product Sales and Distribution

Our AMA: (1) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors; (2) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age; (3) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors; (4) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products; (5) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products; (6) opposes the distribution of free tobacco products by any means and supports the enactment of legislation

prohibiting the disbursement of samples of tobacco and tobacco products by mail; (7) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; (8) opposes the sale of tobacco at any facility where health services are provided; and (9) supports that the sale of tobacco products be restricted to tobacco specialty stores.

CSA Rep. 3, A-04 Appended: Res. 413, A-04 Reaffirmation A-07 Amended: Res. 817, I-07 Reaffirmation A-08 Reaffirmation I-08 Reaffirmation A-09 Reaffirmation I-13 Reaffirmation A-14 Reaffirmation I-14 Reaffirmation A-15 Modified in lieu of Res. 421, A-15 Modified in lieu of Res. 424, A-15

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 922
(I-16)

Introduced by: Michigan

Subject: Responsible Parenting and Access to Family Planning

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, Nearly 50 percent of the pregnancies in the United States of America are unplanned;
and

Whereas, Michigan's recent information shows that only 33 percent of reproductive age women
with a chronic deteriorating medical condition receive prescribed contraception in spite of their
increased risk for obstetrical adverse outcomes; and

Whereas, A significant number of those pregnancies impact the birth outcome and the short and
long term health of the newborn and frequently increase the maternal risk for significant
morbidity or even mortality; and

Whereas, Family planning services and methods should be considered an essential health care
service no different than any other form of health care; and

Whereas, These services must not depend on the woman's ability to pay and must be included
within any health care coverage that facilitates the woman's access to obtain it; therefore be it

RESOLVED, That our American Medical Association reaffirm its commitment to work with all of
the national medical societies and other interested organizations involved in women's health
care to ensure the education of women on the proper use of Food and Drug Administration-
approved methods of family planning and assure that reproductive counseling is accessible and
appropriately funded. (Reaffirm HOD Policy)

Reference(s):

1. Receipt of prescription contraception by commercially insured women with chronic medical conditions. DeNoble AE, Hall KS, Xu, X, Zochowski MK, Piehl K, Dalton VK. Obstet Gynecol 2014. 123(6) 1213-20
2. Health insurance coverage and prescription contraceptive use among young women at risk for unintended pregnancy. Nearn J. Contraception, 2009. 79 (2) 105-10
3. American College of Obstetricians & Gynecologists, Improve access to contraception. December 22, 2014
4. Return on investment A fuller assessment of the benefits and cost savings of the US publicly funded family planning program. Frost JJ, Sonfield A, Zolna MR, Finer LB. Milbank Q. 2014. 92 (4) 696-749

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

Reducing Unintended Pregnancy H-75.987

Our AMA: (1) urges health care professionals to provide care for women of reproductive age, to assist them in planning for pregnancy and support age-appropriate education in esteem building, decision-making and family life in an effort to introduce the concept of planning for childbearing in the educational process; (2) supports reducing unintended pregnancies as a national goal; and (3) supports the training of all primary care physicians and relevant allied health professionals in the area of preconception counseling, including the recognition of long-acting reversible contraceptives as efficacious and economical forms of contraception.

Res. 512, A-97 Reaffirmed: CSAPH Rep. 3, A-07 Reaffirmation A-15 Appended: Res. 502, A-15

Extension of Medicaid Coverage for Family Planning Services H-75.988

The AMA supports legislation that will allow states to extend Medicaid coverage for contraceptive education and services for at least two years postpartum for all eligible women.

Sub. Res. 201, I-93 Reaffirmed: BOT Rep. 28, A-03 Modified: CMS Rep. 4, A-13

Family Planning Clinic Funds H-75.992

Our AMA supports the concept of adequate funding for family planning programs.

Res. 102, A-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10 Reaffirmed: Res. 227, A-11

Support for Access to Preventive and Reproductive Health Services H-425.969

Our AMA supports access to preventive and reproductive health services for all patients and opposes legislative and regulatory actions that utilize federal or state health care funding mechanisms to deny established and accepted medical care to any segment of the population.

Sub. Res. 224, I-15

Preconception Care H-425.976

1. Our AMA supports the 10 recommendations developed by the Centers for Disease Control and Prevention for improving preconception health care that state:

(1) Individual responsibility across the lifespan--each woman, man, and couple should be encouraged to have a reproductive life plan;

(2) Consumer awareness--increase public awareness of the importance of preconception health behaviors and preconception care services by using information and tools appropriate across various ages; literacy, including health literacy; and cultural/linguistic contexts;

(3) Preventive visits--as a part of primary care visits, provide risk assessment and educational and health promotion counseling to all women of childbearing age to reduce reproductive risks and improve pregnancy outcomes;

(4) Interventions for identified risks--increase the proportion of women who receive interventions as follow-up to preconception risk screening, focusing on high priority interventions (i.e., those with evidence of effectiveness and greatest potential impact);

(5) Inter-conception care--use the inter-conception period to provide additional intensive interventions to women who have had a previous pregnancy that ended in an adverse outcome (i.e., infant death, fetal loss, birth defects, low birth weight, or preterm birth);

(6) Pre-pregnancy checkup--offer, as a component of maternity care, one pre-pregnancy visit for couples and persons planning pregnancy;

(7) Health insurance coverage for women with low incomes--increase public and private health insurance coverage for women with low incomes to improve access to preventive women's health and pre-conception and inter-conception care;

(8) Public health programs and strategies--integrate components of pre-conception health into existing local public health and related programs, including emphasis on inter-conception interventions for women with previous adverse outcomes;

(9) Research--increase the evidence base and promote the use of the evidence to improve preconception health; and

(10) Monitoring improvements--maximize public health surveillance and related research mechanisms to monitor preconception health.

2. Our AMA supports the education of physicians and the public about the importance of preconception care as a vital component of a woman's reproductive health.

Res. 414, A-06 Reaffirmation I-07

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 923
(I-16)

Introduced by: Michigan

Subject: Reverse Onus in the Manufacture and Use of Chemicals

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, Michigan and the Great Lakes region continue to suffer significant chemical
2 contamination as a result of past manufacturing practices and inadequate business and
3 governmental stewardship; and
4

5 Whereas, This historic contamination, particularly by bio-accumulative, persistent chemicals
6 continues to affect the environment and human health; and
7

8 Whereas, Some chemical contaminants, including pesticides and herbicides in the Great Lakes
9 ecosystem have been associated with developmental delays and neurological impairments in
10 children and other human health effects; and
11

12 Whereas, There is continuing concern about the potential environmental and human health
13 impacts of chemicals still in common use; and
14

15 Whereas, Exposure of the environment and human health to chemicals that are later found to
16 have significant health impacts can result in irreversible health problems in those exposed, as
17 well as significant costs to industry and government for clean-up; and
18

19 Whereas, The state of Michigan has a responsibility to exercise leadership in protection of the
20 Great Lakes ecosystem by virtue of its geographic position at the heart of the Great Lakes basin
21 and the linkage between the health of the lakes and the health of Michigan; therefore be it
22

23 RESOLVED, That our American Medical Association reaffirm its commitment to encourage the
24 Environmental Protection Agency to do the following:

- 25 - Adopt and advocate policies that prevent avoidable harm to the environment and human
26 health by placing the burden of proof, where there is scientific evidence of harm, for the
27 safety of chemicals on those manufacturing, handling, importing, or proposing to
28 introduce into commerce such chemicals prior to their use;
- 29 - Adopt and advocate policies based on the precautionary principle where there is scientific
30 evidence of harm, which holds that when an activity raises threats of harm to human
31 health or the environment, precautionary measures should be taken;
- 32 - Ensure the burden of proof should be on the user or producer of a hazardous chemical or
33 product to convince government authorities that the product does not deserve to be
34 restricted and that it is the least damaging alternative available; and,
- 35 - Adopt policies discouraging use of substances that are persistent and liable to bio-
36 accumulate and advocate adoption of federal laws and policies that ban the use of such
37 substances. (Reaffirm HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/30/16

RELEVANT AMA POLICY

Modern Chemicals Policies D-135.987

Our AMA: (1) will call upon the United States government to implement a national modern, comprehensive chemicals policy that is in line with current scientific knowledge on human and environmental health, and that requires a full evaluation of the health impacts of both newly developed and industrial chemicals now in use; and (2) encourages the training of medical students, physicians, and other health professionals about the human health effects of toxic chemical exposures.

Citation: (Sub. Res. 404, A-08; Reaffirmation A-10)

Modern Chemicals Policies H-135.942

Our AMA supports: (1) the restructuring of the Toxic Substances Control Act to serve as a vehicle to help federal and state agencies to assess efficiently the human and environmental health hazards of industrial chemicals and reduce the use of those of greatest concern; and (2) the Strategic Approach to International Chemicals (SAICM) process leading to the sound management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that minimize adverse effects on human health and the environment.

Citation: (Sub. Res. 404, A-08; Reaffirmation A-10; Reaffirmed: CSAPH Rep. 5, A-11)

Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976 D-135.976

Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and (3) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).

Citation: (Res. 515, A-12; Modified: Res. 907, I-13; Reaffirmation I-13)

Human and Environmental Health Impacts of Chlorinated Chemicals H-135.956

The AMA: (1) encourages the Environmental Protection Agency to base its evaluations of the potential public health and environmental risks posed by exposure to an individual chlorinated organic compound, other industrial compound, or manufacturing process on reliable data specific to that compound or process; (2) encourages the chemical industry to increase knowledge of the environmental behavior, bioaccumulation potential, and toxicology of their products and by-products; and (3) supports the implementation of risk reduction practices by the chemical and manufacturing industries.

Citation: (Sub. Res. 503, A-94; Reaffirmation I-98; Reaffirmed: CSAPH Rep. 2, A-08)

EPA and Green House Gas Regulation H-135.934

Our AMA supports the Environmental Protection Agency's authority to promulgate rules to regulate and control greenhouse gas emissions in the United States.

Citation: (Res. 925, I-10; Reaffirmed in lieu of Res. 526, A-12; Reaffirmed: Res. 421, A-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 924
(I-16)

Introduced by: American Association of Public Health Physicians
Subject: AMA Advocacy for Environmental Sustainability and Climate
Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

Whereas, AMA policy recognizes “the potential adverse public health effects of global climate change” (AMA Policy H-135.938); and

Whereas, Adopting environmental sustainability and other measures to halt global climate change often saves money for physicians¹ and hospitals²; and

Whereas, AMA policies favor environmental education and stewardship (H-135.973, H-135.969, H-135.939) and the need for improved energy efficiency in our offices and medical centers (D-155.999), and other aspects of environmental sustainability but our AMA offers no programs to help physicians to implement these policies; and

Whereas, Our AMA does not have a policy that the AMA itself, representing America's doctors, will be an advocate for environmental sustainability and efforts to halt global climate change; and

Whereas, Our AMA has in the past taken advocacy positions on subjects which have broad potential impacts on human health, such as nuclear weapons testing, vaccinations, tobacco use, and chemical warfare; and

Whereas, Our AMA includes 40 topics as part of its advocacy mission³, yet environmental sustainability is not among them, despite the potential benefits to physician practices and the health risks posed by climate change; and

Whereas, A few state or specialty medical societies offer environmental sustainability programs to their members, which could be offered by the AMA at little cost; therefore be it

RESOLVED, That our American Medical Association develop a strategy to advocate for governments and other organizations to promote environmental sustainability and other efforts to halt global climate change (Directive to Take Action); and be it further

RESOLVED, That our AMA incorporate principles of environmental sustainability within its institutional mission and business operations (Directive to Take Action); and be it further

RESOLVED, That our AMA offer programs to physicians to assist them to adopt environmental sustainability in their practices and to help physicians to share these concepts with their patients and with their communities. (Directive to Take Action)

¹ “Florida Medical” 2007, pp 41-45

² Sustainable Healthcare (Wiley-Blackwell, 2013) p16

³ <http://www.ama-assn.org/ama/pub/advocacy/topics.page>

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 09/30/16

RELEVANT AMA POLICIES

Global Climate Change and Human Health H-135.938

Our AMA:

1. Supports the findings of the Intergovernmental Panel on Climate Change's fourth assessment report and concurs with the scientific consensus that the Earth is undergoing adverse global climate change and that anthropogenic contributions are significant. These climate changes will create conditions that affect public health, with disproportionate impacts on vulnerable populations, including children, the elderly, and the poor.
 2. Supports educating the medical community on the potential adverse public health effects of global climate change and incorporating the health implications of climate change into the spectrum of medical education, including topics such as population displacement, heat waves and drought, flooding, infectious and vector-borne diseases, and potable water supplies.
 3. (a) Recognizes the importance of physician involvement in policymaking at the state, national, and global level and supports efforts to search for novel, comprehensive, and economically sensitive approaches to mitigating climate change to protect the health of the public; and (b) recognizes that whatever the etiology of global climate change, policymakers should work to reduce human contributions to such changes.
 4. Encourages physicians to assist in educating patients and the public on environmentally sustainable practices, and to serve as role models for promoting environmental sustainability.
 5. Encourages physicians to work with local and state health departments to strengthen the public health infrastructure to ensure that the global health effects of climate change can be anticipated and responded to more efficiently, and that the AMA's Center for Public Health Preparedness and Disaster Response assist in this effort.
 6. Supports epidemiological, translational, clinical and basic science research necessary for evidence-based global climate change policy decisions related to health care and treatment.
- CSAPH Rep. 3, I-08 Reaffirmation A-14

Stewardship of the Environment H-135.973

- The AMA: (1) encourages physicians to be spokespersons for environmental stewardship, including the discussion of these issues when appropriate with patients;
- (2) encourages the medical community to cooperate in reducing or recycling waste;
 - (3) encourages physicians and the rest of the medical community to dispose of its medical waste in a safe and properly prescribed manner;
 - (4) supports enhancing the role of physicians and other scientists in environmental education;
 - (5) endorses legislation such as the National Environmental Education Act to increase public understanding of environmental degradation and its prevention;
 - (6) encourages research efforts at ascertaining the physiological and psychological effects of abrupt as well as chronic environmental changes;
 - (7) encourages international exchange of information relating to environmental degradation and the adverse human health effects resulting from environmental degradation;
 - (8) encourages and helps support physicians who participate actively in international planning and development conventions associated with improving the environment;
 - (9) encourages educational programs for worldwide family planning and control of population growth;
 - (10) encourages research and development programs for safer, more effective, and less expensive means of preventing unwanted pregnancy;
 - (11) encourages programs to prevent or reduce the human and environmental health impact

from global climate change and environmental degradation.

(12) encourages economic development programs for all nations that will be sustainable and yet nondestructive to the environment;

(13) encourages physicians and environmental scientists in the United States to continue to incorporate concerns for human health into current environmental research and public policy initiatives;

(14) encourages physician educators in medical schools, residency programs, and continuing medical education sessions to devote more attention to environmental health issues;

(15) will strengthen its liaison with appropriate environmental health agencies, including the National Institute of Environmental Health Sciences (NIEHS);

(16) encourages expanded funding for environmental research by the federal government; and

(17) encourages family planning through national and international support.

CSA Rep. G, I-89 Amended: CLRPD Rep. D, I-92 Amended: CSA Rep. 8, A-03 Reaffirmed in lieu of Res. 417, A-04 Reaffirmed in lieu of Res. 402, A-10

Environmental Health Programs H-135.969

Our AMA (1) urges the physicians of the United States to respond to the challenge for a clean environment individually and through professional groups by becoming the spokespersons for environmental stewardship; and (2) encourages state and county medical societies to establish active environmental health committees.

Res. 124, A-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10

Green Initiatives and the Health Care Community H-135.939

Our AMA supports: (1) responsible waste management policies, including the promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are non-toxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities.

CSAPH Rep. 1, I-08 Reaffirmation A-09 Reaffirmed in lieu of Res. 402, A-10 Reaffirmed in lieu of: Res. 504, A-16

Energy Efficiency and Medical Practice D-155.999

Our AMA will urge its individual members and organizational affiliates to participate in energy efficiency activities in all medical facilities including hospitals, clinics, offices and research facilities.

Res. 413, I-98 Reaffirmed: CLRPD Rep. 1, A-08

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 925
(I-16)

Introduced by: American College of Cardiology
Heart Rhythm Society
American Society of Echocardiography

Subject: Graphic Warning Label on all Cigarette Packages

Referred to: Reference Committee K
(Paul A. Friedrichs, MD, Chair)

1 Whereas, Diseases directly caused by cigarette tobacco smoking continue to be common,
2 resulting in death and disability of many Americans; and
3

4 Whereas, Positive advertising of cigarettes is known to promote smoking and is prohibited; and
5

6 Whereas, Negative advertising in the form of graphic warnings on cigarette packages is an
7 effective smoking deterrent; and
8

9 Whereas, The public health of the United States would be improved if smoking rates were
10 further reduced; and
11

12 Whereas, The Family Smoking Prevention and Control Act of 2009 required the Secretary of
13 Health and Human Services to issue regulations requiring color graphic depictions of the
14 negative health consequences of smoking to appear on all cigarette packages; and
15

16 Whereas, In 2011 the Food and Drug Administration finalized regulations establishing
17 requirements for graphic warning labels, but tobacco companies successfully challenged the
18 constitutionality of the requirements in federal appeals court; and
19

20 Whereas, The Department of Justice chose not to request Supreme Court review of the appeals
21 court decision and FDA has failed to issue revised regulations; therefore be it
22

23 RESOLVED, That our American Medical Association evaluate all opportunities for effective
24 advocacy by organized medicine to require graphic warning labels depicting the dangers of
25 smoking on all cigarette packages (Directive to Take Action); and be it further
26

27 RESOLVED, That our AMA endorse efforts of the Campaign for Tobacco Free Kids and the
28 Food and Drug Administration to require tobacco companies to include graphic warning labels
29 depicting the dangers of smoking on all cigarette packages. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 10/12/16

Informational Reports

BOT Report(s)

- 01 2016 AMA Advocacy Efforts
- 04 Redefining the AMA's Position on the ACA and Healthcare Reform - Update
- 10 AMA Initiatives on Pharmaceutical Costs
- 11 2017 Strategic Plan

CEJA Opinion(s)

- 01 Modernized Code of Medical Ethics
- 02 Ethical Practice in Telemedicine

CEJA Report(s)

- 03 CEJA and House of Delegates Collaboration
- 04 Ethical Physician Conduct in the Media

CSAPH Report(s)

- 02 National Drug Shortages: Update

REPORT 1 OF THE BOARD OF TRUSTEES (I-16)
2016 AMA Advocacy Efforts

EXECUTIVE SUMMARY

Policy G-640.005, “AMA Advocacy Analysis,” calls on the Board of Trustees (BOT) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year’s advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The BOT has prepared the following report to provide an update on 2016 American Medical Association (AMA) advocacy activities.

The AMA had a very productive year once again on the advocacy front led by our Board, Councils, and staff from the Advocacy Group, Strategic Focus Areas, Health and Science, Health Solutions, Enterprise Communications and Marketing, and other AMA units. Our collaborative efforts with the Federation are integral to our successes as well.

Implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), is a major task. The AMA is cognizant of the need to get this right at the practice and policymaking levels, and we are striving to do so. On the insurance merger front, we have had good success in challenging proposed mergers, but the final outcome will be decided in litigation. The opioid crisis continues to ravage our nation, but we are tackling this crisis head on and making progress on some key strategies. We are focusing on other top issues for medicine such as insurer networks, telemedicine, diabetes prevention, and addressing rising pharmaceutical costs. We also continue to call on our nation’s leaders to address Zika before it becomes a more dire situation and more children face lifelong health concerns and a diminished quality of life.

At the time of this writing, we do not know the federal election results, so the political environment in which we will seek to advance our goals in 2017 is to be determined. However, AMPAC is backing candidates who support physician and patient priorities. Our grassroots team will also promote our legislative priorities in 2017 through our various channels. We are also in contact with both presidential campaigns and will engage the presidential transition team to lay out our vision for health care reform on other key issues.

We appreciate the collaboration with the Federation in 2016, and look forward to further work and success in 2017 at the federal and state levels.

Staff note: This report was prepared in September 2016, and may be updated prior to the Interim Meeting based on more recent advocacy developments.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 1-I-16

Subject: 2016 AMA Advocacy Efforts

Presented by: Patrice A. Harris, MD, MA, Chair

Policy G-640.005, “AMA Advocacy Analysis,” calls on the Board of Trustees (BOT) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year’s advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The BOT has prepared the following report to provide an update on 2016 American Medical Association (AMA) advocacy activities.

DISCUSSION OF 2016 ADVOCACY EFFORTS

MACRA Implementation

With the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) behind us, our attention turned immediately to MACRA implementation through the regulatory process where numerous key decisions will be made. MACRA is a complex law, and the proposed regulations to implement it are long and complicated. Compared to the current Medicare physician payment framework, the MACRA law and proposed/final regulations provide significant improvements. Changes to the proposed rule are still needed, and we are advocating forcefully to achieve them in order to reduce regulatory burdens on physicians and to create greater flexibility and choice so physician practices can thrive.

To help guide our MACRA implementation efforts, the AMA established a MACRA Task Force comprised of national medical specialty societies, state medical associations, the American Osteopathic Association, and the Medical Group Management Association to develop strategic approaches and consistent messaging.^{1,2} We also set up staff workgroups on two key MACRA components – the Merit-based Incentive Payment System (MIPS) and alternative payment models (APMs) to help inform our activities.^{3,4} We have also organized Centers for Medicare & Medicaid Services (CMS) listening sessions with representatives of national medical organizations and state medical associations to improve understanding of MACRA and offer feedback to CMS from across the Federation. Further, we have met regularly with key officials at CMS and the White House on MACRA, and we are keeping Congress apprised of regulatory developments. In addition, the AMA’s 2016 Physician Practice Benchmark Survey will include questions to measure physicians’ awareness of MACRA and intended pathways for participation.

Earlier this year in April, CMS released the first MACRA proposed rule. In response, the AMA filed extensive comments that would lead to a better final rule. (The AMA’s full comments to CMS are available at ama-assn.org/go/medicarepayment.) There are some positive developments in the proposed rule:

- The proposed rule attempts to align three previously disparate and highly burdensome federal reporting programs tied to Medicare payment (Meaningful Use [MU], Physician Quality Reporting System [PQRS], and the Value-based Modifier [VBM]).

- For the MIPS quality component, the proposed rule reduces the number of quality measures, grants more flexible reporting, and allows for partial credit.
- In Advancing Care Information (the replacement for the MU program), the proposed rule modifies the 100 percent pass/fail approach and reduces the number of required measures.
- The proposed rule creates exemptions for physicians whose practices have under \$10,000 in Medicare claims and fewer than 100 patients.
- It establishes a pathway for physicians to participate in APMs and receive five percent bonus payments from 2019-2024.

In our comments to the propose rule, we highlighted our top priorities for improvements in the final rule:

- A more realistic start date is needed for reporting requirements under the MIPS program, specifically July 1, 2017 rather than January 1, 2017.
- Further accommodations are needed for small and rural practices including increasing the low-volume threshold to under \$30,000 in Medicare claims or fewer than 100 patients which AMA estimates will exempt about 29 percent of physicians from MIPS reporting requirements.
- The four components of the MIPS program are still too complex for physician practices, so further enhancements and streamlining are needed.
- The APM requirements are too stringent and will lead to too few APM options for physicians, so further flexibility, a more reasonable risk standard, and a more diverse set of models are needed.

Our comments also discussed other provisions in the proposed rule where refinements are needed.

In response to advocacy efforts by the AMA and other physician organizations, CMS Acting Administrator Andy Slavitt announced on September 8 in the CMS Blog that the agency was making significant changes to the physician reporting requirements under MACRA for 2017. According to the blog post, the only physicians who risk any negative payment adjustment in 2019 will be those who opt not to report at all under MACRA in 2017. Those who do choose to report will have three options with no risk of penalties. Physicians who report for the full year, beginning on January 1, 2017, will be eligible for an unspecified “modest positive payment adjustment.” Under a second option, those who report for part of the calendar year will be eligible for an unspecified “small positive payment adjustment.” Finally, physicians who submit a small amount of data during the year under a “test” option will avoid any negative payment adjustments. Qualified physicians who participate in an Advanced Alternative Payment Model in 2017 will remain eligible for a 5 percent incentive payment in 2019.

Knowing that this is a complicated and confusing time for physicians as they prepare to adapt their practices to MIPS or seek to participate in an APM, AMA staff from Professional Satisfaction and Practice Sustainability, Advocacy, and Enterprise Communications and Marketing collaborated to develop tools and resources for physicians to assist them with these decisions (ama-assn.org/go/medicarepayment). The Payment Model Evaluator (also available at ama-assn.org/go/medicarepayment) was released in September and is a tool for physicians to assess the impact of MACRA on their practices and obtain implementation resources to maximize their success. The AMA also produced a “[MACRA Checklist](#)” to help physicians prepare for the new payment system. The AMA’s STEPSForward™ program has been recognized by CMS as eligible for Clinical Practice Improvement credit under MACRA. In addition, the AMA is a Support and Alignment Network under the CMS Transforming Clinical Practice Initiative and is providing MACRA education to independent and small practices via Practice Transformation Networks across the country. Additional resources for practices are in development.

1 The final MACRA rule is expected to be released prior to the Interim Meeting. With this report
2 being prepared for the HOD in September, it does not include information on the final rule. Please
3 watch for alerts from the AMA and information on our website. Further information will be
4 available at the Interim Meeting as well assuming that the final rule has been released.

5 6 *Insurer Mergers*

7
8 The Federation and the AMA achieved a major accomplishment when the US Department of
9 Justice (DOJ) and a number of state attorneys general (AGs) filed suit to block the Anthem-Cigna
10 and Aetna-Humana mergers. By working together, the AMA and the state medical associations
11 rang the alarm nationally about the potential negative effects that these mergers could have for
12 patients and physicians. Our collaborative work was instrumental in convincing the DOJ and many
13 state AGs that the proposed mega-mergers should not proceed. The AMA will continue to oppose
14 these mergers aggressively as they enter the litigation phase.

15
16 For over a decade, the AMA has produced research highlighting that health insurance markets in
17 most geographic areas are highly concentrated, and thus provide health insurers with
18 anticompetitive contracting leverage in these markets. This is detrimental to patients and
19 physicians. The 2015 edition of *Competition in Health Insurance: A Comprehensive Study of US*
20 *Markets* was publicized widely in the media and highlighted to policymakers and antitrust
21 regulators such as DOJ and AGs. The AMA also conducted special analyses of states and
22 metropolitan areas, to identify the states and metropolitan areas that would be most negatively
23 affected by one or both of the proposed mergers.

24
25 The AMA showcased this research in testimony before federal and state lawmakers several times.
26 AMA President Andrew W. Gurman, MD, and AMA Trustee Barbara L. McAneny, MD, testified
27 at congressional hearings to discuss our research and express our concerns about health insurance
28 market concentration. We testified and wrote letters to legislators, AGs, and insurance
29 commissioners in several states as well.

30
31 We also regularly convened those state medical associations most likely to be negatively affected
32 by the mergers, to facilitate the exchange of information and strategy, and to ensure that the AMA
33 was providing optimal support to those associations in their merger advocacy. We also had
34 discussions with national groups such as the National Association of Attorneys General (NAAG)
35 and select state insurance regulators. For example, AMA worked very successfully with the
36 Missouri State Medical Association and the California Medical Association to convince their
37 respective insurance regulators to oppose the mergers. AMA filed comments in a number of states,
38 including Florida, Missouri, California, Indiana, Georgia and New York – and worked with a
39 number of others behind the scenes. We brought in economists and legal experts to bolster our
40 case. We worked closely with consumer groups too. The AMA also prepared a member survey for
41 states to gauge the effect of the proposed mergers in their physician communities and passed the
42 results on to the DOJ, as well as state AGs and insurance regulators.

43
44 We expect the health insurers to defend the mergers vigorously, but we will continue to oppose
45 them and continue to build strong coalitions that will challenge them at the federal level, the state
46 level, in the courts, and in public opinion.

47 48 *Opioid Misuse*

49
50 With over 78 deaths per day, the opioid epidemic remains one of the biggest health challenges
51 facing our nation. The AMA is continuing our advocacy and communications efforts through the

1 AMA Task Force to Reduce Opioid Abuse (Task Force), which is comprised of more than 25
2 physician organizations including the AMA, American Osteopathic Association, American Dental
3 Association, national medical specialty societies and state medical associations.⁵ The Task Force
4 has coalesced around pursuing five clear actions:

- 5
- 6 • Increasing physicians' registration and use of effective prescription drug monitoring programs;
- 7 • Enhancing physicians' education on safe, effective and evidence-based prescribing of opioids;
- 8 • Reducing the stigma of pain and promoting comprehensive assessment and treatment;
- 9 • Reducing the stigma of substance use disorder and enhancing access to treatment; and
- 10 • Supporting overdose prevention efforts by expanding access to naloxone and providing Good
11 Samaritan protections.
- 12

13 The severity of the epidemic led to an [open letter](#) from AMA Immediate Past President
14 Steven J. Stack, MD, to physicians on the responsibilities and roles they must play to reduce the
15 opioid epidemic and to make sure physicians are trained in safe prescribing practices.

16

17 At the state level, there were more than 1,000 individual pieces of legislation concerning
18 prescription drug misuse, overdose and death in 2016 – nearly double from 2015. The AMA
19 worked with states individually on pressing bills, and helped more than 10 states secure victories
20 on issues ranging from prescription drug monitoring programs (PDMPs) to increased access to
21 naloxone. We also continued our work with national groups such as the National Governors
22 Association (NGA) which led to a major accomplishment when the AMA and the NGA issued a
23 national joint statement on key recommendations that physician leaders and governors could
24 mutually support. This was the first time that the AMA and NGA had issued such a statement -
25 which included all of the Task Force recommendations. AMA Chair Patrice A. Harris, MD, MA,
26 testified at the NGA's Winter Meeting in support of the recommendations. Furthermore, the Task
27 Force recommendations were emphasized in more than 10 published op-eds and letters to the
28 editor, many of which were joint efforts with state medical associations.

29

30 At the federal level, the AMA expressed support for the recently enacted Comprehensive Addiction
31 and Recovery Act (CARA). The final version of CARA authorizes numerous grant programs
32 focused on prevention of opioid addiction, alternatives to incarceration, increasing the availability
33 of naloxone, supporting PDMPs, promoting medication-assisted therapy and expanding drug take-
34 back programs. The legislation also included other AMA-supported proposals, such as the
35 reauthorization of the National All Schedules Prescription Electronic Reporting Act, which
36 supports state PDMPs, and allows partial fills of Schedule II drugs. While CARA authorizes
37 hundreds of millions of dollars in funding for these programs, Congress must still appropriate the
38 funds in order to fulfill its promise. The AMA will continue to urge Congress to take this critical
39 next step.

40

41 Also at the federal level, a proposed rule issued in July regarding Medicare hospital outpatient and
42 ambulatory surgical center payments in 2017 includes a provision to eliminate the current pain
43 management questions in the Hospital Consumer Assessment of Healthcare Providers and Systems
44 (HCAHPS) patient experience care survey from performance scores beginning in 2018. This was
45 done in response to advocacy by the AMA and others expressing concern that the link between
46 scoring well on the survey and higher facility payments interferes with efforts to curb over-
47 prescribing of opioids. CMS is developing alternative questions for the pain management
48 dimension to address these concerns.

Telemedicine

States saw a flurry of activity on telemedicine in 2016, with dozens of laws and regulations proposed to address telemedicine licensure, reimbursement, and practice standards. Many of these laws were based on the AMA “Telemedicine Act,” which addresses these and other issues related to telemedicine. This year, five bills based on this AMA model bill were signed into law.

While most attention was given to debates over how to establish a patient-physician relationship via telemedicine – in person, using two-way interactive audio-video technology or over the phone – states continued to make gains in passage of coverage parity laws, ensuring that physicians will be compensated for treating their patients via telemedicine. AMA advocacy was instrumental in many of these victories. The AMA is already working towards 2017 legislation with many medical associations from states that lack coverage parity, using the AMA “Telemedicine Act” as a guide. States also continue to advance the “Interstate Medical Licensure Compact,” with 17 states now having enacted it. The Compact facilitates interstate licensure for telemedicine services.

There has also been significant activity around telemedicine at the federal level. Our AMA continues to advance several major priorities to accelerate the integration of telemedicine into regular clinical practice, including expanding coverage in federal health care programs for telemedicine services, building the evidence base through federal funding for research, and supporting widely supported standards. We are also strongly advocating against efforts by some telecommunications groups to undermine existing state licensure laws, including proposals to create a national licensure scheme or change the site of practice from the state where the patient is located to the state where the physician is located for the purpose of providing telemedicine services to Medicare, the Veterans Health Administration (VA), or DOD TRICARE patients. On the coverage front, the AMA is working with telemedicine stakeholders to draft comments in support of expanded coverage of telehealth services in the Medicare program in response to the proposed 2017 Medicare Physician Fee Schedule, and convening national medical specialty societies to support and urge acceleration of initiatives that grow the evidence base, increase national specialty clinical practice guidelines, and other strategic engagements that ensure physicians have the information and tools to support implementation.

Electronic Health Records (EHR) Meaningful Use (MU)

In October 2015, CMS announced that the 2015 MU reporting period would be reduced from 365 to 90 days. The AMA has consistently urged CMS to implement a shorter reporting period for MU, due to the program’s pass-fail nature and the unforeseeable reporting disruptions that occur due to system failures, the adoption of new vendor products, and other factors beyond a physician’s control. Physicians had until March 15, 2016, to apply for a hardship exemption from three percent MU financial penalties in effect for the 2015 program year. In direct response to AMA advocacy, CMS announced that it would broadly grant hardship exemptions as a result of the delayed publication of the final regulations that announced the policy change, since physicians were left with insufficient time to report that year under the modified program requirements. This inclusive approach to allowing hardship exemptions is a result of the “Patient Access and Medicare Protection Act,” passed just before Congress adjourned for the 2015 holidays, [which directed CMS to make AMA-supported changes](#) to the previously limited exemption process.

In July, CMS proposed to implement a 90-day MU reporting period for 2016, as well. The announcement was made in draft regulations pertaining to Medicare hospital outpatient and ambulatory surgical center payment systems for 2017. The AMA has urged CMS to finalize its

proposal promptly, to avoid the extraordinary measures that were needed for the 2015 exemptions process due to tardy publication of the regulations.

Finally, in the MACRA draft regulations, CMS proposed 2017 as the first performance period for MIPS. As it happens, 2017 is also the last year that first-time participants in the MU program may attest to avoid penalties in 2018. Therefore, a new MU participant would be required to participate in both the MU program and the new Advancing Care Information performance category of MIPS in 2017 to avoid any payment adjustment, despite the significant overlap of these two programs. Following AMA advocacy efforts, the proposed rule on Medicare outpatient hospital and ambulatory surgical center payments for 2017 offered a change in this approach, and would allow physicians who have not previously demonstrated MU to apply for a significant hardship exemption from the 2018 payment adjustment and so avoid the duplicative reporting requirements.

Insurer Networks/Balance Billing

In late 2015, the National Association of Insurance Commissioners (NAIC) finalized its network adequacy model bill, prompting insurance commissioners across the country to push for its adoption by their legislatures. The AMA was heavily involved in the NAIC's process of drafting the model legislation, and as a result of AMA and medicine's advocacy, many important provisions that would improve access to care for patients were included in the final bill. Unfortunately, also included were provisions that threaten access to care and the ability of physicians to negotiate fair contracts with insurers. The AMA offers a detailed, edited version of the NAIC model bill for states to use. As states, such as Connecticut and Maryland, took up the NAIC model this year, medical societies, with assistance from the AMA, worked off of the AMA's version to amend their legislation to better serve patients and physicians and were highly successful in doing so. It is very likely that more states will be proposing versions of the NAIC model next year, and the Federation is already working with insurance commissioners and legislators to propose changes to their version of the legislation.

When legislators tackle network adequacy issues, balance billing discussions arise as well. In 2016, many states engaged in difficult debates over what should happen when a patient receives a bill from an out-of-network physician while at an in-network facility. With AMA assistance, state medical associations worked hard to accurately frame the issue as a symptom of the larger problems with provider networks and unfair contracting practices. The AMA is working with several coalitions including a work group that we convened with several specialty and state medical associations to find workable solutions.

Pharmaceutical Costs

In response to a call for action by the HOD at I-15, the AMA convened a Task Force on Pharmaceutical Costs,⁶ chaired by AMA Chair-Elect Gerald E. Harmon, MD, to develop principles to guide grassroots efforts aimed at addressing pharmaceutical costs and improving patient access. Board of Trustees Report 10-I-16, "AMA Initiatives on Pharmaceutical Costs," contains a full update on this issue, but to provide a snapshot, the Task Force recommended that increasing transparency among pharmaceutical companies, health plans and pharmacy benefit managers (PBMs) should be the focus of Phase I of the HOD-directed grassroots campaign. The AMA launched and is promoting an online petition that calls on Congress to demand that these companies introduce a basic level of transparency to the general public. The petition is being featured on cause-oriented websites frequented by online activists on both sides of the political spectrum (e.g., standunited.org), as well as specifically promoted to the AMA's Patient's Action Network. This fall, a campaign-specific microsite focused on drug pricing transparency will be

launched in order to build on the initial interest generated by the online petition and related promotional activities. Following the November elections, additional public opinion research and message testing will be conducted to help provide further guidance on how to best advocate on this topic.

Zika Prevention Funding

On May 26, 2016, the AMA wrote the bipartisan leadership of Congress, urging “immediate action to make available the necessary resources to prepare our nation to address the growing threat of the Zika virus.” The AMA has also joined the efforts of a broad coalition of organizations, including the March of Dimes, the American Congress of Obstetricians and Gynecologists, and the American Academy of Pediatrics in continuing to advocate for congressional action. Though Congress recessed for the summer without taking final action on funding, AMA continues to press for a resolution to the funding dispute as soon as possible. The AMA is also working with the coalition on state strategies to combat the spread of Zika.

Proposed Medicare Fee Schedule

The annual proposed rule on the Medicare physician payment schedule, issued in July, included both favorable and unfavorable policy proposals. Policies in the proposed rule that the AMA will support in its comments include:

- Following up on an announcement earlier this year, the draft regulation proposes to expand the duration/scope of the Diabetes Prevention Program (DPP) model. Under the new program, to be known as the Medicare Diabetes Prevention Program (MDPP), providers could deliver services either in-person or via remote technologies.
- Several policy updates were made for primary care services, including improved payments for chronic care management services and a separate payment for behavioral health integration models.
- Despite statements made earlier in the year by former CMS officials, the agency did not propose to revise existing policies and will continue to exclude industry support for independent continuing medical education in the Open Payments Program (Sunshine Act) reporting data base.

Other policies outlined in the proposed rule are more problematic:

- As part of a data collection effort on the frequency of and inputs involved in providing global surgical services, CMS is proposing to require comprehensive claims-based reporting on the number and level of pre- and post-operative services furnished during 10- and 90-day global periods. This would require physicians to report a set of time-based G-codes (in 10-minute increments) that distinguish between the setting of care and whether the services are provided by a physician or their clinical staff. The extraordinary administrative burden would be imposed during the first MACRA reporting year – on January 1, 2017 – when physicians are already adapting to broad regulatory changes. The AMA is working with a coalition of specialty organizations to stop this proposal and replace it with a data collection effort more in line with congressional intent.
- CMS is proposing an add-on code that could be billed with an evaluation and management service for physicians treating patients with mobility-related impairments. Payments for this add-on code would be funded through an across-the-board cut in Medicare payment rates in 2017. The AMA is exploring alternative approaches to recommend for improving access to care for these patients.

Tobacco Regulation

In August, the US Food and Drug Administration (FDA) released its [final rule](#) regulating e-cigarettes, cigars, hookah and other previously unregulated tobacco products. The new rules are sweeping in scope, and for the first time, extend federal regulatory authority to e-cigarettes, banning their sale to minors under the age of 18 and requiring health warnings.

Also required under the rules:

- Adults under the age of 26 must show a photo identification to buy these tobacco products.
- Producers must register with the FDA and provide a detailed accounting of the ingredients in their products and their manufacturing processes.
- Manufacturers are prohibited from making unproven health claims.
- Manufacturers must apply to the FDA for permission to sell their products.

As recommended by the AMA and other public health stakeholders, the FDA extended the rules to all cigars, rejecting proposals to exempt so-called “premium cigars.” The AMA has long called for e-cigarettes to be subject to the same regulations and oversight that the FDA applies to tobacco and nicotine products, and supports the final rule as an important step in protecting the public’s health, especially that of minors. However, the AMA believes further regulation is necessary with regard to marketing e-cigarettes and banning flavored e-cigarettes, which are particularly enticing to minors.

The AMA is also assisting state medical associations with efforts to raise the minimum age for purchasing tobacco and electronic smoking devices. For example, with AMA support, California raised the age to purchase tobacco products to 21 this year, making it the second state to do so.

Medical Liability Reform

The AMA and the Federation continue to promote and defend medical liability reform (MLR). Most of the activity is occurring at the state level in recent years. In 2016, states considered bills that promoted a variety of reforms, including expert witness guidelines, affidavit of merit requirements, collateral source reform and bills that established structures such as pretrial screening panels or health court systems. Most of these bills did not progress to enactment. A handful of states had to engage in defensive efforts as they faced attempts to raise caps on non-economic damages. Most efforts to defeat cap bills were successful, while at the eleventh hour, the Indiana legislature passed a long-pending bill to raise the state’s 18-year old cap from \$1.25 million to \$1.65 million in 2017 and \$1.8 million in 2019.

Team-based Care/Scope of Practice

In 2016, the AMA continued to promote physician-led teams at the state level and to fight inappropriate scope of practice legislation. State legislatures considered over 500 bills seeking to eliminate team-based care models of health care delivery and/or expand the scope of practice of non-physician health care professionals. The AMA expects this high level of legislative activity to continue in 2017.

Though tough fights in all cases, most bills that threatened passage were defeated with the support of the AMA, in close coordination with state and specialty medical associations. For example, bills pursuing independent practice of advanced practice nurses were defeated in 12 states. In two of those states – Arizona and Ohio – grants from the Scope of Practice Partnership (SOPP) played a

1 key role in supporting efforts to defeat independent practice bills from nurse anesthetists and nurse
2 practitioners, respectively. AMA advocacy and SOPP support also helped to defeat bills to allow
3 psychologists to prescribe psychotropic medication. To date, the SOPP has granted nearly \$1.4
4 million to state and specialty medical societies in support of scope of practice, truth in advertising,
5 and physician-led team advocacy efforts.

6 7 *Nurse Practitioners in the Veterans Health Administration*

8
9 The Veterans Health Administration (VA) published a [proposed rule](#) in May that would give full
10 practice authority to four categories of advanced practice registered nurses (APRN): certified nurse
11 practitioner, certified registered nurse anesthetist, clinical nurse specialist, and certified nurse-
12 midwife. The proposal would allow APRNs working within the scope of VA employment to
13 provide services without the clinical oversight of a physician, regardless of state or local law
14 restrictions on that authority. Efforts at the VA to permit independent nursing practice go back
15 several years but gained momentum when significant staffing shortages and long patient wait times
16 were uncovered in 2014.

17
18 In addition to meetings of AMA Trustees with VA officials on this subject, the AMA submitted
19 comments opposing the proposed rule and urged members of the Federation to do the same. The
20 AMA submitted a [sign-on letter](#) on behalf of 98 specialty and state medical societies urging the VA
21 not to move forward with the proposal.

22 23 *Prior Authorization*

24
25 The AMA is conducting a major research project on prior authorization (see “New Advocacy
26 Research” section that follows) and has formed a work group with Federation groups and other
27 stakeholders to address this issue. In 2016, the AMA worked with several states to propose new
28 legislative ideas on this problematic issue. Delaware enacted legislation based on the AMA model
29 prior authorization bill that requires reporting of prior authorization statistics by insurers or benefit
30 managers to a state database. The data is likely to prove invaluable in studying the impact and
31 utility of prior authorization. Additionally, Ohio and Delaware were able to include AMA model
32 provisions in their new laws that make prior authorizations valid for a year and prevent retroactive
33 denials. They were also both able to include a transition to electronic prior authorization (ePA) to
34 automate the prior authorization process, a major priority of the AMA.

35 36 2016 GRASSROOTS/GRASSTOPS ACTIVITIES

37
38 In order to provide both patient and physician advocates with the best tools and resources, the
39 AMA Patient’s Action Network and Physicians’ Grassroots Network recently made changes to
40 their online advocacy platforms. On the patient side, this included: an updated website design
41 for [PatientsActionNetwork.org](#); a new call to action on freeing up regulations that affect electronic
42 health records and interfere with the patient-physician relationship; even more resources to help
43 enhance advocacy efforts; an interactive “share your story” feature; and, stronger social media tools
44 to make it easier to connect with fellow advocates. For physicians, changes focused on broadening
45 the scope of [BreaktheRedTape.org](#) to include new issues important to medicine such as the opioid
46 misuse crisis, MACRA, telemedicine, and drug pricing transparency. New action-taking tools and
47 online resources will be available to physicians as well, enabling them to communicate with
48 lawmakers on these important issues through social media channels and new, interactive video-
49 sharing technologies.

1 In conjunction with the Medical Student Advocacy and Region Conference held earlier this year,
2 the AMA has also launched an updated version of SaveGME.org. The updates include new
3 resources and content, including video submissions from medical students and a call to action on
4 the Public Service Loan Forgiveness Program. In addition, new videos and social media outreach
5 expected to be unveiled in the fall will be focused on expanding the SaveGME campaign's mission
6 to focus on raising awareness with the general public on the urgent need to preserve adequate
7 funding for graduate medical education.

8 9 2016 AMPAC ACTIVITIES

10
11 AMPAC has once again worked closely with its state medical association PAC partners this
12 election cycle on contribution support decisions for candidates running for the US House of
13 Representatives and Senate. A report summarizing AMPAC activities will be distributed at the
14 Interim Meeting in Orlando.

15 16 FEATURED ADVOCACY RESOURCES

17
18 The AMA has also produced new resources to assist physicians:

- 19
20 • [Guide to Physician-focused Alternative Payment Models](#): The AMA worked with Harold
21 Miller at the Center for Healthcare Quality and Payment Reform, a member of the newly
22 appointed Physician-Focused Payment Models Technical Advisory Committee to the federal
23 government, to develop a guide to help physicians understand the various types of APMs and
24 how their practice may be able to participate in a new model.
- 25 • [HIPAA podcast](#): The AMA and the Healthcare Information and Management Systems Society
26 (HIMSS) produced this podcast to answer questions about providing patients access to their
27 health information, as required by the Health Insurance Portability and Accountability Act
28 (HIPAA).
- 29 • [AMA Health Workforce Mapper](#): The AMA launched an update of the AMA Health
30 Workforce Mapper, an interactive online resource that illustrates the distribution of physicians
31 and non-physician clinicians by specialty, state, county, or metropolitan areas. The AMA
32 Health Workforce Mapper provides a useful visual tool to demonstrate to law- or policymakers
33 the geographic distribution of the health care workforce in a given state or nationally, to assist
34 them in making appropriate, evidence-based decisions. The updated Health Workforce Mapper
35 now integrates CDC data on morbidity, mortality, health care access and quality, health
36 behavior demographics and social environments, further helping to ensure that patients have
37 access to the care they need.
- 38 • [Workers' Compensation and Auto Injury Toolkit](#): The AMA recently updated its Workers'
39 Compensation and Auto Injury Toolkit. This resource offers a primer on property and casualty
40 billing, as well as provides valuable practice tips for transitioning from manual to electronic
41 processes for these business lines.

42 43 NEW ADVOCACY RESEARCH

44
45 The AMA has also produced the following studies to assist in our efforts:

- 46
47 • [Policy Research Perspective - Payment and Delivery in 2014: The Prevalence of New Models
48 Reported by Physicians](#): This publication presents a national view of physician participation in
49 new payment and delivery models by specialty, practice type and practice ownership. Based on
50 the 2014 Physician Practice Benchmark Survey, it concludes that although the majority (59.0
51 percent) of physicians worked in practices that received revenue from at least one alternative

payment model, fee-for-service payment was still the dominant payment method used by insurers to pay physician practices. An average of 71.9 percent of practice revenue came from fee for service. A 2016 edition of this study is forthcoming in 2017.

- Competition in Health Insurance: A Comprehensive Study of US Markets: In this report, the AMA produces the largest, most complete picture of competition in the commercial health insurance markets across the US. It is a valuable resource for physicians, policymakers, regulators, researchers, and patients. It has been a vital component of our campaign to halt the proposed insurance mergers.
- Prior Authorization: The AMA is partnering with the University of Southern California Schaeffer Center for Health Policy & Economics in an ambitious research project focused on prior authorization. Through rigorous analysis of claims and clinical data, this study will assess the impact of prior authorization on resource utilization, costs (both for a particular service and overall health care expenditures), and patient outcomes. While health plans endorse prior authorization as a mechanism to control costs, the more holistic analysis proposed for this study may show an overall lack of value for the health care system. Results from the study will be targeted for publication in a peer-reviewed journal in 2017 and will provide valuable support to the AMA's evidence-based advocacy on this issue.
- Narrow Network Regulation: Recent research conducted by the Georgetown University Health Policy Institute (Georgetown), commissioned by the AMA, presents important findings regarding the regulation of narrow networks, specifically with regard to consideration of quality as a component of regulation. As highlighted by Georgetown researchers, state regulators generally do not define or regulate "narrow networks" or "tiered networks" any differently than standard networks. Additionally, when the Georgetown researchers drilled down on the issue of quality and asked state regulators and other stakeholders whether state provider network rules should incorporate the concept of quality, especially when assembling narrow networks, they found little to no focus on quality in network design, even in the narrowest of networks. At the time of this writing, the research, along with a supplemental AMA discussion document, is set to be released in September to complement and enhance the AMA's state advocacy on network adequacy and physician profiling issues.
- National survey: Physician perceptions and practices on opioid prescribing, education, barriers to care, naloxone: The AMA released the findings of a national physician survey that showed strong support for key policies and recommendations to help reverse the nation's opioid epidemic, including ways to improve prescription drug monitoring programs, enhance physician education as well as remove barriers to care. The survey found, among other things, that PDMPs need improvement to integrate with electronic health records, provide real-time data and other key features that would make them even more useful. The survey also found that a majority of respondents have taken continuing medical education (CME) on safe opioid prescribing and strong support for increasing access to naloxone.

CONCLUSION

As shown by this report, the AMA continues to advocate for physicians and patients on numerous, vital health care issues, and we continue to have a positive impact. In 2017, our advocacy efforts will focus on MACRA implementation (with a particular emphasis on assisting small practices); the opioid crisis; health insurer mergers; pharmaceutical pricing; health insurer networks; public health topics; and other issues that arise. We are gearing up for a new Administration and Congress and will be ready to move forward once our new federal and state officials assume office. We appreciate the collaboration with the Federation in 2016, and look forward to further work and success in 2017 at the federal and state levels.

REFERENCES

- ¹ National Medical Specialty Societies – American Academy of Family Physicians, American Academy of Ophthalmology, American Association of Neurological Surgeons, American Association of Orthopaedic Surgeons, American College of Cardiology, American College of Emergency Physicians, American College of Physicians, American College of Surgeons, American Psychiatric Association, and American Society of Clinical Oncology.
- ² State Medical Associations – Illinois State Medical Society, Massachusetts Medical Society, North Carolina Medical Society, Ohio State Medical Association, Texas Medical Association, Washington State Medical Association, and Wisconsin Medical Society.
- ³ MIPS workgroup – American Association for Clinical Endocrinology, American Association of Neurological Surgeons, American College of Cardiology, American College of Radiology, American Osteopathic Association, AMDA (The Society for Post-Acute and Long-Term Care Medicine), American Society of Cataract and Refractive Surgery, American Society of Gastrointestinal Endoscopy, Illinois State Medical Society, Maine Medical Association, Medical Group Management Association, North Carolina Medical Society, Society of Gynecologic Oncology, and Texas Medical Association.
- ⁴ APM workgroup – American Academy of Otolaryngology-Head and Neck Surgery, American College of Emergency Physicians, American College of Physicians, American College of Surgeons, American Psychiatric Association, American Gastroenterological Society, American Society of Clinical Oncology, American Society for Therapeutic Radiology and Oncology, American Urological Association, American Uro-gynecologic Society, California Medical Association, Massachusetts Medical Society, Society of Gynecologic Oncology, Society of Thoracic Surgeons, Washington State Medical Association, and Wisconsin Medical Society.
- ⁵ AMA Task Force to Reduce Opioid Abuse (Task Force) – American Academy of Addiction Psychiatry, American Academy of Family Physicians, American Academy of Hospice and Palliative Medicine, American Academy of Orthopaedic Surgeons, American Academy of Neurology, American Academy of Pain Medicine, American Academy of Pediatrics, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American College of Emergency Physicians, American College of Occupational and Environmental Medicine, American College of Physicians, American College of Rheumatology, American Congress of Obstetricians and Gynecologists, American Dental Association, American Medical Association, American Osteopathic Association, American Psychiatric Association, American Society of Addiction Medicine, American Society of Anesthesiologists, Arkansas Medical Society, Massachusetts Medical Society, Medical Society of the State of New York, New Mexico Medical Society, Ohio State Medical Association, Oregon Medical Association, and Utah Medical Association.
- ⁶ AMA Task Force on Pharmaceutical Costs – AMA Council on Legislation, AMA Council on Medical Service, AMA Council on Science and Public Health, Medical Association of the State of Alabama, California Medical Association, Massachusetts Medical Society, Minnesota Medical Association, American Academy of Dermatology, American Academy of Pediatrics, American College of Cardiology, American College of Physicians, and American Society of Clinical Oncology.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 4-I-16

Subject: Redefining the AMA's Position on the ACA and Health Care Reform - Update

Presented by: Patrice A. Harris, MD, MA, Chair

At the 2013 Annual Meeting of the House of Delegates (HOD), the HOD adopted Policy D-165.938, "Redefining AMA's Position on ACA and Healthcare Reform," which called on our American Medical Association (AMA) to "develop a policy statement clearly outlining this organization's policies" on a number of specific issues related to the Affordable Care Act (ACA) and health care reform. The adopted policy went on to call for our AMA to report back at each meeting of the HOD. Board of Trustees (BOT) Report 6-I-13 accomplished the original intent of the policy. This report serves as an update on the issues and related developments occurring since the most recent meeting of the HOD.

REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR

As previously reported, the repeal of the Sustainable Growth Rate (SGR) was accomplished with the enactment of the "Medicare Access and CHIP Reauthorization Act of 2015" (MACRA) on April 16, 2015.

On April 28, 2016, the Centers for Medicare & Medicaid Services (CMS) released proposed implementing regulations [Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS-5517-P)]. Following consultation with state and national medical specialty societies, the AMA responded with extensive comments¹ on June 27, 2016. Our AMA and 118 state and national medical specialty societies sent a separate comment letter² on June 24, 2016 outlining areas of broad agreement among physician organizations.

PAY-FOR-PERFORMANCE

Inherent in the implementation of MACRA is the opportunity to reshape current pay-for-performance programs. As stated in AMA comments to CMS, "the intent of MACRA was not to merely move the current incentive programs into MIPS but to improve and simplify these programs into a single more unified approach." AMA comments on the proposed regulations are lengthy and may be accessed at: ama-assn.org/go/medicarepayment. In the most general terms, our AMA has called on CMS to create a transition reporting period so that physicians may prepare for a successful implementation, provide additional flexibility for solo and small group practices, and provide more timely and actionable feedback in a usable and clear format. More specifically, our AMA made 13 high-level recommendations:

- Establish a transitional period to allow for sufficient time to prepare physicians to have a successful launch of MACRA.
- Provide more flexibility for solo physicians and small group practices, including raising the low volume threshold.

- 1 • Provide physicians with more timely and actionable feedback in a more usable and clear
- 2 format.
- 3 • Align the different components of MIPS so that it operates as a single program rather than four
- 4 separate parts, such as creating a common definition for small practices.
- 5 • Simplify reporting burdens and improve chances of success by creating more opportunities for
- 6 partial credit and fewer required measures within MIPS.
- 7 • Reduce the thresholds for reporting on quality measures.
- 8 • Reward reporting of outcome or cross-cutting measures under a bonus point structure rather
- 9 than a requirement in order to achieve the maximum quality score.
- 10 • Improve risk adjustment and attribution methods before moving forward with the resource use
- 11 category.
- 12 • Replace current cost measures that were developed for hospital-level measurement and refine
- 13 and test new episode measures prior to widespread adoption.
- 14 • Permit proposals for more relevant measures, rather than keeping the current MU Stage 3
- 15 requirements.
- 16 • Remove the pass-fail component of the Advancing Care Information (ACI) score.
- 17 • Reduce the number of required Clinical Practice Improvement Activities (CPIAs) and allow
- 18 more activities to count as “high-weighted.”
- 19 • Simplify and lower financial risk standards for Advanced APMs.

20
21 Though final regulations are not expected until autumn, our AMA continues to encourage all
22 physicians to prepare for the transition. Numerous resources have been made available on the
23 AMA MACRA webpage (ama-assn.org/go/medicarepayment), including an action kit
24 (download.ama-assn.org/resources/doc/washington/16-0384-advocacy-macra-action-kit.pdf)
25 detailing steps that practices should take now as well as explanatory material on the two options for
26 participating, the Merit-based Incentive Payment System and Alternative Payment Models.
27 Additionally, the AMA’s STEPSForward™ practice improvement initiatives provide a step-by-step
28 process to help prepare practices for value-based care.

29 30 REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

31
32 As noted in BOT Report 7-A-16, the House of Representatives has passed H.R. 1190, the
33 “Protecting Seniors’ Access to Medicare Act of 2015,” repealing the IPAB. While the AMA
34 supported the passage of the House bill, the funding provisions, specifically cuts to the ACA
35 Prevention and Public Health Fund, are contrary to AMA policy. Our AMA continues to explore
36 possible pathways for consideration of the Senate-introduced bill though no action has been
37 scheduled at this time.

38 39 SUPPORT FOR MEDICAL SAVINGS ACCOUNTS, FLEXIBLE SPENDING ACCOUNTS, 40 AND THE MEDICARE PATIENT EMPOWERMENT ACT

41
42 H.R. 1270, the “Restoring Access to Medication Act of 2015” was passed by the House on July 6,
43 2016 by a vote of 243-164. The legislation would repeal a provision of the Affordable Care Act
44 that prohibited the use of Flexible Spending Accounts for the purchase of over the counter
45 medications without a prescription and increase allowable contributions to Health Savings
46 Accounts. The White House has announced that the President would veto the measure if it were
47 presented for signature. In releasing the White House Statement of Administration Policy, the
48 Office of Management and Budget expressed opposition to provisions in the legislation that would
49 “provide additional tax breaks that disproportionately benefit those with higher incomes” and
50 “increase taxes paid by low- and middle-income families.” This objection refers to the funding
51 provision of the House-passed bill that would pay for increases in HSA contributions by increasing

1 subsidy recapture provisions for those who receive subsidies for the purchase of ACA coverage.
2 The Senate has not scheduled action on the bill.

3
4 As previously reported, the “Medicare Patient Empowerment Act” has been reintroduced in the
5 current Congress by Rep. Tom Price, MD, (R-GA) and Sen. Lisa Murkowski (R-AK). The House
6 version, H.R. 1650, currently has 30 cosponsors while the Senate bill, S. 1849, has six cosponsors.
7 Neither bill has been scheduled for consideration at this time.

8 9 STEPS TO LOWER HEALTH CARE COSTS

10
11 The AMA continues to seek opportunities to advance policies that will lower health care costs.
12 Central to these efforts is the AMA’s work on Improving Health Outcomes. One key component of
13 the work of our AMA on improving health outcomes is the expansion of coverage for the Diabetes
14 Prevention Program (DPP). As part of the CY 2017 Medicare Physician Fee Schedule Proposed
15 Rule published on July 15, 2016, CMS proposes to expand the duration and scope of the DPP
16 model test, and refer to the new program as the Medicare Diabetes Prevention Program (MDPP).
17 The proposed rule provides a basic framework for the MDPP, and CMS notes that if finalized, they
18 will engage in additional rulemaking within the next year to establish specific MDPP requirements.
19 This development represents a significant step forward in efforts to expand coverage for DPP.

20 21 REPEAL NON-PHYSICIAN PROVIDER NON-DISCRIMINATION PROVISIONS OF THE 22 ACA

23
24 Legislation repealing the non-physician provider non-discrimination provisions of the ACA has not
25 been introduced in the current Congress to date.

26 27 CONCLUSION

28
29 AMA Policy D-165.938 calls for updates at each meeting of the HOD on a number of specific
30 policies related to the ACA. Our AMA continues to pursue these issues. Other key advocacy issues
31 will continue to be addressed in the annual Advocacy report at each Interim Meeting of the House.

REFERENCES

¹ <https://download.ama-assn.org/resources/doc/washington/ama-macra-comments-27june2016.pdf>

² <https://download.ama-assn.org/resources/doc/washington/macra-state-specialty-sign-on-letter.pdf>

REPORT OF THE BOARD OF TRUSTEES

B of T Report 10-I-16

Subject: AMA Initiatives on Pharmaceutical Costs

Presented by: Patrice A. Harris, MD, MA, Chair

Physician concerns about the impact of the current and projected growth in pharmaceutical spending and pricing on patient access, affordability and adherence to prescription drugs resulted in the adoption of new American Medical Association (AMA) policy and directives at the 2015 Interim Meeting. Notably, Council on Medical Service Report 2-I-15, “Pharmaceutical Costs,” established policy that encourages drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies; supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of generic drug rises faster than inflation; encourages Federal Trade Commission actions to limit anticompetitive behavior by pharmaceutical companies to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives; and supports legislation to shorten the exclusivity period for biologics (Policy H-110.987). In addition, the report was amended to include the following two directives:

- That our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
- That our AMA generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.

The following report, which is presented for the information of the House of Delegates (HOD), summarizes the work of the Task Force on Pharmaceutical Costs and describes the first phase of the AMA’s grassroots campaign on drug pricing.

TASK FORCE ON PHARMACEUTICAL COSTS

The AMA Board of Trustees appointed a 13-member task force in December 2015, consisting of representatives of three AMA councils (Council on Legislation, Council on Medical Service, and Council on Science and Public Health), four state medical associations (Medical Association of the State of Alabama, California Medical Association, Massachusetts Medical Society, and Minnesota Medical Association) and five national medical specialty societies (American Academy of Dermatology, American Academy of Pediatrics, American College of Cardiology, American College of Physicians, and American Society of Clinical Oncology). Current AMA Board of Trustees Chair-Elect Gerald E. Harmon, MD, was appointed chair of the task force.

1 Per the directive of the HOD, the charge of the task force was focused: to review current AMA policy
2 and develop principles to help guide AMA advocacy and grassroots efforts aimed at addressing
3 pharmaceutical costs and improving patient access and adherence to medically necessary prescription
4 drugs. In particular, the task force was asked to offer recommendations on which combination of
5 existing AMA policies should be pursued to advance a cohesive vision in order to successfully
6 influence public policy.

7
8 The task force was asked to complete its work within six months—prior to the 2016 Annual Meeting.
9 In January 2016, the task force held a face-to-face meeting in Washington, DC. At the meeting, the
10 task force reviewed AMA policy on pharmaceutical costs and pricing; reviewed a draft document on
11 possible metrics for evaluating AMA policy for inclusion in an AMA grassroots campaign; received a
12 briefing on the 2016 political landscape and the impact of the presidential and congressional elections
13 on this issue; heard from task force members on specific campaigns/advocacy efforts that their
14 respective organizations have undertaken; and held an initial discussion on potential issues and issue
15 combinations to feature in an AMA grassroots campaign.

16
17 The task force held follow-up conference calls in March, April and May of 2016, during which it
18 reviewed and discussed documents that described advocacy campaign opportunities on the issue of
19 transparency (for pharmaceutical companies, health plans and pharmacy benefit managers [PBMs]);
20 explained Medicare drug price negotiations and compared how drug prices are currently determined
21 by Medicare Part D and the Veterans Administration; summarized current federal legislation to allow
22 such negotiation; and presented cost savings estimates from Congressional Budget Office, the Centers
23 for Medicare & Medicaid Services' Office of the Actuary, and others.

24
25 In summary, the task force reached consensus on the following:

- 26
- 27 • Agreement on the use of a set of metrics for evaluating current AMA policy for inclusion in an
28 AMA grassroots campaign (see appendix).
 - 29
 - 30 • Agreement that neither drug importation nor a ban on direct-to-consumer advertising should be
31 pursued as part of the grassroots campaign at this time.
 - 32
 - 33 • Agreement that increasing transparency among pharmaceutical companies, health plans and PBMs
34 should be the focus of Phase I of the grassroots campaign (remainder of 2016).
 - 35
 - 36 • Agreement that the specifics of Phase II of the grassroots campaign (2017) should be determined
37 after the 2016 presidential and congressional elections and after any additional policy is
38 established by the House of Delegates following completion of the planned I-16 report by the
39 Council on Medical Service (e.g., value-based drug pricing and/or Medicare drug price
40 negotiation). However, strong consideration should be given to including Medicare drug price
41 negotiation in Phase II of the campaign.
 - 42

43 AMA GRASSROOTS CAMPAIGN AND FURTHER POLICY DEVELOPMENT

44

45 To raise initial awareness regarding the need for pharmaceutical companies, health plans and PBMs to
46 inject greater transparency in their process for determining drug prices, the AMA launched and
47 promoted an online petition during the summer of 2016, calling on Congress to demand these
48 companies introduce a basic level of transparency to the general public. The petition is currently
49 featured on cause-oriented websites frequented by online activists on both sides of the political
50 spectrum (e.g., standunited.org), and is also being specifically promoted to the AMA's Patient Action

1 Network, along with other information including articles and other policy pieces that discuss the issue,
2 through the network's website, email newsletters, and social media channels.

3
4 A specific campaign microsite, focused on drug pricing transparency, was scheduled to be launched in
5 the fall of 2016 in order to build on the initial interest generated by the online petition and related
6 promotional activities. The site will have a serious and generally hard-hitting tone in order to reinforce
7 the importance of the issue and the need for people to get involved and take action. Although the
8 primary audience is the general public and anyone concerned about the rising cost of drugs, specific
9 content and resources for physicians to impact the debate will be made available as well. As the online
10 hub for the campaign, the website will act primarily as a platform for activists to make their voices
11 heard with members of Congress and potentially state legislators through email and social media
12 communications. Additional key components of the site will include: lead/feature video summarizing
13 the campaign's central arguments through flash animation or a still photo/headline carousel; a "get the
14 facts" section housing one-pagers and links to more in-depth policy analysis and interactive
15 infographics that showcase the campaign's arguments on cost, pricing, and the relationship between
16 health insurers and PBMs; a news section with links to stories about what is happening on the issue at
17 the state and national level; a "share-your-story" section that will prompt both patient and physician
18 visitors to the site to share their experiences in grappling with the high-cost of prescription drugs; and
19 an "action center" that in addition to the basic advocacy tools enabling users to email, tweet and post
20 Facebook messages to their lawmakers, will house the campaign's main petition, as well as a tool that
21 will help them in submitting letters-to-the-editor on this issue in publications in their local
22 communities.

23
24 Following the November elections, additional public opinion research and message testing will be
25 conducted. The extensive polling conducted in California related to its ballot initiative on drug pricing
26 will provide substantial insight to further refine AMA messaging on this subject.

27
28 Finally, before the House of Delegates at its meeting, the Council on Medical Service presents a new
29 report on "Incorporating Value in Pharmaceutical Pricing" (CMS Report 5-I-16). This report proposes
30 a series of principles to guide the use of value-based drug pricing which the Council believes will
31 serve as a more impactful and politically viable approach on this issue than further delineating AMA
32 policy on Medicare drug price negotiation.

33
34 The Board of Trustees will continue to keep the HOD apprised of ongoing AMA advocacy and
35 grassroots efforts to help put forward solutions to make prescription drugs more affordable for all
36 patients.

APPENDIX

**METRICS FOR EVALUATING AMA POLICY
FOR INCLUSION IN AMA GRASSROOTS CAMPAIGN ON PHARMACEUTICAL COSTS**

- **Impact on patient access, safety and medication adherence**
Would the policy directly or indirectly impact patient access to necessary therapies and high-quality care, cost-sharing and medication adherence? Would the policy lead to a pharmaceutical marketplace that works better for patients? How would the policy impact innovation and the development of better treatment options for patients? Would the policy pose potential risks to patient safety?
- **Impact on physicians and physician practices**
How would the implementation of the policy impact physicians and physician practices?
- **Likelihood of successful implementation**
What is the likelihood that legislation or regulations to implement the policy will be successful on the state and federal levels? Would an advocacy campaign on the issue lend itself to the AMA partnering with patient organizations to achieve success?
- **Issue/Message cohesion**
If the task force considers multiple policies to feature in the advocacy campaign, are the policies complementary? Will they work together in media messaging and in a larger advocacy strategy?
- **Unique perspective of the AMA on the issue**
Is it appropriate for the AMA to take the lead on the issue? Does it make sense for physicians and patients to advocate on the issue? Can the AMA bring an effective, unique perspective to the table?
- **Alignment with strategic focus areas**
Does the policy support the ability of the AMA to improve health outcomes, create thriving physician practices, or create the medical school of the future?
- **Alignment with other AMA advocacy priorities**
How does the policy align with other AMA advocacy priorities?
- **Ability of grassroots advocates to understand the policy/combination of policies**
Will members of the AMA Physicians' Grassroots Network and the Patients' Action Network be able to understand the policy proposals we are asking them to help advance?
- **Ability to differentiate from political campaign messaging**
Will the AMA be able to effectively differentiate from the campaign messaging of presidential, federal and statewide candidates in its advocacy campaign on the issue? Could it be possibly interpreted that the AMA is endorsing proposals of a particular candidate?
- **Balanced impact on stakeholders involved in pharmaceutical pricing**
Would the policy impact and engage the range of stakeholders involved in pharmaceutical pricing, including but not limited to pharmaceutical companies, health plans and pharmacy benefit managers? Would an advocacy campaign on the policy align the AMA with one stakeholder while targeting another?

REPORT OF THE BOARD OF TRUSTEES

B of T Report 11-I-16

Subject: 2017 Strategic Plan

Presented by: Patrice A. Harris, MD, MA Chair

Our AMA is making progress on its multi-year strategy to achieve significant positive impact for physicians, medical students and patients. The strategy, launched in 2013, identifies three areas of focus: Improving Health Outcomes, Accelerating Change in Medical Education, and Shaping Care Delivery and Payment for Professional Satisfaction and Practice Sustainability. These focus areas provide for tangible and meaningful implementation of our AMA's mission to promote the art and science of medicine and the betterment of public health.

Through this report, the Board of Trustees affirms AMA's multi-year strategic focus. This report summarizes what is on the horizon for each of the focus areas in 2017 and highlights other work to modernize the means through which physicians can engage in advancement of the mission.

CARE DELIVERY AND PAYMENT: PROFESSIONAL SATISFACTION AND PRACTICE SUSTAINABILITY

For nearly two decades, work toward repeal of the sustainable growth rate (SGR) formula was a core component of AMA's strategy. Since enactment of the Medicare and CHIP Reauthorization Act of 2015 (MACRA), our work has refocused – with even greater intensity – to ensure that MACRA's implementation supports a health care system that delivers better care and more visible value while also supporting a sustainable practice environment. The goal is to create a pathway for physicians to choose from a broad array of alternative payment and health care delivery models, including viable fee-for-service options.

Successful navigation and implementation of evolving public and private payment systems requires heightened physician awareness, informed assessment of options, and, potentially, new ways of capturing, analyzing and reporting practice information. To support physicians through this changing landscape and improve care delivery and professional satisfaction, AMA will work in 2017 to:

- Advocate for legislative and regulatory changes that enhance prospects for physicians to succeed.
- Generate awareness and encourage physicians to prepare for impending payment model changes.
- Provide multi-modal, multi-channel physician education about what new payment model options mean for physicians and patients.
- Update the MACRA physician payment model evaluation tool, which was introduced in 2016, and supplement it with additional resources that not only help physicians make informed decisions, but also help them take steps to implement the decisions effectively.
- Guide physicians toward the best outcome in value-based care systems and establish the AMA as a valued source of support on issues spanning a wide range of care delivery and payment models.
- Expand the resources delivered through the STEPS Forward: Practice Improvement Strategies program to help physicians in a variety of practice settings learn new techniques to improve practice workflow, patient care and professional satisfaction.

- Increase the awareness and importance of professional satisfaction and support the Quadruple Aim through new research, partnerships, and resources to assist physicians throughout the various settings and stages of their careers.
- Discover and promote the physician perspective across health technology sectors, directing development for improved usability, productive access to data, and respect for the patient-physician relationship.

With a view toward the longer-term horizon, in 2017 AMA will also expand current work toward modernizing medical information coding systems that will give physicians access to data needed to reliably report performance, assess financial risk and inform negotiations for new risk-sharing payment models.

IMPROVING HEALTH OUTCOMES (IHO)

Initiatives focused on health outcomes underscore AMA's foundational commitment to improving the health of the nation. Concentrating on risk factors for cardiovascular disease and type 2 diabetes, our AMA is working with physicians and care teams to bring new approaches for anticipating, preventing, and managing widely prevalent chronic conditions that often carry acute consequences for patients.

To achieve the scale required for this ambitious set of programs, AMA has developed multi-year strategic relationships with the Centers for Disease Control and Prevention (CDC) and the American Heart Association (AHA), whose national reach and influence reinforce and complement AMA resources. Our shared goals with the CDC and the AHA include significantly increasing the number of physician practices, health care systems and federally qualified health centers that:

- Screen patients for prediabetes and refer eligible patients to CDC-recognized diabetes prevention programs (DPPs) as the preferred option for preventing type 2 diabetes, and
- Improve care for patients with hypertension to achieve and sustain 70 percent or higher blood pressure control rates within the communities they serve.

AMA will expand collaboration with partner organizations to offer evidence-based products, tools and services to support physicians, care teams, health system leaders and medical students in achieving the health outcomes we seek. Materials are being developed and distributed for use in practice settings ranging from small private practices to large integrated systems. Examples include resources available through the AMA-AHA Target BP website (<http://targetbp.org/targetbp/participant-resources-and-tools/>) as well as plans for a new AHA-AMA Target BP "Recognition Program" as a vehicle for engaging healthcare delivery systems in improving blood pressure control nationally. We continue to define and promote the "business case" for public and private payer coverage of proven interventions such as diabetes prevention programs (for which Medicare announced coverage in 2016) and self-measured blood pressure monitoring devices.

Involving patients is an important element of change as we will continue to seek venues to bring messages to broad public audiences, such as was accomplished through the national prediabetes awareness campaign launched in 2016.

ACCELERATING CHANGE IN MEDICAL EDUCATION (ACE)

The AMA is collaborating to accelerate change in medical education by creating a system that trains physicians to meet the needs of today's patients and to anticipate future changes. The initiative has funded major innovations at 32 medical schools and brought these schools together into a Consortium that shares best practices and lessons learned. The Consortium is disseminating the proven transformation strategies emerging from these leading medical schools across the medical education environment.

1 Highlights of major plans for 2017 include:

- 2 • Building on prototyping/models for the medical school of the future (faculty development;
3 developmental models for health system science and health data analytics; competency-based
4 assessment, etc.)
- 5 • Collaborating with other focus areas on student and trainee wellness; resilience/burnout; and new
6 models for linking students, physicians and communities in shared goals of chronic disease
7 management and health equity
- 8 • Developing work themes around transition to residency and transition to practice, including
9 exploration of new ideas with the National Residency Match Program

10
11 In parallel with implementation of ACE-sponsored education innovations, AMA along with participating
12 schools and partners will work in 2017 to develop a sustainable plan for the ACE Consortium into the
13 future, ready for implementation in 2018.

14 15 ENGAGING PHYSICIANS IN ADVANCEMENT OF THE MISSION

16
17 Continuing physician professional development is a cornerstone of the strategy for activating the focus
18 area objectives, which require changes in physician (and team) knowledge, skills and practice. The focus
19 area objectives and other national imperatives--such as reducing opioid-related harm and increasing
20 access to treatment for patients with opioid use disorders--require AMA to provide physicians and their
21 team members pragmatic educational offerings, tools, and leadership training designed to address real-
22 world practice and care delivery issues.

23
24 AMA's strategy in this domain calls for development of an improved Education Center portal and
25 platform over the next two years. New capabilities and an improved user experience will be introduced in
26 2017. The Introduction to the Practice of Medicine program, currently deployed in approximately 150
27 residency settings across the country, will also be modernized and incorporated into the Education Center
28 in 2017. As the multi-year effort progresses, our physician stakeholders will have access to educational
29 tools and resources from diverse sources through a highly functional platform tailored to individual needs,
30 accessible from desktops and mobile devices, with streamlined support for transcripts, reporting to
31 boards, employers and payers to serve credentialing, licensing and certification requirements.

32
33 Evidence of AMA mission impact continues to grow, creating an opportunity for AMA to refresh its
34 brand identify among physicians and other stakeholders. We will achieve this by linking relevant
35 offerings and activities throughout the career lifecycle of students, residents, and practicing physicians.
36 The goal is to strengthen the AMA brand through deeper stakeholder engagement. Traditional and
37 interactive/social/digital media will be deployed to create new connections, awareness, and opportunities
38 to interact with the AMA. More sophisticated monitoring of interactions also will yield insight into
39 physician preferences so that we can continuously improve services to physicians, residents and fellows,
40 and medical students so as to retain and grow our membership base.

41
42 The momentum that supports this multi-year strategy is a reflection of collaboration and shared
43 commitment across the AMA and the Federation of medicine, academic institutions, public and private
44 health sector organizations, technology innovators, physicians, and physicians in training. Together we
45 will chart a course for health care delivery that will improve the health of the nation.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 1-I-16

Subject: Modernized *Code of Medical Ethics*

Presented by: Ronald A. Clearfield, MD, Chair

- 1 At the 2016 Annual Meeting, the American Medical Association House of Delegates adopted the
- 2 recommendation of Council on Ethical and Judicial Affairs Report 2-A-16, “Modernized *Code of*
- 3 *Medical Ethics*.” The Council issues the Opinions of the modernized *Code*, which will appear in
- 4 full in AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.
- 5
- 6 The Council thanks the members of the House of Delegates who brought typographical errors in
- 7 the draft modernized *Code* to its attention. These have been corrected.
- 8
- 9 The Council wishes to advise the House that where appropriate throughout the Opinions of the
- 10 modernized *Code* the phrase “in keeping with ethical guidelines” has been replaced by the phrase
- 11 “in keeping with ethics guidance” for clarity. For example, Opinion 1.2.3, “Consultation, Referral,
- 12 and Second Opinions,” would read, “(b) Share patient’s health information in keeping with ethics
- 13 guidance on confidentiality.”

* Opinions of the Council on Ethical and Judicial Affairs will be placed on the Consent Calendar for informational reports, but may be withdrawn from the Consent Calendar on motion of any member of the House of Delegates and referred to a Reference Committee. The members of the House may discuss an Opinion fully in Reference Committee and on the floor of the House. After concluding its discussion, the House shall file the Opinion. The House may adopt a resolution requesting the Council on Ethical and Judicial Affairs to reconsider or withdraw the Opinion.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 2-I-16

Subject: Ethical Practice in Telemedicine

Presented by: Ronald A. Clearfield, MD, Chair

At the 2016 Annual Meeting, the American Medical Association House of Delegates adopted the recommendation of Council on Ethical and Judicial Affairs Report 1-A-16, “*Ethical Practice in Telemedicine*.” The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

1.2.12 Ethical Practice in Telemedicine

Innovation in technology, including information technology, is redefining how people perceive time and distance. It is reshaping how individuals interact with and relate to others, including when, where, and how patients and physicians engage with one another.

Telehealth and telemedicine span a continuum of technologies that offer new ways to deliver care. Yet as in any mode of care, patients need to be able to trust that physicians will place patient welfare above other interests, provide competent care, provide the information patients need to make well-considered decisions about care, respect patient privacy and confidentiality, and take steps to ensure continuity of care. Although physicians’ fundamental ethical responsibilities do not change, the continuum of possible patient-physician interactions in telehealth/telemedicine give rise to differing levels of accountability for physicians.

All physicians who participate in telehealth/telemedicine have an ethical responsibility to uphold fundamental fiduciary obligations by disclosing any financial or other interests the physician has in the telehealth/telemedicine application or service and taking steps to manage or eliminate conflicts of interests. Whenever they provide health information, including health content for websites or mobile health applications, physicians must ensure that the information they provide or that is attributed to them is objective and accurate.

Similarly, all physicians who participate in telehealth/telemedicine must assure themselves that telemedicine services have appropriate protocols to prevent unauthorized access and to protect the security and integrity of patient information at the patient end of the electronic encounter, during transmission, and among all health care professionals and other personnel who participate in the telehealth/telemedicine service consistent with their individual roles.

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Physicians who respond to individual health queries or provide personalized health advice electronically through a telehealth service in addition should:

- (a) Inform users about the limitations of the relationship and services provided.
- (b) Advise site users about how to arrange for needed care when follow-up care is indicated.
- (c) Encourage users who have primary care physicians to inform their primary physicians about the online health consultation, even if in-person care is not immediately needed.

Physicians who provide clinical services through telehealth/telemedicine must uphold the standards of professionalism expected in in-person interactions, follow appropriate ethical guidelines of relevant specialty societies and adhere to applicable law governing the practice of telemedicine. In the context of telehealth/telemedicine they further should:

- (d) Be proficient in the use of the relevant technologies and comfortable interacting with patients and/or surrogates electronically.
- (e) Recognize the limitations of the relevant technologies and take appropriate steps to overcome those limitations. Physicians must ensure that they have the information they need to make well-grounded clinical recommendations when they cannot personally conduct a physical examination, such as by having another health care professional at the patient's site conduct the exam or obtaining vital information through remote technologies.
- (f) Be prudent in carrying out a diagnostic evaluation or prescribing medication by:
 - (i) establishing the patient's identity;
 - (ii) confirming that telehealth/telemedicine services are appropriate for that patient's individual situation and medical needs;
 - (iii) evaluating the indication, appropriateness and safety of any prescription in keeping with best practice guidelines and any formulary limitations that apply to the electronic interaction; and
 - (iv) documenting the clinical evaluation and prescription.
- (g) When the physician would otherwise be expected to obtain informed consent, tailor the informed consent process to provide information patients (or their surrogates) need about the distinctive features of telehealth/telemedicine, in addition to information about medical issues and treatment options. Patients and surrogates should have a basic understanding of how telemedicine technologies will be used in care, the limitations of those technologies, the credentials of health care professionals involved, and what will be expected of patients for using these technologies.
- (h) As in any patient-physician interaction, take steps to promote continuity of care, giving consideration to how information can be preserved and accessible for future episodes of care in keeping with patients' preferences (or the decisions of their surrogates) and how follow-up care can be provided when needed. Physicians should assure themselves how

1 information will be conveyed to the patient's primary care physician when the patient
2 has a primary care physician and to other physicians currently caring for the patient.
3

4 Collectively, through their professional organizations and health care institutions, physicians
5 should:
6

- 7 (i) Support ongoing refinement of telehealth/telemedicine technologies, and the
8 development and implementation of clinical and technical standards to ensure the safety
9 and quality of care.
- 10 (j) Advocate for policies and initiatives to promote access to telehealth/telemedicine
11 services for all patients who could benefit from receiving care electronically.
12
- 13 (k) Routinely monitor the telehealth/telemedicine landscape to:
14
- 15 (i) identify and address adverse consequences as technologies and activities evolve; and
16
17 (ii) identify and encourage dissemination of both positive and negative outcomes.
18

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3-I-16

Subject: CEJA and House of Delegates Collaboration

Presented by: Ronald A. Clearfield, MD, Chair

Policy D-600.957 asks the AMA to evaluate:

- how the collaborative process between the House of Delegates and the Council on Ethical and Judicial Affairs can best be improved to allow HOD input to CEJA deliberation while still preserving CEJA autonomy; and
- how a periodic review of *Code of Medical Ethics* guidelines and reports can best be implemented.

Testimony supported looking more closely into the collaboration between the Council on Ethical and Judicial Affairs and the House of Delegates and encouraged a more clearly delineated review process for the *Code of Medical Ethics*. It also was noted that ethics guidance is intended to be timeless.

RELEVANT AMA POLICY

AMA policy is largely silent with respect to the means by which CEJA should collaborate with the House of Delegates. The Bylaws grant CEJA authority to interpret the Principles of Medical Ethics (6.5.2.1) and to investigate and make recommendations to the House regarding “general ethical conditions and all matters pertaining to the relations of physicians to one another or to the public” (6.5.2.3). Bylaw 2.13.1.1 provides that all matters pertaining to the Principles of Medical Ethics, including CEJA reports, be referred to the Reference Committee on Amendments to Constitution and Bylaws. Bylaw 2.13.1.7.2 provides that CEJA Opinions be treated as informational and filed and that motions may be made to extract an opinion and a request made to CEJA to withdraw or reconsider it. Bylaw 2.13.1.7.2 also provides that the House may adopt, refer, or not adopt CEJA reports, but that they may be amended only with the concurrence of the Council.

Policy G-615.040, “Opinions and Reports of CEJA,” provides that CEJA will present its opinions as informational and may provide to the House an analysis of issues and explanation for its opinion at the council’s discretion. G-615.040 also replicates provisions of Bylaw 2.13.1.7.2 regarding treatment of CEJA opinions, as well as provisions regarding the treatment of CEJA reports.

CEJA’s internal administrative rules provide only that matters under consideration by the council be treated as confidential until the council itself approves its report and recommendations. This has been interpreted to mean that CEJA reports in development are confidential until the council itself

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

releases them, whether by formally presenting a report for House action or otherwise making a report available for review and comment (eg, through the council's online forum).

CEJA PRACTICE

Independent of the special project to comprehensively review the *Code*, AMA ethics guidance is regularly updated whenever House of Delegates adopts a CEJA report and the report's recommendations are subsequently issued as an opinion, generally at the next meeting of the House. This includes amendments to existing guidance in response to significant changes in medical science or practice or to address newly raised questions about a particular ethics topic as well as de novo reports on new topics. Normal House processes enable delegations to submit resolutions asking CEJA to re-examine existing guidance.

Historically, in addition to the reference committee process and its Open Forum sessions at each Annual and Interim Meeting, CEJA has used a variety of strategies to obtain input, including individually inviting written review or presenting work in progress in small face-to-face meetings with key stakeholders on a report-by-report basis. In response to concerns about opportunity to provide input to the modernization of the *Code of Medical Ethics*, CEJA also scheduled special informal "open house" sessions at both the 2015 Annual and Interim Meetings to enable delegates to share comments in person.

Since 2012, CEJA has made materials available to a wider audience for input by posting content to its online discussion forum (www.ama-assn.org/go/cejaforum), allowing anyone with an AMA sign-on to read and post comments. CEJA alerts stakeholders from whom it particularly desires comment that material is available for review online. In general, CEJA has restricted printing, copying, or sharing of documents in development in keeping with its administrative rule regarding confidentiality of work not yet approved by the council for presentation to the House.

Consistent with the experience of online posting of the delegate Handbook, CEJA has had only limited success using its online forum as a means of engaging stakeholders. For the most part, although there has usually been reasonable traffic to the site, few viewers have actually posted comments. CEJA has heard concerns that the platform itself is cumbersome, and that document protections that prohibited individuals from printing or copyediting material significantly reduced the opportunity or ability to provide input.

OPPORTUNITIES TO ENHANCE COLLABORATION

Preserving CEJA's independence is essential to its role as the voice of ethics for the profession, and flexibility in its work processes is important. As a practical matter, experience suggests that opportunities to enhance collaboration between the House of Delegates and CEJA are somewhat limited. An important consideration in this regard is timing.

Over the past several years, CEJA has systematized its process of developing reports in ways that enable the council to seek input at different stages in the process, from an initial outline of salient issues through a draft ethics analysis to draft recommendations. CEJA should take advantage of this evolution to solicit input more proactively, especially by requesting comment on its outline of issues and its draft recommendations. AMA's technology staff may be able to help identify appropriate tools to enhance delegates' and members' opportunity to offer comment electronically.

However, it seems unrealistic to expect that significant active collaboration with the House as a whole can take place outside the framework of Annual and Interim Meetings. In CEJA's

1 experience, there has been little to no response to materials available online well in advance of
2 meetings. With rare exceptions, it appears that delegations overall understandably deploy their
3 limited resources for reviewing proposed policy almost exclusively immediately in advance of
4 meetings—ie, only after the delegate Handbook has been posted. This limits the opportunity for
5 CEJA to engage around work in development, particularly because there is no mechanism for
6 incorporating work products in their “pre-final” stages into the Handbook.

7
8 For the House as a whole, dedicating some portion of the schedule at Annual and Interim Meetings
9 for delegations to share reflections in person seems to hold the best hope for meeting the perceived
10 need for additional or enhanced collaboration. The “open house” model actually worked well with
11 respect to modernizing the *Code*. It offered concerned delegates the opportunity to present critique
12 in person in an informal, collegial environment and allowed CEJA to engage in discussion of
13 points raised as well as to receive valuable feedback. Participants in the A-15 and I-15 open house
14 sessions appeared to find the Saturday morning time slot reasonably convenient.

15
16 Sessions could be publicized in the Speakers’ Letter and materials posted to CEJA’s forum
17 (without protection) for prospective participants to download and print—or could be requested
18 directly from staff by email. CEJA’s Open Forum would not be an appropriate venue given the
19 educational criteria the Open Forum must meet to receive *AMA PRA Category 1 Credit*[™] and the
20 fact that it competes with multiple other sessions on the Monday morning of Annual and Interim
21 Meetings.

22
23 The Council on Ethical and Judicial Affairs therefore proposes to convene “pilot” open house
24 sessions at the 2017 Annual and Interim Meetings; seek ways to enhance its online forum for input
25 between meetings; and evaluate the value of these activities as mechanisms for enhancing
26 collaboration.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

CEJA Report 4-I-16

Subject: Ethical Physician Conduct in the Media

Presented by: Ronald A. Clearfield, MD, Chair

1 Policy D-140.957 asks that American Medical Association (AMA):

- 2
- 3 1. Report on the professional ethical obligations for physicians in the media, including
- 4 guidelines for the endorsement and dissemination of general medical information and
- 5 advice via television, radio, internet, print media, or other forms of mass audio or video
- 6 communication;
- 7
- 8 2. Study disciplinary pathways for physicians who violate ethical responsibilities through
- 9 their position on a media platform; and
- 10
- 11 3. Release a statement affirming the professional obligation of physicians in the media to
- 12 provide quality medical advice supported by evidence-based principles and transparent to
- 13 any conflicts of interest, while denouncing the dissemination of dubious or inappropriate
- 14 medical information through the public media including television, radio, internet, and
- 15 print media.
- 16

17 The resolution seeks to address concerns about the conduct of physicians who make medical
18 information available to the public through various media outlets. The resolution focuses primarily
19 on the potential for medical information to influence behavior, the importance of ensuring the
20 accuracy of medical information, and the obligation to report unethical behavior among physicians.
21 It does not explicitly acknowledge conflict of interest, physicians' responsibilities with respect to
22 health promotion, or physicians' use of online and social media.

23
24 Council on Ethical and Judicial Affairs' (CEJA) deliberations on this topic are ongoing; CEJA
25 therefore intends to submit its final report at the 2017 Annual Meeting.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-16

Subject: National Drug Shortages: Update

Presented by: Bobby Mukkamala, MD, Chair

INTRODUCTION

Policy H-100.956, “National Drug Shortages,” directs the Council on Science and Public Health (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the U.S. This informational report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2015 to August 2016, using the text term “drug shortages” combined with “impact,” “crisis,” “oncology,” “chemotherapy,” “antibacterial,” “pediatric(s),” “nutrition,” and “parenteral.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA), American Society of Health-System Pharmacists (ASHP), Government Accountability Office (GAO), Pew Charitable Trusts, Generic Pharmaceutical Association, the Pharmaceutical and Research Manufacturers of America (PhRMA) and by direct contact with key FDA and ASHP staff who manage drug shortage issues on a daily basis.

BACKGROUND

The Council has issued six previous reports on drug shortages.¹⁻⁶ The findings and conclusions from these reports are summarized in CSAPH Report 2-I-15.⁶ The remainder of this report will update current information on drug shortages since that report was developed.

CURRENT TRENDS IN DRUG SHORTAGES

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug Information Service and the Drug Shortage Program at the FDA.^{7,8} For a reminder on how the ASHP and FDA information and statistics on drug shortages are developed, see Table 1. The ASHP defines a drug shortage as “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.” The FDA defines shortages as a period of time when the demand or projected demand for a medically necessary drug in the United States exceeds its supply. Medically necessary drugs are defined by FDA as “any drug product used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other drug that is judged to be an appropriate substitute or there is an inadequate supply of an acceptable alternative.”

Because their criteria differ (the main distinction being the FDA’s definition of a “medically necessary drug”), the ASHP site lists more drug shortages than the FDA site.

American Society of Health-System Pharmacists

As of September 13, 2016, ASHP’s Drug Shortage Resource Center identified 135 drugs in shortage, down from 180 at the same time in 2015. Among these drug shortages, 17 products were not commercially available at all.⁸ Sixty-nine manufactured drugs have been discontinued since 2010, an increase of 9 from a year ago. The top active shortages by drug class remain central nervous system agents, electrolytes and nutritional components, antimicrobials, cardiovascular drugs, and chemotherapeutic agents. For a longitudinal view of new drug shortages on an annual basis, and the number of active drugs shortages quarterly, see the Appendix. Active shortages include both new and unresolved drug shortages. According to ASHP, the number of new shortages continues to decrease, while the number of active shortages has stabilized to a certain degree.

Food and Drug Administration

As of September 13, 2016, the FDA reported that 61 drugs were currently in shortage (compared with 67 one year ago), and 10 had been resolved.⁸ The latter are closely monitored because they may be at risk for falling back into shortage. Based on passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, companies are required to notify FDA of a permanent discontinuance or an interruption in manufacturing of certain drug products six months in advance, or if that is not possible, as soon as practicable. The shortage notification requirement has apparently reduced the number of new shortages by allowing FDA additional time to work with manufacturers to prevent shortages. The FDA’s drug shortages website lists drugs that meet these criteria, reflecting shortage information supplied by manufacturers.⁸ A Final Rule published on July 27, 2015 provides further guidance on the notification process and adds biologic products to the requirements for notification about potential supply disruptions.⁹

Drug Shortages Metrics Reported by FDA. The FDA’s third annual report on drug shortages (required by FDASIA) noted the following metrics during the first three quarters of calendar year 2015.¹⁰

- FDA was notified of 131 potential shortage situations by 47 different manufacturers, comparable to the numbers reported in 2014.
- 128 new drug shortages were prevented in the first three quarters of 2015, a 64% increase over the comparable time period for 2014.
- The review of 102 generic abbreviated new drug or supplemental applications was expedited, comparable to the numbers reported in 2014.
- 11 inspections were prioritized to address a drug shortage, comparable to the number reported in 2014.
- 11 fewer new drug shortages occurred in the first three quarters of 2015 (22) compared with the same period in 2014 (33).
- FDA exercised regulatory flexibility and discretion in 19 instances affecting 37 medically necessary products. Most of these involved measures to mitigate risks such as removing particulate matter, extra testing for quality, third-party oversight of production, provision of special instructions to prescribers and/or patients, or approval of foreign sources. With respect to the last of these mitigation strategies, the FDA now conducts regular virtual

meetings with their international regulatory counterparts to share information on drug shortages and mitigation strategies impacting patients in other countries.

The FDA also has developed apps for both the iPhone and Android operating systems that provide access to drug shortage information as well as notifications about new and resolved drug shortages.

Reporting a Drug Shortage

Physicians can directly [report](#) a drug shortage via the ASHP drug shortage website. Physicians can directly report a drug shortage to the Center for Drug Evaluation and Research via email (drugshortages@fda.hhs.gov) or by phone at 240-402-7770.

GAO REPORT

In a follow-up to its 2014 report on drug shortages, the Government Accountability Office (GAO) evaluated trends in drug shortages from 2010-2015 in an effort to identify influential factors.¹¹ This evaluation confirmed that the FDA had prioritized 383 new, abbreviated, and supplemental drug applications to address drug shortages, mostly for sterile injectable products. The use of this prioritization scheme was temporally associated with reductions in active and ongoing shortages. Analysis of selected categories (i.e., sterile injectable anti-infective and cardiovascular drugs) confirmed that shortages were strongly associated with previously identified key drivers, namely a decline in the number of manufacturers, existence of a generic product, and an emergent problem with manufacturing capability in at least one manufacturer that was sufficiently serious to cause a warning letter to be issued. Shortages were more likely to affect generic drugs with low profit margins, although drug price itself was not predictive in this study.

GENERIC PHARMACEUTICAL ASSOCIATION

Given that the majority of drug shortages involve generic products, the GPhA created a voluntary approach called the Accelerated Recovery Initiative in 2013 intended to accelerate the recovery of certain critical drugs in short supply.^{4,12} This multi-stakeholder approach relies on voluntary, confidential communication between an independent third party (IMS Health) and pharmaceutical companies involved in the manufacturing of generic injectable drugs in shortage. Additionally, wholesalers, distributors, and the FDA can provide information to assist companies with making timely decisions to help avert or mitigate a shortage. While this program is apparently still operational, there are no publicly available reports evaluating its degree of success.¹²

CLINICAL IMPLICATIONS

Despite increasing success in preventing or mitigating drug shortages and an overall decrease in the number of new drug shortages, critical drug shortages continue to occur across multiple therapeutic categories. While the existence of a sole source manufacturer is a risk factor for shortages, it also has been the focus of some recent exorbitant drug price escalations. Reviews of shortages affecting the operation of emergency departments identified several intravenous formulations that remain in short supply and are affecting patient care including certain opioid analgesics, antiemetics, selected antimicrobials, benzodiazepines and other drugs used for rapid induction of anesthesia, electrolytes, and local anesthetics.^{13,14} Shortages of various antidotes also have been noted, and the implications of drug shortages for pediatric patients, those with cardiovascular disease or those who are acutely ill have been studied.¹⁵⁻¹⁸ In some cases, work-arounds have been successful in maintaining patient safety and achieving satisfactory clinical outcomes.¹⁹

1 SUMMARY

2

3 Manufacturers are notifying the FDA about potential disruptions in supply or shortages earlier than
4 in the past and the FDA is expediting the review of new applications intended to address shortages.
5 Accordingly, the total number of new drug shortages continues to decline and the extent of ongoing
6 shortages has stabilized over the past two years. However, the drug supply for many acutely and
7 critically ill patients in the United States remains vulnerable despite federal efforts.²⁰ Some
8 progress is being made, but permanent solutions remain elusive and beyond the control of
9 individual practitioners and the health care system.

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Table 1. Contrasting the FDA (CDER) and ASHP Drug Shortage Websites

	FDA	ASHP
Purpose	Provides information obtained from manufacturers about current shortages, estimated duration, and discontinuations and provides information about FDA's and other stakeholders' roles in addressing and preventing shortages	Notification of new shortages and status of ongoing shortages; drug shortage management resources
Audience	Public	Healthcare practitioners
Scope of shortage list	All drugs are listed that are confirmed to be a national shortage by FDA. A shortage is considered to be the period of time when the demand for the drug within the United States exceeds the supply of the drug. ^a	All drug and biologic shortages reported and confirmed with manufacturer that are national in impact.
Source of shortage report	Manufacturers notify FDA of production disruption and voluntarily provide updates. Reports are also received from ASHP and from public via drugshortages@cder.fda.gov Note: Manufacturer-provided information represents shortage status at drug firm level.	Voluntary reports from practitioners, patients, pharmaceutical industry representatives and others Note 1: Information is updated based on release dates from manufacturers. Note 2: Reports reflect status at healthcare provider level.
Criteria for inclusion on list	Manufacturers cannot meet current market demand for the drug based on information provided by manufacturers and market sales research. Drug listed are defined as "medically necessary."	(1) Shortage is verified with manufacturers and (2) affects how pharmacy prepares or dispenses a product, or (3) requires use of alternative drugs, which may affect patient care.
Criteria for resolving shortage	One or more manufacturers are in production and able to meet full market demand.	All manufacturers of the drug restore all formulations and dosage sizes to full availability. Note: Products are listed despite partial or restricted availability as supply chain disruptions can result in intermittent shortages at the provider or patient level.
Reason for shortage	Provided by manufacturers using reasons required by legislation. ^b FDA encourages firms to provide additional information about reasons and other information which, if proprietary, is nondisclosable without the firm's permission.	Provided by manufacturer, if willing to disclose. Note: May differ from FDA's due to different sources of information and legislation requiring FDA to use specified reasons
Other information	Estimated duration, links to regulatory information such as recalls and Dear Healthcare Provider Letters	Estimated duration, list of available products, implications for patient care and safety, shortage management strategies, therapeutic alternatives

^a Note: A separate shortage webpage for vaccines and some biologics is maintained by the Center for Biologics Evaluation and Research.

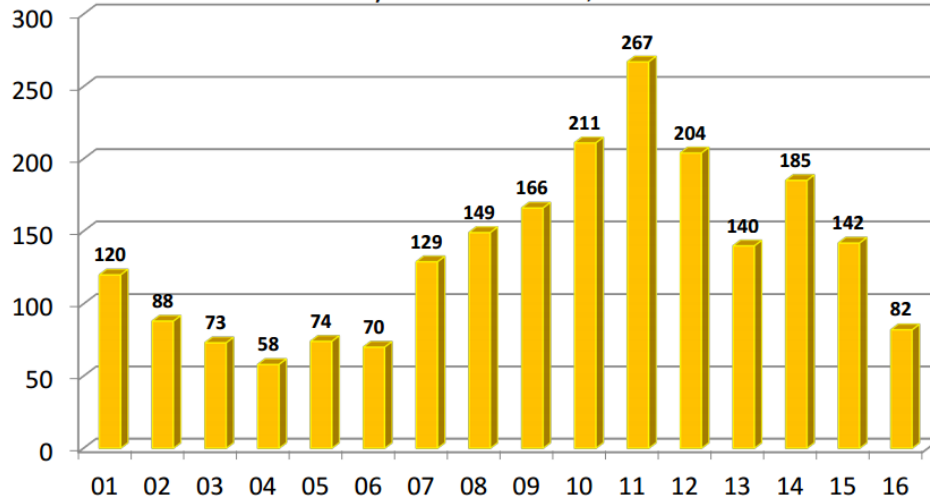
^b Categories include (a) requirement related to complying with good manufacturing practices; (b) regulatory delay; (c) shortage of an active ingredient

APPENDIX

National Drug Shortages

Annual New Shortages by Year

January 2001 to June 30, 2016

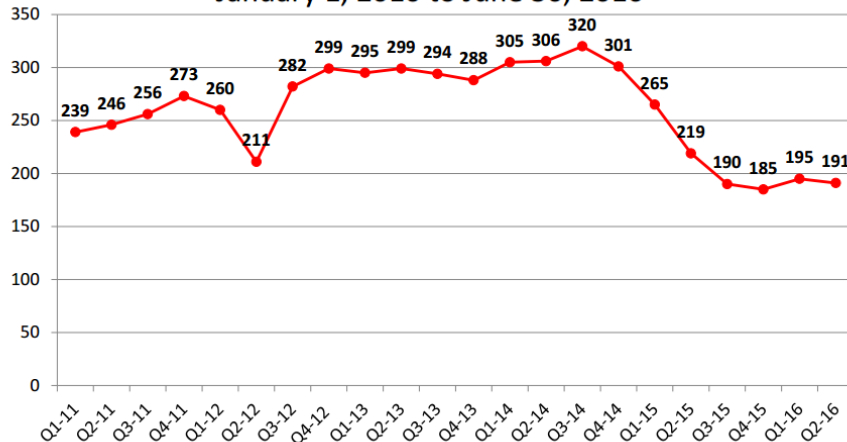


University of Utah Drug Information Service
Contact Erin.Fox@hsc.utah.edu, @foxerinr for more information

National Drug Shortages

Active Shortages by Quarter

January 1, 2010 to June 30, 2016



Note: These data represent the count of active shortages on the last day of each quarter, and should not be interpreted as total shortages for that period.

University of Utah Drug Information Service
Contact Erin.Fox@hsc.utah.edu, @foxerinr for more information

Not for consideration

Resolutions not for consideration

601 Sexual Orientation and Gender Identity Demographic Collection by the AMA and Other Medical Organizations

605* Study of Models of Childcare Provided at Healthcare Institutions

* contained in Handbook Addendum

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 601
(I-16)

Introduced by: Medical Student Section

Subject: Sexual Orientation and Gender Identity Demographic Collection by AMA and Other Medical Organizations

Referred to: Reference Committee F
(Gary R. Katz, MD, Chair)

Whereas, An estimated 5.2 to 9.5 million adults (2.2% to 4.4% of the adult population) in the United States identify as lesbian, gay, bisexual, and/or transgender (LGBT);¹ and

Whereas, Physician diversity that is reflective of patient demographics has been positively associated with improved patient health outcomes, reduced stigmatization of the LGBT demographic, and enhanced workforce development;^{2,3,4,5} and

Whereas, Medical organizations (e.g. Association of American Medical Colleges), public-policy research groups (e.g. The Williams Institute), and healthcare providers (e.g. The Fenway Institute) collect sexual orientation and gender identity demographics in population-based surveys and in the clinical setting;^{6,7,8} and

Whereas, Pursuant to AMA Policy G-635.125, the AMA gathers stratified demographics of its AMA membership, the nature of which includes age, gender, race/ethnicity, education, life stage, present employment, and self-designated specialty; and

Whereas, The AMA does not have existing policy to collect sexual orientation and gender identity within the AMA Physician Masterfile;^{9,10} and

Whereas, Expanding the collection of demographic data to include a member's sexual orientation and gender identity will allow the AMA to identify and address professional satisfaction needs of a formerly unidentified population of both existing and potential new members;⁸ therefore be it

¹ Gates, GA. LGBT Demographics: Population-based surveys. The Williams Institute. Available from: URL: <http://williamsinstitute.law.ucla.edu/wp-content/uploads/lgbt-demogs-sep-2014.pdf>. Published September 2014.

² Cooper, L. et al. Patient-Centered Communication, Ratings of Care, and Concordance of Patient and Physician Race. *Annals of Internal Medicine*. 2003;139(11):907. doi:10.7326/0003-4819-139-11-200312020-00009.

³ Paez, K. et al. Physician Cultural Competence and Patient Ratings of the Patient-Physician Relationship. *J GEN INTERN MED*. 2009;24(4):495-498. doi:10.1007/s11606-009-0919-7.

⁴ Department of Health and Human Services (US), Health Resources and Services Administration, Bureau of Health Professions. The rationale for diversity in the health professions: a review of the evidence. Available from: URL: <http://bhpr.hrsa.gov/healthworkforce/reports/diversityreviewevidence.pdf>. Published October 2006.

⁵ Mansh M. et al. From Patients to Providers. *Academic Medicine*. 2015;90(5):574-580. doi:10.1097/acm.0000000000000656.

⁶ Association of American Medical Colleges (AAMC). Matriculating Student Questionnaire 2015 All Schools Summary Report.; 2015. Available at: <https://www.aamc.org/download/450608/data/msq2015report.pdf>. Accessed March 1, 2016.

⁷ Gender Identity in U.S. Surveillance (GenIUSS) Group. Best Practices for Asking Questions to Identify Transgender and Other Gender Minority Respondents on Population-Based Surveys. The Williams Institute. 2014. Available from: URL: <http://williamsinstitute.law.ucla.edu/wp-content/uploads/geniuss-report-sep-2014.pdf>.

⁸ Do Ask, Do Tell: A Toolkit for Collecting Data on Sexual Orientation and Gender Identity in Clinical Settings. The Fenway Institute and Center for American Progress. 2016. Available from: URL: <http://doaskdotell.org>. Accessed February 29, 2016.

⁹ Confirmed by email with J. Mori Johnson, MA, AMA Director of Large Practice Engagement, December 2015.

- 1 RESOLVED, That our American Medical Association develop a plan with input from the LGBT
- 2 Advisory Committee to expand the demographics we collect about our members to include both
- 3 sexual orientation and gender identity information, which will be given voluntarily by members
- 4 and handled in a confidential manner. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.

Received: 09/29/16

RELEVANT AMA POLICY

AMA Membership Demographics G-635.125 - 1. Stratified demographics of our AMA membership will be reported annually and include information regarding age, gender, race/ethnicity, education, life stage, present employment, and self-designated specialty. 2. Our AMA will immediately release to each state medical and specialty society, on request, the names, category and demographics of all AMA members of that state and specialty.
BOT Rep. 26, A-10 Reaffirmed: CCB/CLRPD Rep. 3, A-12

The Demographics of the House of Delegates G-600.035 - 1. A report on the demographics of our AMA House of Delegates will be issued annually and include information regarding age, gender, race/ethnicity, education, life stage, present employment, and self-designated specialty. 2. As one means of encouraging greater awareness and responsiveness to diversity, our AMA will prepare and distribute a state-by-state demographic analysis of the House of Delegates, with comparisons to the physician population and to our AMA physician membership every other year. 3. Future reports on the demographic characteristics of the House of Delegates will identify and include information on successful initiatives and best practices to promote diversity, particularly by age, of state and specialty society delegations. 4. Our AMA will convene a group of stakeholders at a forum in conjunction with the 2016 Annual Meeting to identify viable solutions with which to promote diversity, particularly by age, of state and specialty society delegations, with a summary of the findings to be included in the next CLRPD report on the demographic characteristics of the House of Delegates.
CCB/CLRPD Rep. 3, A-12 Appended: Res. 616, A-14 Appended: CLRPD Rep. 1, I-15

Strategies for Enhancing Diversity in the Physician Workforce H-200.951 - Our AMA supports increased diversity across all specialties in the physician workforce in the categories of race, ethnicity, gender, sexual orientation/gender identity, socioeconomic origin and persons with disabilities.
CME Rep. 1, I-06 Reaffirmed: CME Rep. 7, A-08 Reaffirmed: CCB/CLRPD Rep. 4, A-13
Modified: CME Rep. 01, A-16 Reaffirmation A-16

Revisions to AMA Policy on the Physician Workforce H-200.955 - It is AMA policy that: (1) any workforce planning efforts, done by the AMA or others, should utilize data on all aspects of the health care system, including projected demographics of both providers and patients, the number and roles of other health professionals in providing care, and practice environment changes. Planning should have as a goal appropriate physician numbers, specialty mix, and geographic distribution. (2) Our AMA encourages and collaborates in the collection of the data needed for workforce planning and in the conduct of national and regional research on physician supply and distribution. The AMA will independently and in collaboration with state and specialty societies, national medical organizations, and other public and private sector groups, compile and disseminate the results of the research. (3) The medical profession must be integrally involved in any workforce planning efforts sponsored by federal or state governments, or by the private sector. (4) In order to enhance access to care, our AMA

collaborates with the public and private sectors to ensure an adequate supply of physicians in all specialties and to develop strategies to mitigate the current geographic maldistribution of physicians. (5) There is a need to enhance underrepresented minority representation in medical schools and in the physician workforce, as a means to ultimately improve access to care for minority and underserved groups. (6) There should be no decrease in the number of funded graduate medical education (GME) positions. Any increase in the number of funded GME positions, overall or in a given specialty, and in the number of US medical students should be based on a demonstrated regional or national need. (7) Our AMA will collect and disseminate information on market demands and workforce needs, so as to assist medical students and resident physicians in selecting a specialty and choosing a career.

CME Rep. 2, I-03 Reaffirmation I-06 Reaffirmation I-07 Reaffirmed: CME Rep. 15, A-10

Reaffirmation: I-12 Reaffirmation A-13

Increasing Demographically Diverse Representation in Liaison Committee on Medical Education Accredited Medical Schools D-295.322 - Our AMA will continue to study medical school implementation of the Liaison Committee on Medical Education (LCME) Standard IS-16 and share the results with appropriate accreditation organizations and all state medical associations for action on demographic diversity.

Res. 313, A-09 Modified: CME Rep. 6, A-11

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 605
(I-16)

Introduced by: American Medical Women's Association

Subject: Study of Models of Childcare Provided at Healthcare Institutions

Referred to: Reference Committee F
(Gary R. Katz, MD, Chair)

1 Whereas, Physicians with pre-school age children face significant difficulties finding childcare
2 that is easily accessible to their work place, is affordable, and accommodates the unpredictable
3 work hours faced by physicians; and
4

5 Whereas, This lack of childcare can place additional stress on already stressful careers,
6 especially for younger physicians; and
7

8 Whereas, Some businesses are starting to provide childcare services, utilizing a variety of
9 funding models; and
10

11 Whereas, Some healthcare institutions are also starting to provide these services; and
12

13 Whereas, Provision of these services could help with retention of physicians, especially those
14 earlier in their careers; and
15

16 Whereas, The number and size of institutions offering this and the models that they use to do so
17 are unknown; therefore be it
18

19 RESOLVED, That our American Medical Association study which healthcare institutions
20 currently provide accessible, affordable childcare services, the size of the institutions (in terms
21 of number of physicians) providing these services, the impact of these services on residents and
22 faculty (especially in terms of decreasing stress and increasing retention), and the various
23 funding models used for these (Directive to Take Action); and be it further
24

25 RESOLVED, That our AMA report back to the House of Delegates with this information at the
26 Annual Meeting in 2017. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 11/12/16