Memo to: Committee on Rules and Credentials
From: Roger Brown
Date: June 3, 2009
Subject: Committee Meeting, June 13, 2009

On behalf of the Speakers, I am requesting that the Committee on Rules and Credentials meet on Saturday, June 13, at 8:30 a.m. in the Columbus H Room at the Hyatt Regency Chicago. The agenda will include several responsibilities:

1. Reviewing the election ballots for accuracy. In addition, the committee will be responsible for supervising distribution of “authority to vote” slips at the elections, Tuesday, June 17, from 7:30 a.m. to 8:45 a.m.

2. Reviewing routine reports regarding rules and procedures (draft reports attached).

3. Auditing reports of those registered as official delegates; the committee chair will present the credentials report at the beginning of all sessions of the House of Delegates. Please note that this audit is only necessary if there are questions raised about credentialing of delegates; the committee chair will get the report each day from AMA registration.

4. Reviewing late resolutions and making recommendations to the House regarding their acceptance. Any late resolutions received by noon on Friday, June 12, will be presented to the committee at the meeting. Sponsors of the resolutions are invited to briefly explain to the committee the timeliness and/or urgency of the resolution, why it was submitted late, and why it should be accepted for business at the meeting.

5. Reviewing recommendations for placing resolutions on the Reaffirmation Consent Calendar. Attached are resolutions that staff research shows to be essentially a reaffirmation of existing policy. The relevant AMA policies are also attached for your review. Please review the proposed resolutions along with the material prepared by staff and decide whether in your judgment the proposed resolution is “identical or substantially identical to existing policy.” Those items that the committee considers as reaffirmations will be placed on the Reaffirmation Consent Calendar, while items not placed on the consent calendar will be handled as business in each reference committee. For resolutions on the Reaffirmation Consent Calendar that are not extracted during Sunday’s “Second Opening,” the existing, pertinent AMA policy will be deemed to be reaffirmed in lieu of the submitted resolution, resetting the sunset clock for ten years. (See Policy G-600.060 for more information.)

Attachments

cc: Jeremy A. Lazarus, MD
    Andrew W. Gurman, MD
    Lee Ann Conti
    Carla Frenzel
Mister Speaker, Members of the House of Delegates:

Your Committee on Rules and Credentials recommends that:

1. House Security

Maximum security shall be maintained at all times to prevent disruptions of the House, and only those individuals who have been properly badged will be permitted to attend.

2. Credentials

The registration record of the Committee on Rules and Credentials shall constitute the official roll call at each meeting of the House.

3. Order of Business

The order of business as published in the Handbook shall be the official order of business for all sessions of the House of Delegates. This may be varied by the Speaker if, in his judgment, it will expedite the business of the House, subject to any objection sustained by the House.

4. Privilege of the Floor

The Speaker may grant the privilege of the floor to such persons as may be presented by the President, or Chair of the Board of Trustees, or others who may expedite the business of the House, subject to objections sustained by the House.

5. Procedures of the House of Delegates


6. Limitation on Debate

There will be a 3-minute limitation on debate per presentation subject to waiver by the Speaker for just cause.

7. Nominations and Elections

The House will receive nominations for President-Elect, Speaker, Vice Speaker, Trustees and Council Members on Saturday afternoon, June 13. Speeches will be limited to candidates for officers, with no seconding speeches permitted. The order will be selected by lottery.
The Association’s 2009 annual election balloting shall be held Tuesday, June 16, between the hours of 7:30 a.m. and 8:45 a.m., as specified in Sections 3.40 and 6.80 of the Bylaws, and the following procedures shall be adopted:

Accredited Delegates may vote any time between 7:30 a.m. and 8:45 a.m. by reporting to the polls in Columbus K-L of the Hyatt Regency Chicago. The Committee on Rules and Credentials will certify each delegate and give him/her an “authority to vote” slip. The slip will then be handed to an election teller, who will provide the voter with a ballot and provide assistance as necessary.

The announcement and confirmation of the election results will be called for as soon as possible and appropriate.

In instances where there is only one nominee for an office, a majority vote without ballot shall elect on Saturday.

8. Conflict of Interest

Members of the House of Delegates who have a substantial financial interest in a commercial enterprise, which interest will be materially affected by a matter before the House of Delegates, must publicly disclose that interest before testifying at a reference committee on the matter or speaking on the floor of the House of Delegates on the matter.

9. Conduct of Business by the House of Delegates

Each member of the House of Delegates, and the AMA Officers and Board of Trustees resolutely affirm a commitment to be courteous, respectful and collegial in the conduct of House of Delegate actions, characteristics which should exemplify the members of our respected and learned profession.

Mister Speaker, this concludes the Report of the Committee on Rules and Credentials and we recommend its adoption.

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Mississippi
Chair

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Charles J. Hickey, MD
Ohio

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Blanton Bessinger, MD, MBA (Alternate)
Minnesota

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Albert M. Kwan, MD (Alternate)
New Mexico

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Michael Best
Regional Medical Student, Pennsylvania

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David J. Lindquist, MD
Oregon

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Theodore A. Calianos, II, MD (Alternate)
Massachusetts
Mister Speaker, Members of the House of Delegates:

Your Committee on Rules and Credentials wishes to report that out of 543 delegates have been accredited. This is percent of the membership of the House and constitutes a quorum.

Mister Speaker, I move this report be accepted as information.

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Mister Speaker, Members of the House of Delegates:

Your Committee on Rules and Credentials wishes to commend the Speaker, Doctor Lazarus, and the Vice Speaker, Doctor Gurman, for the outstanding manner in which they have assisted our deliberations by their fair and impartial conduct of the House of Delegates and to commend the members of the House for their cooperation in expediting the business before us.

Your Committee wishes at this time to offer the following Resolution:

Whereas, The Annual Meeting of the House of Delegates of the American Medical Association has been convened in Chicago, Illinois during the period of June 13-17, 2009; and

Whereas, This Annual Meeting of the House of Delegates has been most profitable and enjoyable from the viewpoint of policy deliberations and fellowship; and

Whereas, The City of Chicago has extended to the members attending this Meeting the utmost hospitality and friendliness; therefore be it

RESOLVED, That expressions of deep appreciation be made to the AMA Board of Trustees for arranging this meeting, to the management of the Hyatt Regency Chicago, to the City of Chicago, to the members of the Alliance who always contribute so substantially to our meetings, and to the splendid men and women of our American Medical Association staff who participated in the planning and conduct of this Annual Meeting of the House of Delegates.

Mister Speaker, this concludes the Report of the Committee on Rules and Credentials, and we recommend its adoption.
The procedure for Late Resolutions is as follows:

The Committee on Rules and Credentials will review the resolution and make a recommendation to the House on whether to accept or not accept the resolution as business. A member of your delegation (or other representative) is invited to the Rules and Credentials Committee meeting to briefly discuss the reasons for the resolution's lateness, and explain the timeliness/urgency of the issue to the committee. The representative should not discuss the merits of the resolution itself, but purely the reasons why it was submitted late and why it should be considered by the House at this meeting.

The Rules and Credentials Committee will meet at 8:30 a.m., Saturday, June 13, in the Columbus H Room at the Hyatt Regency Chicago. Late resolutions will be among the first agenda items for the committee, so your representative should plan to arrive around 8:35 a.m., and wait outside the room until invited in to discuss the resolution. After your representative's presentation to the committee, the committee will meet in executive session to form its recommendation to the House. A 2/3 affirmative vote by the House during its “Second” Opening Session on Sunday, June 15, is required for acceptance of a late resolution as official business of the House.
Whereas, The World Health Organization has declared a level 5 status-imminent pandemic of H1N1 Novel strain (Swine) influenza, and a level 6 pandemic influenza will be declared if and when two or more continents develop sustained human to human transmission; and

Whereas, The US now has more confirmed or probable cases spread among many states of H1N1 novel strain (Swine) influenza than any other country, some complicated by deaths; and

Whereas, Airline travel poses risk to nearby passengers when droplet spread of influenza occurs by poor hygiene, repeated coughing or sneezing; and

Whereas, The Transportation Security Administration (TSA) can and has in the past set guidelines for US airlines and for international flights bound to the US; and

Whereas, The H1N1 novel influenza strain is likely to become Tamiflu resistant as it recombines with seasonal influenza; and

Whereas, No vaccine is yet available for the novel H1N1 strain influenza; and

Whereas, The said novel strain may become more virulent during the normal influenza season next fall and winter; and

Whereas, The Centers for Disease Control and Prevention has issued prudent hygienic guidelines concerning novel H1N1 strain influenza for population protection during flights to and from Mexico, which are NOT being universally adhered to by ALL airlines at this time; therefore be it

RESOLVED, That our American Medical Association call upon the Centers for Disease Control and Prevention, the Department of Homeland Security and the Transportation Security Administration to urgently develop, disseminate and implement clear and consistent guidelines developed with input from appropriate public health, aerospace and infectious disease experts, aimed at protection of airline passengers and flight attendants from others who are known or suspected to have flu like symptoms with evidence based community hygienic measures, use of masks, use of hand washing/sanitizers and tissues (Directive to Take Action); and be it further

RESOLVED, That our AMA submit a progress report at the 2009 Interim Meeting on the development, dissemination and implementation of Flu Protection Guidelines for Airline Travel. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $4,479.

Received: 05/22/09
Mister Speaker, Members of the House of Delegates:

The Committee on Rules and Credentials met Saturday, June 13, 2009 to discuss Late Resolution(s) 1001. Sponsors of late resolutions that are received prior to a week before the opening of the House of Delegates are informed of the time the Committee on Rules and Credentials meets to consider late resolutions, 8:30 a.m. on Saturday, and the opportunity to present for the Committee's consideration the reason the resolution could not be submitted in a timely fashion and the urgency of consideration by the House of Delegates at this meeting. The sponsor of Late Resolution(s) 1001 appeared to discuss their resolution.

(1) LATE RESOLUTIONS

Recommended for Acceptance:

Recommended Not Be Accepted:

(2) - REAFFIRMATION RESOLUTIONS

The Speakers asked the Committee on Rules and Credentials to review the recommendations for placing resolutions introduced at this meeting of the House of Delegates on the Reaffirmation Calendar. Reaffirmation of existing policy means that the policies reaffirmed remain active policies within the AMA policy database and therefore are part of the body of policy that can be used in setting the AMA’s agenda. It also resets the “sunset clock,” so such policies will remain viable for 10 years from the date of reaffirmation. The Committee recommends that current policy be reaffirmed in lieu of the following resolutions (current policy and AMA activities are listed in the Appendix to this report):

1. Resolution 102 - Domestic Violence Insurance Discrimination
2. Resolution 109 - Obesity
3. Resolution 110 - “Public Option” Health Insurance
4. Resolution 111 - Payment for Email Consultations by Medicare
5. Resolution 114 - Financial Barriers to Specialty Care
6. Resolution 117 - Access to Affordable and Adequate Diabetes Supplies
7. Resolution 118 - Transparency of Preventative Care Services
8. Resolution 119 - Commercial Insurance for All Expansion of Health Care
9. Resolution 122 - Extension of Veterans Affairs Pharmacy Benefit to all Veterans
10. Resolution 125 - Adjustments Made to Relative Scale to Include Increased Paperwork for Physicians
11. Resolution 128 - Insurance Companies and ACIP
12. Resolution 201 - Americans’ Health
13. Resolution 203 - Right to Privately Contract
14. Resolution 204 - Criminalization of PLI
15. Resolution 205 - Electronic Prescribing of Class 3 Substances
16. Resolution 206 - Interpretive Services
17. Resolution 208 - Protection to Practice
18. Resolution 209 - Health System and Litigation Reform
19. Resolution 210 - Geographic Devaluation of Medicare Payments for PQRI
20. Resolution 211 - Geographic Devaluation of E-Prescribing Payments
21. Resolution 212 - Geographic Practice Code Index (GPCI) Adjustment to Technical Component Fees for Imaging Procedures
22. Resolution 213 - Stricter Fines for Violating Direct-to-Consumer Advertisements
23. Resolution 215 - Insurance Companies Use of Contractors to Recover Payments
24. Resolution 216 - Electronic Submission of Schedule II-V Narcotic Prescriptions
25. Resolution 218 - Open Source Code Electronic Medical Records
26. Resolution 219 - Out of Network Payments
27. Resolution 403 - Banning Tobacco Product Sales in Pharmacies
28. Resolution 405 - Raising the Age of Alcohol Consumption in the Territory of Guam
29. Resolution 408 - The Physician’s Obligation to Identify and Treat Prenatal and Perinatal Addiction
30. Resolution 411 - Reduction or Elimination of Gun Violence in the Mass Media
31. Resolution 508 - State Vaccine Registry Interfaces
32. Resolution 511 - Reducing Medication Waste From Extended Care Facilities
33. Resolution 513 - Novel Antibiotics and Antimicrobial Resistance
34. Resolution 518 - Generic Drugs From Foreign Manufacturers Sold in the US
35. Resolution 525 - Research Visa Waiver for Physician Scientists
36. Resolution 602 - Control and Use of Physician Data
37. Resolution /04 - Physician Owned Hospitals
38. Resolution 705 - Office Payment
39. Resolution /06 - Standardized Medical Insurance Cards
40. Resolution /07 - Price Transparency
41. Resolution 708 - Health Insurance and Pharmacies Advise Physicians to Take Action
42. Resolution /10 - Identifying Abusive, Hostile or Non-Compliant Patients
43. Resolution /11 - Physician Representation on Hospital Boards
44. Resolution /12 - Development of a Payment Code for Prior Authorization
45. Resolution /13 - ‘Advance Directives for All’ Campaign
46. Resolution /18 - Hospital Restrictions on Access to Medical Records
47. Resolution /21 - Uniform Overhead Emergency Codes
48. Resolution /24 - Reimbursement for Services
49. Resolution 727 - Medical Directors as “Peer” Reviewers When Pre-Adjudicating Prescribed Tests and Procedures
50. Resolution /28 - Physician Profiling / Grading and Report Cards
51. Resolution 730 - Medical Staff Self Governance
52. Resolution /33 - Medical Smart Cards
53. Resolution 734 - National Practitioner Data Bank: Length of Time for Storing Medical Malpractice Data
Mister Speaker, this concludes the Supplementary Report of the Committee on Rules and
Credentials. I would like to thank Blanton Bessinger, MD, MBA, Michael Best, Theodore A.
Calianos, II, MD, Charles J. Hickey, MD, Albert M. Kwan, MD, and David J. Lindquist, MD, and on
behalf of the Committee, those who appeared before the Committee.

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Mississippi
Chair

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APPENDIX - RESOLUTIONS RECOMMENDED FOR REAFFIRMATION OF CURRENT POLICY IN LIEU OF THE RESOLUTIONS WITH REAFFIRMED POLICY AND AMA ACTIVITIES

1. Resolution 102 - Domestic Violence Insurance Discrimination
   • H-185.976 Insurance Discrimination Against Victims of Domestic Violence
   • H-180.981 Rating or Rejection of Applicants for Health Policies

2. Resolution 109 - Obesity
   • H-150.953 Obesity as a Major Public Health Program
   • H-160.938 Disease-Specific Self-Management Programs

3. Resolution 110 - “Public Option” Health Insurance
   • H-165.844 Educating the American People About Health System Reform
   • H-165.888 Evaluating Health System Reform Proposals
   • H-165.916 Government Controlled Medicine
   • H-165.985 Opposition to Nationalized Health Care

4. Resolution 111 - Payment for Email Consultations by Medicare
   • H-390.859 Reimbursement for Telephonic and Electronic Communications

5. Resolution 114 - Financial Barriers to Specialty Care
   • H-160.952 Access to Specialty Care

6. Resolution 117 - Access to Affordable and Adequate Diabetes Supplies
   • H-165.882 Improving Access for the Uninsured and Underinsured
   • H-155.960 Strategies to Address Rising Health Care Costs

7. Resolution 118 - Transparency of Preventative Care Services
   • H-165.846 Adequacy of Health Insurance Coverage Options
   • H-440.875 Assuring Access to ACIP/AAFP/AAP-Recommended Vaccines

8. Resolution 119 - Commercial Insurance for All Expansion of Health Care
   • H-165.844 Educating the American People About Health System Reform
   • H-165.888 Evaluating Health System Reform Proposals
   • H-165.916 Government Controlled Medicine
   • H-165.985 Opposition to Nationalized Health Care
   • D-385.976 Published Reimbursement Schedules by Private Insurers

9. Resolution 122 - Extension of Veterans Affairs Pharmacy Benefit to all Veterans
   • H-510.991 Veterans Administration Health System

10. Resolution 126 - Adjustments Made to Relative Scale to Include Increased Paperwork for Physicians
    • H-240.966 Reimbursement to Physicians and Hospitals for Government Mandated Services

11. Resolution 128 - Insurance Companies and ACIP
12. Resolution 201 - Americans’ Health
   • H-440.875 Assuring Access to ACIP/AAFP/AAP-Recommended Vaccines
   • H-440.860 Financing of Adult Vaccines: Recommendations for Action

   The AMA, in collaboration with the U.S. Department of Health and Human Services’ Health Resources and Services Administration and the Centers for Disease Control and Prevention, convened an expert committee to develop recommendations on the assessment, prevention, and treatment of child and adolescent overweight and obesity, recently published in the attached Pediatrics (December 2007) journal article.

   The AMA participated in a Congressional briefing on childhood obesity, as represented by the attached handout, Childhood Obesity American Medical Association (AMA) Policy and Guidelines, July 30, 2008.

   Letter to the Honorable Lynn Woolsey, April 6, 2009, expressing our support for H.R. 1324, the “Child Nutrition Promotion and School Lunch Act of 2009,” which would help confront the epidemic of child obesity by improving the nutritional quality of food sold in schools outside federally-reimbursed school meal programs.

   Letter to the Honorable Elias A. Zerhouni, MD, Director of the National Institutes of Health, October 9, 2008, discussing our concerns about gaps in the scientific knowledge regarding obesity screening and interventions related to health lifestyle behaviors such as healthy eating and regular physical activity.

   Letter to the Honorable Edward T. Schafer, MBA, Secretary of Agriculture, October 8, 2008, discussing our concerns about gaps in the scientific knowledge regarding high fructose corn syrup and the impact this may have on recommendations regarding its use in the food supply.

   Letter to the Honorable Jeff Bingaman, May 8, 2008, expressing our support for S. 866, the “Health Promotion Funding Integrated Research, Synthesis, and Training (FIRST) Act,” which would encourage the federal government to build a more comprehensive and coordinated plan to develop the basic and applied science of health promotion, synthesize research results into practical guidelines, and disseminate findings to researchers, practitioner, and policy makers.

   Comments to the Food and Drug Administration, March 27, 2008, regarding the FDA’s hearing regarding slat and sodium on food and its willingness to re-examine this issue.

13. Resolution 203 - Right to Privately Contract
   • H-385.961 Medicare Private Contracting
   • D-380.997 Private Contracting by Medicare Patients
   • H-380.989 Patient and Physician Right to Privately Contract for Health Care
   • H-330.932 Cuts in Medicare and Medicaid Reimbursement
   • H-330.969 Medicare Program
   • H-285.995 Managed Care - Policy and Initiatives
   • H-383.993 Negotiations Issue
• Letter to the Honorable Sam Johnson, October 21, 2008 supporting H.R. 7148, the “Medicare Beneficiary Freedom to Choose Act of 2008,” which would allow Medicare beneficiaries to contract privately with a physician for Medicare-covered services and eliminate the current requirement that physicians “opt-out” of the Medicare program for two years if they enter into a private contract with a Medicare beneficiary.
• AMA Executive Summary on “Physician Networks and Antitrust: A Call For A More Flexible Enforcement Policy,” June 2008
• AMA Issue Paper on “Physician Networks and Antitrust: A Call For A More Flexible Enforcement Policy,” June 2008
• AMA Board of Trustees Informational Report to the House of Delegates, Interim Meeting 2007, regarding the AMA’s “Antitrust/Collective Bargaining Strategy,” and advocating that the AMA aggressively pursue changes to the FTC/DOJ Guidelines and use our suggested changes to the Guidelines as a basis for pursuing a legislative strategy.

14. Resolution 204 - Criminalization of PLI
• H-160.954 Criminalization of Medical Judgment
• H-160.946 The Criminalization of Health Care Decision-making
• AMA model state bill, November 2007, to “Prohibit the Criminalization of Health Care Decision-Making.”

15. Resolution 205 - Electronic Prescribing of Class 3 Substances
• D-120.958 Federal Roadblocks to E-Prescribing
• D-120.972 Electronic Prescribing
• H-120.957 Prescription of Schedule II Medications by Fax and Electronic Data Transmission
• AMA letter to the U.S. Drug Enforcement Administration (DEA), September 25, 2008, urging the DEA to properly implement a system for e-prescribing of controlled substances.

16. Resolution 206 - Interpretive Services
• H-160.924 Use of Language Interpreters in the Context of the Patient-Physician Relationship
• H-385.928 Patient Interpreters
• D-385.978 Language Interpreters
• D-160.992 Appropriate Reimbursement for Language Interpretive Services
• H-385.929 Availability and Payment for Medical Interpreters Services in Medical Practices
• D-270.998 Oppose Scope of Limited English Proficiency Guidance
• AMA model federal legislation, March 2004, to require appropriate reimbursement for federally-mandated interpreter services furnished to individuals with limited English proficiency.
• AMA testimony before the Practicing Physicians Advisory Council, September 15, 2003 advocating for method for eliminating the financial burden imposed on physicians for the cost of interpretive services for LEP patients
• Letter to the Honorable C.W. Bill Young, Chairman of the House Appropriations Committee, October 25, 2002, advocating that the federal government take steps to lift the unfunded mandate for providing interpretive services for LEP patients.
• AMA testimony before the House Appropriations Committee, May 15, 2002, advocating for government funding for interpreter services for LEP patients.
• AMA comments to the Office of Civil Rights of the Department of Health and Human Services, April 2, 2002, advocating that the federal government take steps to lift the unfunded mandate for providing interpretive services for LEP patients and provide funding for such services
• AMA letter to the Department of Health and Human Services, March 5, 2002, advocating that the federal government take steps to lift the unfunded mandate for LEP patients and provide funding for such services.

17. Resolution 208 - Protection to Practice
• H-165.985 Opposition to Nationalized Health Care
• H-390.961 Opposition to Mandatory Acceptance of Medicare
• H-275.963 Mandatory Medicare Assignment or Determination of Fee Levels

18. Resolution 209 - Health System and Litigation Reform
• H-435.978 Federal Medical Liability Reform
• H-435.967 Report of the Special Task Force and the Advisory Panel on Professional Liability
• H-435.969 Report of the Special Task Force on Professional Liability and the Advisory Panel on Professional Liability
• H-435.951 Health Court Principles
• AMA advocacy paper advocating “The Case for Medical Liability Reform.”
• AMA advocacy paper advocating “Medical Liability Reform” at the federal and state levels.
• AMA Testimony before the House Energy and Commerce Health Subcommittee, July 13, 2006, regarding “Innovative Solutions to Medical Liability.”

19. Resolution 210 - Geographic Devaluation of Medicare Payments for PQRI
• D-400.985 Geographic Practice Cost Index
• H-400.972 Physician Payment Reform
• D-400.989 Equal Pay for Equal Work
• H-400.988 Medicare Reimbursement, Geographical Differences
• H-390.945 Legal Action to Resolve Medicare Reimbursement Disparities
• H-400.952 Consolidation of Medicare Fee Schedule Areas
• H-400.990 Refinement of Medicare Physician Payment System
• D-390.989 Equal Pay for Equal Work
• H-400.984 Geographic Practice Costs

20. Resolution 211 - Geographic Devaluation of E-Prescribing Payments
• D-400.985 Geographic Practice Cost Index
• H-400.972 Physician Payment Reform
• D-400.989 Equal Pay for Equal Work
• H-400.988 Medicare Reimbursement, Geographical Differences
• H-390.945 Legal Action to Resolve Medicare Reimbursement Disparities
• H-400.952 Consolidation of Medicare Fee Schedule Areas
• H-400.990 Refinement of Medicare Physician Payment System

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• H-400.952 Consolidation of Medicare Fee Schedule Areas
• H-400.990 Refinement of Medicare Physician Payment System
• D-390.989 Equal Pay for Equal Work
• H-400.984 Geographic Practice Costs

22. Resolution 213 - Stricter Fines for Violating Direct-to-Consumer Advertisements
• D-105.998 Direct to Consumer Advertising
• AMA testimony before the House Energy and Commerce Oversight and Investigation Subcommittee regarding “Direct-to-Consumer Advertising: Marketing, Education or Deception?”; May 8, 2008, advocating that DTCA must comply with all other applicable FDA regulations, policies, and guidelines. Following this hearing, PhRMA modified its guidance to its members concerning DTCA to bring it into line with AMA policy.

23. Resolution 215 - Insurance Companies Use of Contractors to Recover Payments
• H-70.926 Reasonable Time Limitations on Post-Payment Audits and Recoupments by Third Party Payers
• D-285.968 Health Insurance Code of Conduct
• H-285.915 AMA Policy on ERISA
• H-285.946 Fair Physician Contracts
• H-285.971 Population Based Practices in Managed Care Systems
• AMA/American Academy of Neurology joint paper regarding “Hoe to Prepare for a Health Plan Retrospective Audit,” 2008.
• AMA model state legislative talking points, October 2007, on “Advancing a Counterattack on Managed Care Payment Policies: Retrospective Audits.”
• AMA model state legislation to “Prevent Retrospective Denial of Payment For Any Previously Authorized or Paid Claim,” September 1999.

24. Resolution 216 - Electronic Submission of Schedule II-V Narcotic Prescriptions
• D-120.958 Federal Roadblocks to E-Prescribing
• D-120.972 Electronic Prescribing
• H-120.957 Prescription of Schedule II Medications by Fax and Electronic Data Transmission
• AMA letter to the U.S. Drug Enforcement Administration (DEA), September 25, 2008, urging the DEA to properly implement a system for e-prescribing of controlled substances.

25. Resolution 218 - Open Source Code Electronic Medical Records
• H-478.995 National Health Information Technology
• D-478.994 Health Information Technology
• D-478.992 Health Information Technology Purchasing Guidance
• AMA letter to the Honorable Max Baucus and Charles Grassley, Chairman and Ranking Member of the Senate Finance Committee, respectively, February 24, 2009, supporting an acceleration of the transition to a connected, nationwide HIT infrastructure and the use of HIT.
• AMA letter to Nancy Pelosi, Speaker of the House of Representatives, January 23, 2009, supporting an acceleration of the transition to a connected, nationwide HIT infrastructure and the use of HIT.

26. Resolution 219 - Out of Network Payments
• H-165.846 Adequacy of Health Insurance Coverage Options
• D-180.985 Health Plan and Insurer Transparency
• AMA testimony before the House Ways and Means Health Subcommittee regarding “Price Transparency in the Health Care Sector,” July 18, 2006, advocating for health plan transparency for patient financial responsibility.

27. Resolution 403 - Banning Tobacco Product Sales in Pharmacies
• H-495.986 Tobacco Product Sales and Distribution

28. Resolution 405 - Raising the Age of Alcohol Consumption in the Territory of Guam
• D-30.986 Uniform Drinking Age Standards
• H-30.986 Alcohol and the Driver

29. Resolution 408 - The Physician’s Obligation to Identify and Treat Prenatal and Perinatal Addiction
• H-420.962 Perinatal Addiction - Issues in Care and Prevention
• H-95.976 Drug Abuse in the United States - the Next Generation

30. Resolution 411 - Reduction or Elimination of Gun Violence in the Mass Media
• H-515.974 Mass Media Violence and Film Ratings
• H-485.995 TV Violence

31. Resolution 508 - State Vaccine Registry Interfaces
• H-440.899 Immunization Registries
• D-440.961 Establishment of a Network of State Immunization Registries
- 10 -

- H-480.971 The Computer-Based Patient Record

32. Resolution 511 - Reducing Medication Waste From Extended Care Facilities
- H-280.959 Recycling of Nursing Home Drugs
- H-135.939 Green Initiatives and the Health Care Community

33. Resolution 513 - Novel Antibiotics and Antimicrobial Resistance
- D-100.998 Combating Antibiotic Resistance Via Physician Action and Education: AMA Activities
- D-100.995 Antimicrobial Use and Resistance
- D-440.991 Antimicrobial Use and Resistance

34. Resolution 518 - Generic Drugs From Foreign Manufacturers Sold in the US
- H-100.969 Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals
- D-100.983 Prescription Drug Importation and Patient Safety
- H-125.984 Generic Drugs

35. Resolution 525 - Research Visa Waiver for Physician Scientists
- H-460.995 Support for Careers in Research
- H-460.994 Support for Careers in Research
- D-255.991 Visa Complications for IMGs in GME

36. Resolution 602 - Control and Use of Physician Data
- D-315.988 Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry

37. Resolution 704 - Physician Owned Hospitals
- H-140.984 Physicians' Involvement in Commercial Ventures
- H-215.968 Specialty Hospitals and Impact on Health Care
- D-215.995 Specialty Hospitals and Impact on Health Care
- The AMA has written letters that expressed its opposition to any amendments or provisions that would arbitrarily restrict or ban physician ownership of hospitals. In one letter, the AMA stated that "Physician-owned hospitals are a win-win for patients and for the health care system as we work to improve care."
- During consideration by the House and Senate of State Children's Health Insurance Program (SCHIP) reauthorization, mental health parity, the Farm Bill and war supplemental legislation, AMA advocated against restrictions on and efforts to ban physician-owned hospitals.

38. Resolution 705 - Office Payment
- H-190.964 Electronic Claims
- H-190.983 Submission of Electronic Claims Through Electronic Data Interchange
- H-380.994 Physicians' Freedom to Establish Their Fees
- H-385.926 Physician Choice of Practice
- The AMA has established “Guiding Principles for Operating a Cash-based Practice.”
The AMA chairs the National Uniform Claim Committee, created to develop a standardized data set for use by the non-institutional health care community to transmit claim and encounter information to and from all third-party payers.

The AMA is a participating organization in the Committee on Operating Rules for Information Exchange, which works to simplify administrative data exchange by streamlining the way eligibility and benefits, claim status and other healthcare administrative information is exchanged electronically.

The AMA’s “Heal the Claims Process” campaign strives to hold payers accountable by calling for full transparency and accurate payment the first time a claim is submitted and to comply fully with the Health Insurance Portability and Accountability Act (HIPAA) electronic standard transactions. The AMA also calls on payers to provide full transparency with respect to fee schedules, medical payment policies and other information necessary to maximize efficiency.

The AMA has developed the following model state legislation: “An Act Concerning Timely Reimbursement of Health Insurance Claims.”

The AMA tracks the implementation of prompt payment state laws, which have been enacted in all 50 states.

The AMA's Practice Management Center has developed the following claims management revenue cycle resources to help physicians and their practice staff understand and navigate the claims process and to receive timely and accurate payment: “Prepare That Claim,” “Follow That Claim,” and “Appeal That Claim.”

39. Resolution 706 - Standardized Medical Insurance Cards
   • D-185.999 Information Included On Health Insurance Identification Cards
   • The AMA is an official supporter of the Medical Group Management Association (MGMA) SwipeIT campaign.
   • The AMA contributed to the content of the Workgroup on Electronic Data Interchange (WEDI) white paper regarding standardized ID cards.

40. Resolution 707 - Price Transparency
   • H-165.846 Adequacy of Health Insurance Coverage Options
   • H-155.960 Strategies to Address Rising Health Care Costs
   • The AMA is a participating organization in the Committee on Operating Rules for Information Exchange, which works to simplify administrative data exchange by streamlining the way eligibility and benefits, claim status and other healthcare administrative information is exchanged electronically. Easier, more reliable access to this information at the point of care reduces the amount of time providers spend on administration by improving the accuracy of claims submitted, providing enhanced information on patient financial responsibility and checking the status of a patient claim.

41. Resolution 708 - Health Insurance and Pharmacies Advise Physicians to Take Action
   • H-285.954 Physician Decision-Making in Health Care Systems
   • H-450.941 Pay-For-Performance, Physician Economic Profiling, and Tiered and Narrow Networks
   • H-120.988 Patient Access to Treatments Prescribed by Their Physicians

42. Resolution 710 - Identifying Abusive, Hostile or Non-Compliant Patients
   • H-70.919 Use of CPT Editorial Panel Process
   • Modifier 2P (Performance Measure Exclusion Modifier Due to Patient Reasons) is currently available to report non-compliant patients. The list of reasons for this modifier
include (1) “patient declined”, (2) “economic, social, or religious reasons”, and (3) “other patient reasons”. This modifier is intended to be used with performance measure Category II codes. CPT Category II Performance Measurement codes are intended to facilitate data collection about the quality of care rendered by coding certain services and test results that support nationally established performance measures and that have an evidence base as contributing to quality patient care. These codes describe clinical components that may be typically included in evaluation and management services or clinical services and, therefore, do not have a relative value associated with them.

43. Resolution 711 - Physician Representation on Hospital Boards
   • H-225.983 Physician Representation on Hospital Governing Boards
   • H-225.957 Principles for Strengthening the Physician-Hospital Relationship

44. Resolution 712 - Development of a Payment Code for Prior Authorization
   • H-70.919 Use of CPT Editorial Panel Process
   • H-285.998 Managed Care

45. Resolution 713 - “Advance Directives for All” Campaign
   • H-70.919 Use of CPT Editorial Panel Process
   • H-390.916 Payment for Patient Conferences Regarding Advance Directives
   • H-385.977 Counseling - Serious Medical Problems
   • A CPT coding mechanism already exists. “Counseling” is a part of each of the Evaluation and Management service codes. It is included as a defined component of “intraservice” of the E/M service. The face-to-face time for Evaluation and Management services is defined as only that time that the physician spends face-to-face with the patient and/or family. This intraservice time includes the time in which the physician performs such tasks as obtaining a history, performing an examination, and counseling the patient. For the purposes of the services provided in an E/M service, counseling is a discussion with a patient and/or family concerning one or more of the following areas:
     − Diagnostic results, impressions, and/or recommended diagnostic studies
     − Prognosis
     − Risks and benefits of management (treatment) options
     − Instructions for management (treatment) and/or follow-up
     − Importance of compliance with chosen management (treatment) options
     − Risk factor reduction
     − Patient and family education
   Each E/M code includes the statement that, “Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient’s and/or family’s needs.” When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then time may be considered the key or controlling factor to qualify for a particular level of E/M services. This includes time spent with parties who have assumed responsibility for the care of the patient or decision making whether or not they are family members (eg, foster parents, person acting in loco parentis, legal guardian). The extent of counseling and/or coordination of care must be documented in the medical record.

46. Resolution 718 - Hospital Restrictions on Access to Medical Records
   • H-315.997 Patients’ Access to Information Contained in Medical Records
   • H-140.989 Informed Consent and Decision-Making in Health Care
47. Resolution 721 - Uniform Overhead Emergency Codes
   • H-215.971 Standardization of Emergency Paging Nomenclature

48. Resolution 724 - Reimbursement for Services
   • H-190.991 Excessive Requests for Information from Insurance Carriers and Delays in Processing Insurance Claims
   • H-385.952 Appropriate Physician Reimbursement by Centers for Medicare & Medicaid Services
   • H-320.968 Approaches to Increase Payer Accountability
   • H-285.945 Establishment of Liability of Managed Care Organizations
   • The AMA’s “Heal the Claims Process” campaign strives to hold payers accountable by calling for full transparency and accurate payment the first time a claim is submitted and to comply fully with the Health Insurance Portability and Accountability Act (HIPAA) electronic standard transactions. The AMA also calls on payers to provide full transparency with respect to fee schedules, medical payment policies and other information necessary to maximize efficiency.
   • The AMA’s Advocacy Resource Center has produced the following legislative template: “Managed Care Campaign: Fair Contracting and Transparency in the Private Health Care Market.”
   • The AMA has developed the following model state legislation: “An Act Concerning Timely Reimbursement of Health Insurance Claims.”
   • The AMA tracks the implementation of prompt payment state laws, which have been enacted in all 50 states.
   • The AMA’s Practice Management Center has developed the following claims management revenue cycle resources to help physicians and their practice staff understand and navigate the claims process and to receive timely and accurate payment: “Prepare That Claim,” “Follow That Claim,” and “Appeal That Claim.”

49. Resolution 727 - Medical Directors as “Peer” Reviewers When Pre-Adjudicating Prescribed Tests and Procedures
   • H-285.998 Managed Care
   • H-285.945 Establishment of Liability of Managed Care Organizations
   • D-285.968 Health Insurance Code of Conduct

50. Resolution 728 - Physician Profiling / Grading and Report Cards
   • H-450.947 Pay-for-Performance Principles and Guidelines
   • H-450.941 Pay-For-Performance, Physician Economic Profiling, and Tiered and Narrow Networks
   • The AMA has developed model state legislation: “An Act Relative to Physician Profiling Programs,” which mandates the transparency, accuracy and oversight necessary to ensure that physician profiling does not undermine the patient-physician relationship nor incentivize physicians to avoid the sickest and poorest patients. The Legislation also prohibits physician rankings based solely on cost and requires profiling at the group level, the rationale for the profiling determination, and opportunities for physicians to make corrections and appeal.
   • The AMA Private Sector Advocacy Practice Management Center has issued the following resource: “Physician Profiling: How to Prepare Your Practice.”

51. Resolution 730 - Medical Staff Self Governance
- H-225.957 Principles for Strengthening the Physician-Hospital Relationship
- The Joint Commission Standard MS.01.01.01 (formerly MS.1.20) and all of its Elements of Performance with the exception of EP 19 has been fully effective since January 1, 2008. Following concerns received from professional organizations and hospitals related to the cost and burden of the newly adopted MS.1.20, The Joint Commission Board established an 18-member Task Force to analyze the potential impact of implementing the revised standard. The AMA is well represented on the Task Force. The Task Force was convened in January 2008. As of May 2009, the Task Force was reaching consensus.

52. Resolution 733 - Medical Smart Cards
- D-185.999 Information Included On Health Insurance Identification Cards
- The AMA contributed to the content of the Workgroup on Electronic Data Interchange (WEDI) white paper regarding standardized ID cards, a prominent white paper on this issue.
- The AMA is an official supporter of the Medical Group Management Association (MGMA) SwipeIT campaign.

53. Resolution 734 - National Practitioner Data Bank: Length of Time for Storing Medical Malpractice Data
- H-355.999 Minimum Reporting Requirements to National Practitioner Data Bank
- H-355.995 National Practitioner Data Bank
We have reviewed the resolutions assigned to Reference Committee A for A-2009, and believe that the following resolutions reaffirm existing policy. Copies of the resolutions are attached along with the existing policy recommended for reaffirmation.

Resolution 102: Domestic Violence Insurance Discrimination This resolution asks the AMA to oppose domestic violence insurance discrimination, and to adopt policy supporting efforts to prohibit insurers from using domestic violence as a basis for underwriting, or to require safeguards such as that they provide written explanation to the applicant or insured. This is addressed by the following policy: H-185.976, which opposes the denial of insurance coverage to victims of domestic violence and abuse and seeks federal legislation to prohibit such discrimination; and (2) advocates for equitable coverage and appropriate reimbursement for all health care, including mental health care, related to family and intimate partner violence. Policy H-180.981 also urges that insurance companies be required to provide a written explanation to insurance applicants for rating or rejection decisions.

Policies H-185.976 and H-180.981 should be reaffirmed.

Resolution 109: Obesity This resolution asks that the AMA recommend consideration of physician supervised diet and exercise programs for insurance coverage, tax deductibility, and flexible spending account qualification. This is addressed by the following policies: H-150.953, which urges the appropriate federal agencies to work with organized medicine and the health insurance industry to develop coding and payment mechanisms for the evaluation and management of obesity; and H-160.938, which states the AMA will seek to have physician-directed benefits of evidence-based disease-specific education and self-management training provided by all payers.

Policies H-150.953 and H-160.938 should be reaffirmed.

Resolution 110: “Public Option” Health Insurance This resolution asks that AMA to express its opposition to public option health insurance proposals. This is addressed by the following policy: H-165.916, which strongly reaffirms the AMA’s unwavering opposition against the encroachment of government in the practice of medicine as well as any attempts to covertly change the American health care system to a government program with the subsequent loss of precious personal freedoms, including the right of physicians and patients to contract privately for health care without government interference. Additional policies H-165.844, H-165.888 and H-165.895 reaffirm the AMA’s support for a pluralistic health care system, and opposition to a single-payer or socialized health care system.

Policies H-165.916, H-165.844, H-165.888 and H-165.895 should be reaffirmed.
Resolution 111: Payment for Email Consultations by Medicare  This resolution asks the AMA to pursue payment for email consultations between physicians and Medicare patients. This is addressed by the following policy: H-390.859, which asks the AMA to press the Centers for Medicare and Medicaid Services and other payers for separate recognition (i.e., payment) of such supplemental communication work, not as bundled into existing service codes.

Policy H-390.859 should be reaffirmed.

Resolution 114: Financial Barrier to Specialty Care  This resolution asks the AMA to oppose financial barriers to specialty care such as higher copays for office visits, and to conduct a study of the effects of financial barriers to specialty care on patient access. This issue is addressed by the following policy: H-160.952, which urges health plans to cover direct access to specialists without financial penalty when access is consistent with collaboratively developed clinically appropriate guidelines.

Policy H-160.952 should be reaffirmed.

Resolution 117: Access to Affordable and Adequate Diabetes Supplies  This resolution asks that the AMA take action to identify ways to ensure affordability of diabetes-related supplies (e.g., affordable copays and deductibles, coverage for adequate amount of supplies). These issues are addressed by the following policies: H-165.882 and H-155.960, which both support the development and implementation of value-based benefit designs that cover with low cost-sharing those services adjudged to have the greatest health benefit.

Policies H-165.822 and H-155.960 should be reaffirmed.

Resolution 118: Transparency of Preventive Care Services  This resolution asks that the AMA seek legislation to require insurance companies to adopt standard language to define coverage for preventive care services, including adequate payment for vaccines. These issues are addressed by the following policies: H-165.846, which supports ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services, and H-440.875, which states the AMA will work through appropriate state entities to ensure all health insurance plans include recommended vaccines in their list of covered benefits, and pay health care professionals fairly for the purchase and administration of ACIP-recommended vaccines.

Policies H-165.846 and H-440.875 should be reaffirmed.

Resolution 119: Commercial Insurance for All Expansion of Health Care  This resolution asks that the AMA support the use of commercial insurance at standard commercial payment rates in all government health care plans, and that the AMA work to get information for the purpose of comparing rates. These issues are addressed by the following policies: H-165.916, which strongly reaffirms the AMA’s unwavering opposition against the encroachment of government in the practice of medicine as well as any attempts to covertly change the American health care system to a government program with the subsequent loss of precious personal freedoms, including the right of physicians and patients to contract privately for health care without government interference. Additional policies H-165.844, H-165.888 and H-165.895 reaffirm the AMA’s support for a pluralistic health care system, and opposition to a single-payer or socialized health care system. Policy D-385.976 advocates that insurers be required to publish payment rates.

Policies H-165.916, H-165.844, H-165.888, H-165.895 and D-385.976 should be reaffirmed.
**Resolution 122: Extension of Veteran’s Affairs Pharmacy Benefit to All Veterans** This resolution asks the AMA to advocate for extension of the VA pharmacy benefit to all outpatient veterans. This is addressed by the following policy: H-510.991, which supports approaches that increase the flexibility of the Veterans Health Administration to provide all veterans with improved access to health care services.

**Policy H-510.991 should be reaffirmed.**

**Resolution 126: Adjustments Made to Relative Scale to Include Increased Paperwork for Physicians** This resolution asks that AMA to seek consideration of work relative value units to capture additional work from documentation requirements. This is addressed by the following policy: H-240.966, which states that government mandated services imposed on physicians and hospitals that are peripheral to the direct medical care of patients be recognized as additional practice cost expense, and strongly urges Congress that the RBRVS and DRG formulas take into account expenses incurred by physicians and hospitals when complying with governmentally mandated regulations and ensure that reimbursement increases are adequate to cover the costs of providing these services.

**Policy H-240.966 should be reaffirmed.**

**Resolution 128: Insurance Companies and ACIP** This resolution asks the AMA to seek legislation mandating that insurance companies pay for vaccines recommended by the Advisory Committee on Immunization Practices, or make explicit information available that says that they do not follow ACIP recommendations. This is addressed by the following policies: H-440.875, which states that the AMA will work through appropriate state entities to ensure all health insurance plans rapidly include newly ACIP-recommended vaccines in their list of covered benefits, and to pay health care professionals fairly for the purchase and administration of ACIP-recommended vaccines, and H-440.860, which calls on insurance companies to universally cover all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines.

**Policies H-440.860 and H-440.875 should be reaffirmed.**
Whereas, Between 1998-2002 there were an estimated 5.4 victims of family violence per 1000 U.S. residents\(^1\); and

Whereas, Family violence is the most prevalent form of violence in the U.S.\(^2\); and

Whereas, Our AMA has strong policy regarding this public health issue, as is evident by Policy D-515.992 Diagnosis and Management of Family Violence; and

Whereas, Victims of family violence are more likely to require health care services in light of physical trauma, psychological abuse and even attempted homicide; and

Whereas, According to the National Women’s Law Center, insurers in D. C and the following 9 states are allowed to deny insurance coverage to domestic violence survivors: Arkansas, Idaho, Mississippi, North Carolina, North Dakota, Oklahoma, South Carolina, South Dakota and Wyoming\(^3\); and

Whereas, While 41 states have legislation with varying degrees of protection for domestic violence victims from discriminatory practices by insurers, \(^4\) according to the Family Violence Prevention fund, only 22 states (Alabama, Arizona, California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Maine, Massachusetts, Montana, Nebraska, New Mexico, Oregon, Pennsylvania, Utah, Virginia, Washington state, West Virginia and Wisconsin) have enacted adequate domestic violence insurance discrimination protections; therefore be it

RESOLVED, That our American Medical Association oppose the practice of domestic violence insurance discrimination (New HOD Policy); and be it further

RESOLVED, That our AMA adopt policy in keeping with the Family Violence Prevention Fund’s advocacy for state legislation addressing domestic violence discrimination, encompassing the following principles:


\(^4\) Noll LN. Domestic violence victims and insurance companies. www.academic.udayton.edu/health/01status/01Noll.htm, accessed March 9, 2009
1. Apply to all lines of health, life and disability insurance;

2. Prohibit insurers from using domestic violence as a basis for underwriting or rating insurance including: denying, canceling, limiting or excluding coverage; charging a higher premium or denying claims because and individual is, has been or is perceived to be a victim of domestic violence. (This prohibition must not be limited to actions based “solely” on domestic violence because “solely” permits actions based on domestic violence with other reasons); and

3. Prohibit insurers from underwriting or rating on the basis of mental and physical conditions or claims resulting from domestic violence or, at a minimum, provide safeguards if insurers are permitted to consider abuse-related medical conditions and claims including written explanation to the applicant or insured. (New HOD Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 04/20/09

Policies recommended for Reaffirmation

**H-185.976 Insurance Discrimination Against Victims of Domestic Violence**
Our AMA: (1) opposes the denial of insurance coverage to victims of domestic violence and abuse and seeks federal legislation to prohibit such discrimination; and (2) advocates for equitable coverage and appropriate reimbursement for all health care, including mental health care, related to family and intimate partner violence. (Res. 814, I-94; Appended: Res. 419, I-00)

**H-180.981 Rating or Rejection of Applicants for Health Policies**
(1) The AMA encourages state medical societies to urge state insurance commissioners to require the following: (a) that when an insurance company rates or rejects any applicant for a health policy, the insurance company must explain in writing in terms understandable to the patient the reason(s) for rating or rejection within 21 days; and (b) that in the case of a rating or rejection of an applicant for a health policy, the applicant, after having been informed of the reason(s) for such action, shall have 21 days to submit further information and to protest such action, and that such rating or rejection shall not be reported to the Medical Information Bureau until such information is reviewed. (2) In those instances where the insurance commissioner lacks the necessary authority or fails to implement the goals set out above on a regulatory basis, the AMA urges state medical associations to pursue legislation to accomplish the intent of the resolution, with appropriate review of the relevant provisions of the National Association of Insurance Commissioners Model Act. (CMS Rep. I, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CMS Rep. 4, A-08)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 109
(A-09)

Introduced by: Illinois Delegation

Subject: Obesity

Referred to: Reference Committee A
(Steve E. Larson, MD, Chair)

Whereas, The obesity rate in the United States continues to escalate, especially in children; and

Whereas, Many medical and surgical weight loss therapies may be covered by medical insurance; and

Whereas, Medications and surgical weight loss techniques may involve life threatening complications; and

Whereas, Appropriate diet and exercise programming is a cornerstone of any weight loss program and should be considered the therapy of first resort; and

Whereas, Diet and exercise programming offer the safest mode of weight loss; therefore be it

RESOLVED, That our American Medical Association recommend consideration of physician prescribed and supervised diet and exercise programming for insurance coverage, IRS tax deductibility or IRS Employer Health Flex Spending program qualification. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $1,859.

Received: 05/05/09

RELEVANT AMA POLICY

D-60.990 Exercise and Healthy Eating for Children
Our AMA shall: (1) seek legislation that would require the development and implementation of evidence-based nutrition standards for all food served in K-12 schools irrespective of food vendor or provider; and (2) work with the US Public Health Service and other federal agencies, the Federation, and others in a coordinated campaign to educate the public on the epidemic of childhood obesity and enhance the K-12 curriculum by addressing the benefits of exercise, physical fitness, and healthful diets for children. (Res. 423, A-02; Reaffirmation A-04; Reaffirmation A-07; Reaffirmation I-07)
Resolution 109

H-150.953 Obesity as a Major Public Health Program

Our AMA will: (1) urge physicians as well as managed care organizations and other third party payers to recognize obesity as a complex disorder involving appetite regulation and energy metabolism that is associated with a variety of comorbid conditions; (2) work with appropriate federal agencies, medical specialty societies, and public health organizations to educate physicians about the prevention and management of overweight and obesity in children and adults, including education in basic principles and practices of physical activity and nutrition counseling; such training should be included in undergraduate and graduate medical education and through accredited continuing medical education programs; (3) urge federal support of research to determine: (a) the causes and mechanisms of overweight and obesity, including biological, social, and epidemiological influences on weight gain, weight loss, and weight maintenance; (b) the long-term safety and efficacy of voluntary weight maintenance and weight loss practices and therapies, including surgery; (c) effective interventions to prevent obesity in children and adults; and (d) the effectiveness of weight loss counseling by physicians; (4) encourage national efforts to educate the public about the health risks of being overweight and obese and provide information about how to achieve and maintain a preferred healthy weight; (5) urge physicians to assess their patients for overweight and obesity during routine medical examinations and discuss with at-risk patients the health consequences of further weight gain; if treatment is indicated, physicians should encourage and facilitate weight maintenance or reduction efforts in their patients or refer them to a physician with special interest and expertise in the clinical management of obesity; (6) urge all physicians and patients to maintain a desired weight and prevent inappropriate weight gain; (7) encourage physicians to become knowledgeable of community resources and referral services that can assist with the management of overweight and obese patients; and (8) urge the appropriate federal agencies to work with organized medicine and the health insurance industry to develop coding and payment mechanisms for the evaluation and management of obesity. (CSA Rep. 6, A-99)

H-160.938 Disease-Specific Self-Management Programs

The AMA: (1) will work with invited medical groups to promote the physician-led team approach to disease-specific patient care as providing the highest quality of patient care; (2) insists that evidence-based disease-specific (eg, diabetes and asthma) education services and self-management training be initiated and continued under the direction of a physician; (3) believes all changes of care or medications by members of the team should be supervised by a physician; (4) will seek to have physician-directed benefits of evidence-based disease-specific education and self-management training provided to the beneficiaries of Medicare, Medicaid, other publicly supported programs, and all other payers; and (5) believes that status reports and all changes made by the disease-specific self-management team be transmitted in a timely fashion to the primary care physician, if the primary care physician is not the supervisor of the management team. (Sub. Res. 515, I-96; Amended by CSA Rep. 4, A-98; Reaffirmed: CSAPH Rep. 2, A-08)
Whereas, A prominent health care reform idea under discussion by Congress and the Administration is a “public option” under which a health insurance plan would be marketed and administered by the federal government; and

Whereas, Critics of the “public option” believe that such a plan, over time, would likely crowd out private health insurance and result in the emergence of a single-payer health insurance system; and

Whereas, Our AMA has in its Proposal for Reform excellent policy on the use of government subsidies to help individuals to afford to purchase private health insurance; therefore be it

RESOLVED, That our American Medical Association express its opposition to “public option” proposals which could result in the elimination of the private health insurance system. (Directive to Take Action

Fiscal Note: Implement accordingly at estimated staff cost of $1,859.

Received: 05/06/09
Resolution 110

H-165.844 Educating the American People About Health System Reform
Our AMA reaffirms support of pluralism, freedom of enterprise and strong opposition to a
single payer system. (Res. 717, I-07)

H-165.888 Evaluating Health System Reform Proposals
Our AMA will continue its efforts to ensure that health system reform proposals adhere to the
following principles: (1) Physicians maintain primary ethical responsibility to advocate for their
patients' interests and needs. (2) \textit{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. (3)
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. (4) 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. (5) 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. (6) 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. (7) 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. (8) True health reform is impossible without true tort reform. (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;
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)

H-165.916 Government Controlled Medicine
Our AMA strongly reaffirms its unwavering opposition against the encroachment of government
in the practice of medicine as well as any attempts to covertly change the American health care
system to a government program with the subsequent loss of precious personal freedoms,
including the right of physicians and patients to contract privately for health care without
government interference. (Res. 141, I-93; Reaffirmed: Sub. Res. 132, A-94; Reaffirmation A-97;
Reaffirmation I-00; Reaffirmation A-01; Reaffirmation A-02; Reaffirmation I-07)
H-165.985 Opposition to Nationalized Health Care
Our AMA reaffirms the following statement of principles as a positive articulation of the Association's opposition to socialized or nationalized health care: (1) Free market competition among all modes of health care delivery and financing, with the growth of any one system determined by the number of people who prefer that mode of delivery, and not determined by preferential federal subsidy, regulations or promotion. (2) Freedom of patients to select and to change their physician or medical care plan, including those patients whose care is financed through Medicaid or other tax-supported programs, recognizing that in the choice of some plans the patient is accepting limitations in the free choice of medical services. (Reaffirmed: BOT Rep. I-93-25; Reaffirmed: CMS Rep. I-93-5) (3) Full and clear information to consumers on the provisions and benefits offered by alternative medical care and health benefit plans, so that the choice of a source of medical care delivery is an informed one. (4) Freedom of physicians to choose whom they will serve, to establish their fees at a level which they believe fairly reflect the value of their services, to participate or not participate in a particular insurance plan or method of payment, and to accept or decline a third party allowance as payment in full for a service. (5) Inclusion in all methods of medical care payment of mechanisms to foster increased cost awareness by both providers and recipients of service, which could include patient cost sharing in an amount which does not preclude access to needed care, deferral by physicians of a specified portion of fee income, and voluntary professionally directed peer review. (6) The use of tax incentives to encourage provision of specified adequate benefits, including catastrophic expense protection, in health benefit plans. (7) The expansion of adequate health insurance coverage to the presently uninsured, through formation of insurance risk pools in each state, sliding-scale vouchers to help those with marginal incomes purchase pool coverage, development of state funds for reimbursing providers of uncompensated care, and reform of the Medicaid program to provide uniform adequate benefits to all persons with incomes below the poverty level. (8) Replacing the present Medicare program with a system developed by the AMA of pre-funded vouchers to older persons to purchase health insurance with comprehensive benefits, including catastrophic coverage. (9) Development of improved methods of financing long-term care expense through a combination of private and public resources, including encouragement of privately prefunded long-term care financing to the extent that personal income permits, assurance of access to needed services when personal resources are inadequate to finance needed care, and promotion of family caregiving. (BOT Rep. U, I-88; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: Sub. Res. 110, A-94; Reaffirmed: CMS Rep. 7, I-97; Reaffirmed by CMS Rep. 9, A-98; Reaffirmed: CMS Rep. 4, A-99; Reaffirmation I-07; Modified: CMS Rep. 8, A-08; Reaffirmed in lieu of Res. 813, I-08)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 111
(A-09)

Introduced by: Michigan Delegation

Subject: Payment for Email Consultations by Medicare

Referred to: Reference Committee A
(Steve E. Larson, MD, Chair)

Whereas, E-mail has been used increasingly by patients to communicate with doctors and ancillary staff; and

Whereas, Up to 72 percent of doctors from a large academic center have used email at least once\(^5\); and

Whereas, The federal government is pushing toward universal electronic medical records that will involve more patients in electronic communications; and

Whereas, Answering e-mail is a time and resource intensive procedure for the physicians; therefore be it

RESOLVED, That our American Medical Association work with the federal government and the Centers for Medicare and Medicaid Services to provide adequate compensation for e-mail consultations and replies to enhance the patient experience and the speedy delivery of health care. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $4,580.

Received: 05/06/09

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\(^5\) Gaster, B; Knight, CL; DeWitt, DE; Sheffield, JV; Assefi, NP; Buchwald, D. Physicians' use of and attitudes toward electronic mail for patient communication. J Gen Intern Med. 2003;18:385–389.
Resolution 111

H-390.859 Reimbursement for Telephonic and Electronic Communications
(1) The policy of our AMA is that physicians should uniformly be compensated for their professional services, at a fair fee of their choosing, for established patients with whom the physician has had previous face-to-face professional contact, whether the current consultation service is rendered by telephone, fax, electronic mail or other form of communication. (2) Our AMA presses CMS and other payers for separate recognition of such supplemental communication work, not as bundled into existing service codes, or have such services recognized as not covered by Medicare and therefore chargeable as a patient convenience service outside the benefit package of Medicare. (Res. 810, A-00; Reaffirmation I-04; Reaffirmation A-05; Reaffirmation A-07; Reaffirmation A-08)
Whereas, Under the Medicare program patients pay the same co-pay amount to either a specialist or a primary care physician; and

Whereas, The Relative Value Units for physician services which are assigned to each CPT code represent the same value of work and thus the same payment for that CPT code for all physicians; and

Whereas, All patients should have the freedom to see any physician in their plan and not have an excessively high financial deterrent that would prevent them from seeing the physician of their choice; and

Whereas, In 2007, the average co-pay for a specialist office visit in Ohio was $24, while the average co-pay for a primary care office visit was $19; and this average difference has increased considerably in 2008 to where a specialist co-pay can be 1½ to 2½ times the primary care co-pay, and in some cases co-payment amounts for specialists are approaching $50 per visit; therefore be it

RESOLVED, That our American Medical Association oppose financial barriers to specialty care, such as excessively high co-pays for office visits (New HOD Policy); and be it further

RESOLVED, That our AMA study the impact on patient access to specialty care when commercial insurance plans place greater responsibility on the patient for expenses at the time of a specialty care office visit. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $3,056.

Received: 04/27/09
Resolution 114

H-160.952 Access to Specialty Care
The AMA: (1) continues to encourage primary care and other medical specialty organizations to collaborate in developing guidelines to delineate the clinical circumstances under which treatment by primary care physicians, referral for initial or ongoing specialist care, and direct patient self-referral to other specialists are appropriate, timely, and cost-effective; (2) encourages the medical specialty organizations that develop referral guidelines to document the impact of the guidelines on the quality, accessibility, timeliness, and cost-effectiveness of care; and (3) urges all health plans that control access to services through a primary care case manager to cover direct access to and services by a specialist other than the case manager without financial penalty when that access is in conformance with such collaboratively developed guidelines. (CMS Rep. 1, A-94; Reaffirmed and Modified: CMS Rep. 7, A-05)
Whereas, Diabetes is a life-threatening disease affecting more than 24 million Americans, and these individuals must manage and treat their condition on a daily basis with the guidance of physicians and other medical professionals; and

Whereas, The Diabetes Control and Complications Trial (DCCT) and the UK Prospective Diabetes Study (UKPDS) demonstrated that in patients with diabetes, complications of the disease could be avoided or significantly reduced when blood glucose levels are strictly regulated; and

Whereas, Self-blood glucose monitoring is an important component of diabetes management and patients with diabetes may use test strips multiple times a day each costing $.80 or more; and

Whereas, Many patients do not have affordable and adequate access to blood glucose test strips and other related supplies required to effectively manage their condition on a daily basis; and

Whereas, Very few manufacturers of glucose testing devices and supplies offer free or low-cost blood glucose test strips to individuals who cannot access or afford them; and

Whereas, Today, 46 states and the District of Columbia require that state-regulated health plans provide coverage for necessary diabetes supplies and medications, including blood glucose test strips and blood glucose meters, though co-pays still apply; other health plans, including those regulated by the federal government, are not bound by such requirements; and

Whereas, Employers have experienced cost savings and decreased absenteeism as a result of providing greater coverage for diabetes care including test strips and reducing employee co-pays; therefore be it

RESOLVED, That our American Medical Association work with federal and state governments to identify ways to ensure the affordability of blood glucose test strips and related supplies that are not hindered by the high cost of co-pays or deductibles (Directive to Take Action); and be it further

RESOLVED, That our AMA work with federal and state governments to ensure that health care coverage options provide access to an adequate number of blood glucose test strips--as determined or prescribed by a physician--to maintain optimal glucose control (Directive to Take Action); and be it further
RESOLVED, That our AMA encourage medical device manufacturers to adopt policies that provide broader access to free or low-cost diabetes supplies such as blood glucose test strips to those without insurance coverage or inadequate coverage. (Directive to Take Action)
Fiscal Note: Implement accordingly at estimated staff cost of $5,080.

Received: 05/06/09

RELEVANT AMA POLICY

H-330.904 Lack of Medicare Coverage for Lipid and Diabetes Screening
Our AMA supports dialogue with the Centers for Medicare & Medicaid Services and Congress to cover screening lipid profiles and blood sugars to prevent complications of lipid disorders and diabetes, where such screening is consistent with evidence-based medicine. (Res. 120, I-01)
Resolution 117

H-165.882 Improving Access for the Uninsured and Underinsured
Our AMA: (1) Will assist state medical associations and local medical societies to work with states and the insurance industry to design value-based private group and individual health insurance policies. Such policies should cover with low cost-sharing those services adjudged to have the greatest health benefit, …

H-155.960 Strategies to Address Rising Health Care Costs
Our AMA: (1) recognizes that successful cost-containment and quality-improvement initiatives must involve physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government; (2) supports the following broad strategies for addressing rising health care costs: (a) reduce the burden of preventable disease; (b) make health care delivery more efficient; (c) reduce non-clinical health system costs that do not contribute value to patient care; and (d) promote "value-based decision-making" at all levels; (3) will continue to advocate that physicians be supported in routinely providing lifestyle counseling to patients through: adequate third-party reimbursement; inclusion of lifestyle counseling in quality measurement and pay-for-performance incentives; and medical education and training; (4) will continue to advocate 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; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers; (5) will continue to advocate 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 and without imposing undue administrative burden, including: clinical guidelines and protocols; relative cost-effectiveness of alternative diagnostic services and treatments; quality measurement and pay-for-performance criteria; patient-specific clinical and insurance information; prompts and other functionality to support lifestyle counseling, disease management, and case management; and alerts to flag and avert potential medical errors; (6) encourages the development and adoption of clinical performance and quality measures aimed at reducing overuse of clinically unwarranted services and increasing the use of recommended services known to yield cost savings; (7) encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are reduced for maintenance medications used to treat chronic medical conditions, particularly when non-compliance poses a high risk of adverse clinical outcome and/or high medical costs. Consideration should be given to tailoring cost-sharing requirements to patient income and other factors known to impact compliance; and (8) supports ongoing investigation and cost-effectiveness analysis of non-clinical health system spending, to reduce costs that do not add value to patient care. (CMS Rep. 8, A-07; Reaffirmed: CMS Rep. 7, A-08; Reaffirmed in lieu of Res. 828, I-08)
Whereas, Physician offices and our insured patients are uncertain of what is covered for preventive care services and recommended vaccines; and

Whereas, Important preventive care services and vaccines may be delayed or payment not made for completed services; therefore be it

RESOLVED, That our American Medical Association seek legislation requiring insurance companies to adopt standardized, readily accessible and understandable terminology spelling out coverage for preventive care services, including adequate payment for recommended vaccine products and services. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $1,188.

Received: 05/06/09

RELEVANT AMA POLICY

D-180.984 Payer Measures for Private and Public Health Insurance
Our AMA will work with state medical associations, employer coalitions, physician billing services, and other appropriate groups to evaluate on an annual basis and recommend standards for "payer measures" for the insurance industry and government payers to be publicly reported for consumers that may include information such as: 1. Number of patients enrolled 2. Total company and individual plan revenue/expense and profit 3. Procedures covered and not covered by policy 4. Number of primary and specialist physicians 5. Number of denied claims (and %) a. Number denied based on "pre-existing condition" b. Number denied and later allowed c. Number denied for no reason 6. Waiting time for authorization of common procedures 7. Waiting time for authorization of advanced procedures 8. Waiting time for payment 9. Morbidity and mortality due to denied or delayed care 10. Number of appeals by customers or physicians 11. Number of successful appeals by customers or physicians 12. Number of consumer complaints 13. Number of government fines/sanctions 14. Use of economic profiling of physicians to limit physicians on panel 15. Use of quality measures approved by qualified specialty societies (Res. 703, I-06; Reaf A-07; Reaffirmed in lieu of Res. 828, I-08)

D-180.985 Health Plan and Insurer Transparency
Our AMA will: (1) continue to closely monitor any new "transparency" programs unveiled by health plans to determine the impact on physicians; (2) communicate to health plans, employers and patients our concerns about current "transparency" programs, and educate them about "true transparency"; and (3) continue to educate physicians about the complexities of claims adjudication and payment processes to enable them to more efficiently manage their practices. (BOT Rep. 19, A-06; Reaf A-07)
H-165.846 Adequacy of Health Insurance Coverage Options
Our AMA supports the following principles to guide in the evaluation of the adequacy of health insurance coverage options: 1. Any insurance pool or similar structure designed to enable access to age-appropriate health insurance coverage must include a wide variety of coverage options from which to choose. 2. Existing federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations) should be used as a reference when considering if a given plan would provide meaningful coverage. 3. Provisions must be made to assist individuals with low-incomes or unusually high medical costs in obtaining health insurance coverage and meeting cost-sharing obligations. **4. Mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services.** (CMS Rep. 7, A-07; Reaffirmation I-07)

H-440.875 Assuring Access to ACIP/AAFP/AAP-Recommended Vaccines
1. It is AMA policy that all persons, regardless of economic and insurance status, receive all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines as soon as possible following publication of these recommendations in the Centers for Disease Control and Prevention’s (CDC) Morbidity and Mortality Weekly Report (MMWR). 2. Our AMA will continue to work with the federal government, Congress, and other stakeholders to improve liability protection for vaccine manufacturers and health care professionals who provide immunization services and to examine and improve compensation mechanisms for patients who were legitimately injured by a vaccine. 3. Our AMA will continue to work with the federal government, Congress, and other appropriate stakeholders to enhance public opinion of vaccines and to monitor and ensure the continued safety of existing and newly approved vaccines (including providing adequate resources for post-approval surveillance) so as to maintain and improve public confidence in the safety of vaccines. 4. Our AMA will work with appropriate stakeholders, including vaccine manufacturers, vaccine distributors, the federal government, medical specialty societies, and third party payers, to guarantee a robust vaccine delivery infrastructure (including but not limited to, the research and development of new vaccines, the ability to track the real-time supply status of ACIP-recommended vaccines, and the timely distribution of ACIP-recommended vaccines to providers). 5. Our AMA will work with appropriate federal and state agencies and private sector entities to ensure that state Medicaid agencies and private insurance plans pay health care professionals at least the approved Relative Value Unit (RVU) administration Medicare rates for payment when they administer ACIP-recommended vaccines. 6. Our AMA will work with the Centers for Medicare and Medicaid Services to address barriers associated with Medicare recipients receiving live zoster vaccine and the routine boosters Td and Tdap in physicians’ offices. **7. Our AMA will work through appropriate state entities to ensure all health insurance plans rapidly include newly ACIP-recommended vaccines in their list of covered benefits, and to pay health care professionals fairly for the purchase and administration of ACIP-recommended vaccines.** (BOT Action in response to referred for decision Res. 524, A-06; Reaffirmation A-07; Appended: Res. 531, A-07)
Whereas, Government-sponsored health care, such as Medicare, Medicaid, and CHIP, significantly underpay physicians and cause inequality regarding access to care for these patients; and

Whereas, There is concern that government will continue to gradually expand and control a significant portion of health care; therefore be it

RESOLVED, That our American Medical Association endorse and promote the use of commercial insurance at standard commercial physician payment rates in all government health care benefit programs and oppose increased use of government-based payment rates for comparative purposes (Directive to Take Action); and be it further

RESOLVED, That our AMA work with federation stakeholders and appropriate independent third parties to identify data and information tools for the purpose of comparing rates. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $16,580.

Received: 05/06/09
RELEVANT AMA POLICY

D-165.957 State Options to Improve Coverage for the Poor - Our AMA (1) urges national medical specialty societies, state medical associations, and county medical societies to become actively involved in and support state-based demonstration projects to expand health insurance coverage to low-income persons; and (2) encourages state governments to maintain an inventory of private health plans and design an easily accessible, consumer-friendly information clearinghouse for individuals, families, and small businesses on available plans for expanding health insurance coverage. (CMS Rep. 1, A-05)

D-165.955 Status Report on Expanding Health Care Coverage to all Individuals, with an Emphasis on the Uninsured - 1. Our AMA will continue to: (1) place a high priority on expanding health insurance coverage for all; (2) pursue bipartisan support for individually selected and owned health insurance through the use of adequately funded federal tax credits as a preferred long-term solution for covering all; and (3) explore and support alternative means of ensuring health care coverage for all. 2. Our AMA Board of Trustees will consider assisting Louisiana, and other Gulf Coast States if they should desire, in developing and evaluating a pilot project(s) utilizing AMA policy as a means of dealing with the impending public health crisis of displaced Medicaid enrollees and uninsured individuals as a result of the recent natural disasters in that region. (CMS Rep. 1, I-05)

D-165.952 National Health Care Policy Agenda - 1. Our AMA will synthesize current AMA policy for the specific purpose of advocating a comprehensive, patient-centered National Health Care Policy Agenda. 2. This Agenda will strongly address the most important issues affecting physicians and patients in the United States, such as public- and private-sector financing and delivery, care for the uninsured, wellness and personal responsibility, liability, patient safety, and health information technology, and recommend comprehensive and workable solutions. 3. Our AMA will develop an appropriate mechanism to present a draft of the National Health Care Policy Agenda to members of the House of Delegates at the earliest opportunity prior to the 2007 Annual Meeting to allow delegates an appropriate period of time to review and offer feedback prior to the 2007 Annual Meeting. 4. A forum on the National Health Care Policy Agenda will be held at the 2007 Annual Meeting to debate and offer feedback to the Board of Trustees. 5. Once finalized, our AMA will use the National Health Care Policy Agenda as a framework for discussion with leaders of United States medicine, business, health care, employers, and government. 6. Our AMA will present the National Health Care Policy Agenda to the President of the United States, the Congress, the American people, and the major political parties by August 31, 2007, so that it can appropriately frame and drive the health care policy debate in the 2008 presidential election. (Res. 607, I-06)

D-165.950 Educating the American People About Health System Reform - Our AMA will: (1) distribute our policy positions on health system reform to all declared candidates for the presidency of the United States of America and formally request their public support of those positions; and (2) undertake a media campaign designed to educate the American people about AMA policy on health system reform, emphasizing pluralism, individual ownership of health insurance and the insurance market reforms necessary to allow free market principles to function. (Res. 717, I-07)

D-165.945 Study Effects of Individual Health Insurance Mandates - Our AMA will conduct a study of the effects of the Massachusetts individual health insurance mandate on individuals, taxpayers and physicians for report back to the House of Delegates by the 2009 Annual Meeting. The report shall include details on the number of uninsured remaining, public financing required, effect on private health insurance, primary care physician availability, physician reimbursement, and physician public reporting and compliance requirements. (Res. 808, I-08)
Resolution 119

H-165.844 Educating the American People About Health System Reform
Our AMA reaffirms support of pluralism, freedom of enterprise and strong opposition to a single payer system. (Res. 717, I-07)

H-165.888 Evaluating Health System Reform Proposals
Our AMA will continue its efforts to ensure that health system reform proposals adhere to the following principles: (1) Physicians maintain primary ethical responsibility to advocate for their patients’ interests and needs. (2) **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.** (3) 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. (4) 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. (5) 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. (6) 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. (7) 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. (8) True health reform is impossible without true tort reform. (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; Reaffirmation I-07; Reaffirmation in lieu of Res. 113, A-08)

H-165.916 Government Controlled Medicine
Our AMA strongly reaffirms its unwavering opposition against the encroachment of government in the practice of medicine as well as any attempts to covertly change the American health care system to a government program with the subsequent loss of precious personal freedoms, including the right of physicians and patients to contract privately for health care without government interference. (Res. 141, I-93; Reaffirmed: Sub. Res. 132, A-94; Reaffirmation A-97; Reaffirmation I-00; Reaffirmation A-01; Reaffirmation A-02; Reaffirmation I-07)
H-165.985 Opposition to Nationalized Health Care
Our AMA reaffirms the following statement of principles as a positive articulation of the Association's opposition to socialized or nationalized health care: (1) Free market competition among all modes of health care delivery and financing, with the growth of any one system determined by the number of people who prefer that mode of delivery, and not determined by preferential federal subsidy, regulations or promotion. (2) Freedom of patients to select and to change their physician or medical care plan, including those patients whose care is financed through Medicaid or other tax-supported programs, recognizing that in the choice of some plans the patient is accepting limitations in the free choice of medical services. (Reaffirmed: BOT Rep. I-93-25; Reaffirmed: CMS Rep. I-93-5) (3) Full and clear information to consumers on the provisions and benefits offered by alternative medical care and health benefit plans, so that the choice of a source of medical care delivery is an informed one. (4) Freedom of physicians to choose whom they will serve, to establish their fees at a level which they believe fairly reflect the value of their services, to participate or not participate in a particular insurance plan or method of payment, and to accept or decline a third party allowance as payment in full for a service. (5) Inclusion in all methods of medical care payment of mechanisms to foster increased cost awareness by both providers and recipients of service, which could include patient cost sharing in an amount which does not preclude access to needed care, deferral by physicians of a specified portion of fee income, and voluntary professionally directed peer review. (6) The use of tax incentives to encourage provision of specified adequate benefits, including catastrophic expense protection, in health benefit plans. (7) The expansion of adequate health insurance coverage to the presently uninsured, through formation of insurance risk pools in each state, sliding-scale vouchers to help those with marginal incomes purchase pool coverage, development of state funds for reimbursing providers of uncompensated care, and reform of the Medicaid program to provide uniform adequate benefits to all persons with incomes below the poverty level. (8) Replacing the present Medicare program with a system developed by the AMA of pre-funded vouchers to older persons to purchase health insurance with comprehensive benefits, including catastrophic coverage. (9) Development of improved methods of financing long-term care expense through a combination of private and public resources, including encouragement of privately prefunded long-term care financing to the extent that personal income permits, assurance of access to needed services when personal resources are inadequate to finance needed care, and promotion of family caregiving. (BOT Rep. U, I-88; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: Sub. Res. 110, A-94; Reaffirmed: CMS Rep. 7, I-97; Reaffirmed by CMS Rep. 9, A-98; Reaffirmed: CMS Rep. 4, A-99; Reaffirmation I-07; Modified: CMS Rep. 8, A-08; Reaffirmed in lieu of Res. 813, I-08)

D-385.976 Published Reimbursement Schedules by Private Insurers
Our AMA will request that all state insurance regulators require all private insurers to make available to each participating physician practice their updated payment schedules on an annual basis, and interim updates to the payment schedule should be provided to contracted physicians at least 90 days prior to the effective date. (Res. 805, I-04)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 122
(A-09)

Introduced by: American Psychiatric Association
American Academy of Child and Adolescent Psychiatry
American Academy of Psychiatry and the Law

Subject: Extension of Veterans Affairs Pharmacy Benefit to all Veterans

Referred to: Reference Committee A
(Steve E. Larson, MD, Chair)

Whereas, The United States Department of Veterans Affairs, through its Pharmacy Benefits Management System, is able to negotiate for bulk purchase of medications and provide these to enrolled veterans at a substantially reduced cost and\(^6\); and

Whereas, In 1999, this system was estimated to save over 1 billion dollars when compared to receiving this same care under the Medicare-based payment system\(^7,8\); and

Whereas, Only approximately one-third of US veterans receive their health care through the Veterans Administration and are eligible for reduced price medications; and

Whereas, Expanding access to the Veteran’s Affairs pharmacy benefit would substantially reduce the pharmaceutical cost to the overall national healthcare system; therefore be it

RESOLVED, That our American Medical Association advocate for the extension of the Veterans Affairs pharmacy benefit to all outpatient veterans who wish to use it. (Directive to Take Action)

Fiscal Note:

Received: 05/14/09

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Resolution 122

H-510.991 Veterans Administration Health System
Our AMA supports approaches that increase the flexibility of the Veterans Health Administration to provide all veterans with improved access to health care services. (CMS Rep. 8, A-99)
Whereas, New regulations continue to be imposed upon physicians; and

Whereas, New regulations increase the amount of paperwork for physicians, geometrically, for hospitalized and/or ambulatory patients; and

Whereas, These new regulations cause a physician to spend more time on documentation in order to comply with changing regulations; and

Whereas, The time a physician spends in an attempt to comply with the imposed regulations costs the physician time and, therefore, money; therefore be it

RESOLVED, That our American Medical Association seek reconsideration of Work Relative Value Units for all AMA CPT codes from the Relative Value Update Committee to capture the additional work forced upon physicians by voluminous documentation requirements resulting from regulatory mandates when reimbursement rates are calculated (Directive to Take Action); and be it further

RESOLVED, That our AMA seek passage of federal regulation and/or legislation to accomplish the sentiments expressed in this resolution. (Directive to Take Action)

Fiscal Note:

Received: 05/14/09
Resolution 126

H-240.966 Reimbursement to Physicians and Hospitals for Government Mandated Services
(1) It is the policy of the AMA that government mandated services imposed on physicians and hospitals that are peripheral to the direct medical care of patients be recognized as additional practice cost expense. (2) Our AMA will accelerate its plans to develop quantitative information on the actual costs of regulations. (3) Our AMA strongly urges Congress that the RBRVS and DRG formulas take into account these additional expenses incurred by physicians and hospitals when complying with governmentally mandated regulations and ensure that reimbursement increases are adequate to cover the costs of providing these services. (4) Our AMA will advocate to the CMS and Congress that an equitable adjustment to the Medicare physician fee schedule (or another appropriate mechanism deemed appropriate by CMS or Congress) be developed to provide fair compensation to offset the additional professional and practice expenses required to comply with the Emergency Medical Treatment and Labor Act. (Sub. Res. 810, I-92; Appended by CMS 10, A-98; Reaffirmation I-98; Reaffirmation A-02; Reaffirmation I-07)
Whereas, The Federal Government has chartered the Advisory Committee on Immunization Practices (ACIP) to provide advice that will lead to a reduction in the incidence of vaccine-preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products; and

Whereas, The Advisory Committee on Immunization Practices (ACIP) consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U. S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC) on the control of vaccine-preventable diseases, and most appropriate selection of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population; and

Whereas, Insurance companies often do not pay for ACIP-recommended vaccines; therefore be it

RESOLVED, That our American Medical Association seek legislation mandating that health insurance companies in applicable states either pay for vaccines recommended by the Advisory Committee on Immunization Practices, or clearly state in large bold font in their notices to patients and businesses that they do not follow the federal advisory body on vaccine recommendations, the Advisory Committee on Immunization Practices. (Directive to Take Action)

Fiscal Note:

Received: 05/14/09
H-440.875 Assuring Access to ACIP/AAFP/AAP-Recommended Vaccines
1. It is AMA policy that all persons, regardless of economic and insurance status, receive all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines as soon as possible following publication of these recommendations in the Centers for Disease Control and Prevention’s (CDC) Morbidity and Mortality Weekly Report (MMWR). 2. Our AMA will continue to work with the federal government, Congress, and other stakeholders to improve liability protection for vaccine manufacturers and health care professionals who provide immunization services and to examine and improve compensation mechanisms for patients who were legitimately injured by a vaccine. 3. Our AMA will continue to work with the federal government, Congress, and other appropriate stakeholders to enhance public opinion of vaccines and to monitor and ensure the continued safety of existing and newly approved vaccines (including providing adequate resources for post-approval surveillance) so as to maintain and improve public confidence in the safety of vaccines. 4. Our AMA will work with appropriate stakeholders, including vaccine manufacturers, vaccine distributors, the federal government, medical specialty societies, and third party payers, to guarantee a robust vaccine delivery infrastructure (including but not limited to, the research and development of new vaccines, the ability to track the real-time supply status of ACIP-recommended vaccines, and the timely distribution of ACIP-recommended vaccines to providers). 5. Our AMA will work with appropriate federal and state agencies and private sector entities to ensure that state Medicaid agencies and private insurance plans pay health care professionals at least the approved Relative Value Unit (RVU) administration Medicare rates for payment when they administer ACIP-recommended vaccines. 6. Our AMA will work with the Centers for Medicare and Medicaid Services to address barriers associated with Medicare recipients receiving live zoster vaccine and the routine boosters Td and Tdap in physicians’ offices. 7. Our AMA will work through appropriate state entities to ensure all health insurance plans rapidly include newly ACIP-recommended vaccines in their list of covered benefits, and to pay health care professionals fairly for the purchase and administration of ACIP-recommended vaccines. (BOT Action in response to referred for decision Res. 524, A-06; Reaffirmation A-07; Appended: Res. 531, A-07)

H-440.860 Financing of Adult Vaccines: Recommendations for Action
1. Our AMA supports the concepts to improve adult immunization as advanced in the Infectious Diseases Society of America’s 2007 document “Actions to Strengthen Adult and Adolescent Immunization Coverage in the United States,” and support the recommendations as advanced by the National Vaccine Advisory Committee’s 2008 white paper on pediatric vaccine financing. 2. Our AMA will advocate for the following actions to address the inadequate financing of adult vaccination in the United States: Provider-related a. Develop a data-driven rationale for improved vaccine administration fees. b. Identify and explore new methods of providing financial relief for adult immunization providers through, for example, vaccine company replacement systems/deferred payment/funding for physician inventories, buyback for unused inventory, and patient assistance programs. c. Encourage and facilitate adult immunization at all appropriate points of patient contact; e.g., hospitals, visitors to long-term care facilities, etc. d. Encourage counseling of adults on the importance of immunization by creating a mechanism through which immunization counseling alone can be reimbursed, even when a vaccine is not given. Federal-related a. Increase federal resources for adult immunization to: (i) Improve Section 317 funding so that the program can meet its purpose of improving adult immunizations; (ii) Provide universal coverage for adult vaccines and minimally, uninsured adults should be covered; (iii) Fund an adequate universal reimbursement rate for all federal and state immunization programs. b. Optimize use of existing federal resources by, for example: (i) Vaccinating eligible adolescents before they turn 19 years of age to capitalize on VFC funding; (ii) Capitalizing on public health preparedness funding. c. Ease federally imposed immunization burdens by, for example: (i) Providing coverage for Medicare-eligible individuals for all vaccines, including new vaccines,
under Medicare Part B; (ii) Creating web-based billing mechanisms for physicians to assess coverage of the patient in real time and handle the claim, eliminating out-of-pocket expenses for the patient; (iii) Simplifying the reimbursement process to eliminate payment-related barriers to immunization. d. The Centers for Medicare & Medicaid Services should raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations.

State-related a. State Medicaid programs should increase state resources for funding vaccines by, for example: (i) Raising and funding the maximum Medicaid reimbursement rate for vaccine administration fees; (ii) Establishing and requiring payment of a minimum reimbursement rate for administration fees; (iii) Increasing state contributions to vaccination costs; and (iv) Exploring the possibility of mandating immunization coverage by third party payers. b. Strengthen support for adult vaccination and appropriate budgets accordingly.

Insurance-related 1. Provide assistance to providers in creating efficiencies in vaccine management by: (i) Providing model vaccine coverage contracts for purchasers of health insurance; (ii) Creating simplified rules for eligibility verification, billing, and reimbursement; (iii) Providing vouchers to patients to clarify eligibility and coverage for patients and providers; and (iv) Eliminating provider/public confusion over insurance payment of vaccines by universally covering all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines. c. Increase resources for funding vaccines by providing first-dollar coverage for immunizations. d. Work with businesses that purchase private insurance to include all ACIP-recommended immunizations as part of the health plan. e. Provide incentives to encourage providers to begin immunizing by, for example: (i) Including start up costs (freezer, back up alarms/power supply, reminder-recall systems, etc.) in the formula for reimbursing the provision of immunizations; (ii) Simplifying payment to and encouraging immunization by nontraditional providers; (iii) Facilitating coverage of vaccines administered in complementary locations (e.g., relatives visiting a resident of a long-term care facility). Manufacturer-related Market stability for adult vaccines is essential. Thus: (i) Solutions to the adult vaccine financing problem should not deter research and development of new vaccines; (ii) Solutions should consider the maintenance of vibrant public and private sector adult vaccine markets; (iii) Liability protection for manufacturers should be assured by including Vaccine Injury Compensation Program coverage for all ACIP-recommended adult vaccines; (iv) Educational outreach to both providers and the public is needed to improve acceptance of adult immunization. 3. Our AMA will conduct a survey of small- and middle-sized medical practices, hospitals, and other medical facilities to identify the impact on the adult vaccine supply (including influenza vaccine) that results from the large contracts between vaccine manufacturers/distributors and large non-government purchasers, such as national retail health clinics, other medical practices, and group purchasing programs, with particular attention to patient outcomes for clinical preventive services and chronic disease management. (CSAPH Rep. 4, I-08)
Memo to: Roger Brown
From: Katie Tenoever
Date: May 27, 2009
Subject: Reaffirmation Resolutions, A-2009 – Reference Committee B

I have reviewed the resolutions assigned to Reference Committee B for A-2009, and believe that the following resolutions are covered by existing policy. Copies of the resolutions along with the existing policies recommended for reaffirmation are included in this memorandum, and background documents related to various resolutions are attached.

Resolution 201 – Americans’ Health

Resolution 201 asks the AMA to: make improving health through increased activity and proper diet a priority; propose legislation calling on the federal government and state governments to develop new and innovative programs in partnership with the private sector that encourage personal responsibility for proper dietary habits and physical activity of individual Americans; and continue working with specialty and other organizations and the federal government to provide educational materials on increased physical activity and improved dietary habits. Extensive AMA policies as well as AMA activities cover the intent of this resolution. **H-440.902** states that our AMA (1) recognizes obesity in children and adults as a major public health problem and (3) will work with other professional medical organizations, and other public and private organizations to develop evidence-based recommendations regarding education, prevention, and treatment of obesity. **H-150.953** states that our AMA will (2) work with appropriate federal agencies, medical specialty societies, and public health organizations to educate physicians about the prevention and management of overweight and obesity in children and adults; (3) urge federal support of research to determine: (a) the causes and mechanisms of overweight and obesity, … (c) effective interventions to prevent obesity in children and adults; and (d) the effectiveness of weight loss counseling by physicians; (4) encourage national efforts to educate the public about the health risks of being overweight and obese and provide information about how to achieve and maintain a preferred healthy weight; (5) urge physicians to assess their patients for overweight and obesity during routine medical examinations and discuss with at-risk patients the health consequences of further weight gain; if treatment is indicated, physicians should encourage and facilitate weight maintenance or reduction efforts in their patients or refer them to a physician with special interest and expertise in the clinical management of obesity; and (7) encourage physicians to become knowledgeable of community resources and referral services that can assist with the management of overweight and obese patients. In addition, **D-440.954** calls on our AMA to assume a leadership role in collaborating with other interested organizations… to discuss ways to finance a comprehensive national program for the study, prevention, and treatment of obesity, as well as public health and medical programs that serve vulnerable populations; and (3) continue to monitor and support state and national policies and regulations that encourage healthy lifestyles and promote obesity prevention. Moreover, **D-440.971** calls on the AMA to (1) work with the Centers for Disease Control and Prevention to convene relevant stakeholders to evaluate the issue of obesity as a disease, using a systematic, evidence-based approach; (2) continue to actively pursue measures to treat obesity as an urgent chronic condition, raise the public’s awareness of the significance of obesity and its related disorders, …(5) develop a school health advocacy agenda that includes funding for school health programs, physical education and physical activity with limits on declining participation, alternative policies for vending machines that promote healthier diets, and standards for healthy a la carte meal offerings. Our AMA will work with a broad partnership to implement this agenda;… In addition, **D-440.980** states that our AMA will strongly encourage through a media campaign the re-establishment of meaningful physical education programs in primary and secondary education as well as family-oriented education programs on obesity prevention. **H-170.995** states that consumers should be encouraged and assisted to learn healthful practices by: (1) educating and motivating the consumers to adopt more
healthful lifestyles; (2) exploring methods of utilizing public communication more effectively in health education efforts directed towards motivating consumers to adopt healthful lifestyles; (3) encouraging consumers, in appropriate risk groups, to utilize professional preventive health care services. H-170.963 states that our AMA (1) Supports an integrated approach to encouraging the adoption of healthy lifestyles, involving coordinated efforts by physicians, other health care providers, insurers, employers, unions, and government. The AMA has numerous additional policies in support of this resolution, many of which are duplicative (D-60.990, H-60.979, H-470.961, D-470.994, H-470.990, H-470.997, H-440.917, H-425.993, H-170.986). Since AMA policy and advocacy activities extensively cover the intent of Resolution 201, it has been placed on the Reaffirmation Calendar.


In addition, The AMA, in collaboration with the U.S. Department of Health and Human Services’ Health Resources and Services Administration and the Centers for Disease Control and Prevention, convened an expert committee to develop recommendations on the assessment, prevention, and treatment of child and adolescent overweight and obesity, recently published in the attached Pediatrics (December 2007) journal article. In July 2008, the AMA participated in a Congressional briefing on childhood obesity (see attached handout). The AMA has also engaged in extensive advocacy in support of the goals of this resolution, as indicated in the attached letters.

**Resolution 203 – Right to Privately Contract**

The first resolve of Resolution 203 asks that our AMA Board of Trustees immediately make as its highest priority the enactment of federal legislation that ensures and protects the fundamental right of physicians to privately contract with patients, without penalties for doing so and regardless of payer within the framework of free market principles with the goal of accomplishing this by 2010. This resolve is fully covered by existing AMA policy and AMA advocacy activities. H-385.961 directs our AMA to: (1) continue to pursue legal and administrative efforts to permit patients to contract privately with their physicians in appropriate circumstances; and (2) support repeal of the restrictions placed on private contracts between physicians and Medicare beneficiaries to ensure that there is no interference with Medicare beneficiaries’ freedom to choose a physician to provide covered services and give priority to this goal as a legislative objective. D-380.997 states that (1) Our AMA reaffirm Policy H-380.989 which states that 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 reaffirm Policy H-165.913(2) which states that the AMA advance 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. H-380.989 states that it is the policy of the AMA: (1) 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; (2) to pursue appropriate legislative and legal means to permanently preserve the patient's basic right to privately contract with physicians for wanted or needed health care services; (3) 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 (4) 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. H-330.932 states that our AMA . . . . : (3) aggressively encourages CMS to affirm the patient's and the physician's
The second resolve of Resolution 203 asks the AMA to work to make changes in statues and regulations so that physicians are able to negotiate fair contracts with private and public sector health plans. The intent of this second resolve of Resolution 203 is fully covered by existing AMA policy and ongoing AMA advocacy activities. H-285.995 asks that our AMA continue to advocate strongly to Congress, the Department of Justice, and the Federal Trade Commission the need for changes in relevant antitrust laws to allow physicians and physician organizations to form bargaining groups to engage in group negotiations with managed care plans. H-383.993 asks that our AMA continue to pursue enhanced roles for physicians in private sector health plans, including lobbying for appropriate modification of the antitrust laws to facilitate physician negotiation with managed care plans. Since existing policy covers the requests of Resolution 203, it has been placed on the Reaffirmation Calendar.


In addition, attached are advocacy documents representing the AMA’s ongoing advocacy activities to achieve the goals of Resolution 203.

Resolution 204 – Criminalization of PLI

Resolution 204 asks our AMA to oppose the criminalization of professional liability concerns and lawsuits. This resolution is covered by existing AMA policy and advocacy activities. H-160.954 calls for our AMA to continue to take all reasonable and necessary steps to insure that medical decision-making, exercised in good faith, does not become a violation of criminal law. H-160.946 expresses our AMA’s strong opposition to the attempted criminalization of health care decision-making especially as represented by the current trend toward criminalization of malpractice. Since existing policy and advocacy activities cover the request of Resolution 204, it has been placed on the Reaffirmation Calendar.

H-160.954 and H-160.946 should be reaffirmed.

In addition, a model state bill, developed and advocated by the AMA to “Prohibit the Criminalization of Health Care Decision-Making,” is attached.

Resolution 205 – Electronic Prescribing of Class 3 Substances

Resolution 216 – Electronic Submission of Schedule II-V Narcotic Prescriptions

Resolution 205 asks that our AMA work through appropriate channels to permit secure electronic prescriptions of controlled substances. Resolution 216 asks that our American Medical Association work with the US Drug Enforcement Agency to allow the electronic submission of prescriptions for Schedule II thru V medications. The intent of these resolutions, which is to allow physicians to e-prescribe controlled substances, is fully covered by existing AMA policy and AMA advocacy activities. D-120.958 calls for our AMA to initiate discussions with the Centers for Medicare and Medicaid Services and state Medicaid directors to remove barriers to electronic prescribing and initiate discussions with the Drug Enforcement Administration to allow electronic prescribing of Schedule II prescription drugs. D-120.972 states that our AMA will ask the Drug Enforcement Administration to accelerate the promulgation of digital certificate standards for direct electronic transmission of controlled substance prescriptions. H-120.957 states that our AMA will encourage the Drug Enforcement Administration to rewrite Section 1306 of Title 21 of the Code of Federal Regulations to accommodate encrypted electronic prescriptions for
Schedule II controlled substances. Since existing policy and AMA advocacy activities cover the requests of Resolutions 205 and 216, they have been placed on the Reaffirmation Calendar.

D-120.958, D-120.972, and H-120.957 should be reaffirmed.

In addition, attached is a September 25, 2008, letter to the U.S. Drug Enforcement Administration (DEA) urging the DEA to properly implement a system for e-prescribing of controlled substances.

Resolution 206 – Interpretive Services

The intent of Resolution 206 is to ensure that the cost of providing interpretive services to patients with limited English proficiency (LEP) is not imposed on physicians, and asks that our AMA initiate legislation or regulation that physicians be reimbursed for the cost of providing interpretive services. Extensive AMA policy supports such legislation as well as the goal of ensuring that LEP interpreter costs are not imposed on physicians. AMA advocacy activities also support Resolution 206. H-160.924 states that physicians cannot be expected to provide and fund translation services for their patients, as the Department of Health and Human Services’ policy guidance currently requires; when trained medical interpreters are needed, the costs of their services shall be paid directly to the interpreters by patients and/or third party payers and physicians shall not be required to participate in payment arrangements. H-385.928 further directs our AMA to support sufficient federal appropriations for patient interpreter services and take other necessary steps to assure physicians are not directly or indirectly required to pay for interpreter services mandated by the federal government. D-385.978 states that our AMA will: (1) continue to work to obtain federal funding for medical interpretive services; (2) redouble its efforts to remove the financial burden of medical interpretive services from physicians; (3) urge the Administration to reconsider its interpretation of Title VI of the Civil Rights Act of 1964 as requiring medical interpretive services without reimbursement; (4) consider the feasibility of a legal solution to the problem of funding medical interpretive services; and (5) work with governmental officials and other organizations to make language interpretive services a covered benefit for all health plans inasmuch as health plans are in a superior position to pass on the cost of these federally mandated services as a business expense. D-160.992 states that our AMA will seek legislation to eliminate the financial burden to physicians, hospitals and health care providers for the cost of interpretive services for patients who are hearing impaired or do not speak English. H-385.929 states that it is our AMA policy: (1) the fullest extent appropriate, to actively oppose the inappropriate extension of the OCR LEP guidelines to physicians in private practice; and (2) continue our proactive, ongoing efforts to correct the problems imposed on physicians in private practice by the OCR language interpretation requirements. Finally, D-270.998 directs that our AMA BOT, to the fullest extent appropriate, will authorize further efforts necessary to actively oppose the inappropriate extension of the Limited English Proficiency Guidance issued by the US Department of Health and Human Services’ Office of Civil Rights’ to physicians in private practice. Since AMA policy and advocacy materials extensively cover the intent of Resolution 206, it has been placed on the Reaffirmation Calendar.


In addition, attached are AMA advocacy documents, including AMA testimony, letters to Congress, regulatory comments to the Administration, and AMA-developed model legislation to require appropriate reimbursement for federally-mandated interpreter services furnished to LEP patients.

Resolution 208 – Protection in Practice

Resolution 208 asks that our AMA: (1) adopt policy that government involvement in the practice of medicine must not force the participation of physicians, allowing their participation to remain voluntary; and (2) take action to officially reject any future attempt by individual state and/or federal legislative bodies to require acceptance of any private or government third party payments or contracts as a condition of licensure. The goals of Resolution 208 are covered by existing AMA policy. H-165.985 asks that our AMA reaffirm the following statement of principles as a positive articulation of the Association's opposition to socialized or nationalized health care:
. . . (4) Freedom of physicians to choose whom they will serve, to establish their fees at a level which they believe fairly reflect the value of their services, to participate or not participate in a particular insurance plan or method of payment, and to accept or decline a third party allowance as payment in full for a service . . . H-390.961 states that the AMA (1) continues to actively oppose, through appropriate political and legal means, any and all actions by any government body or legislative body, which would require mandatory acceptance of Medicare assignment; and (2) encourages all concerned physicians to join with the AMA in the active opposition to such oppressive action. H-275.963 asks that our AMA support federal legislation that would prohibit states from enacting legislation to require that acceptance of Medicare assignment or the Medicare allowance of reimbursement be a condition of medical licensure, or used in determinations of unprofessional conduct, or made effectively mandatory in any other fashion. Since AMA policy covers the goals of Resolution 208, it has been placed on the Reaffirmation Calendar.

H-165.985, H-390.961, and H-275.963 should be reaffirmed.

Resolution 209 – Health System and Litigation Reform

The intent of Resolution 209 is to ensure effective medical litigation reforms as part of the federal health system/insurance reform debate, along with negotiation with federal policymakers on a wide range of litigation reform policy options to gain inclusion as a remedy in the health system reform package. The AMA has significant policy and advocacy activities covering Resolution 209 and advocating for medical liability reforms at the federal and state levels and exploring alternative reforms, such as health courts, that have the potential to improve the current litigation climate. H-435.978 calls on our AMA to support federal legislative initiatives including effective medical liability reform, based on the California Medical Injury Compensation Reform Act (MICRA) model. H-435.967 supports demonstration projects to implement potentially effective alternative dispute resolution (ADR) mechanisms. H-435.969 calls on our AMA to reaffirm its support for investigating promising Alternative Dispute Resolution (ADR) mechanisms, in the context of demonstration projects designed to evaluate whether they resolve medical liability claims fairly and in a more timely and cost-effective manner. H-435.951 outlines AMA’s Health Court Principles.


In addition, AMA documents advocating for the goals of Resolution 209, including AMA testimony, letters to Congress, fact sheets, and health court principles, are attached.

Resolution 210 – Geographic Devaluation of Medicare Payments for PQRI

Resolution 211 – Geographic Devaluation of E-Prescribing Payments

Resolution 212 – Geographic Practice Cost Index (GPCI) Adjustment to Technical Component Fees for Imaging Procedures

Resolution 210 asks that our AMA: (1) reaffirm the concept of equal pay for equal work; (2) affirm the concept of equal pay for equal quality; and (3) lobby Congress and the Centers for Medicare & Medicaid Services to prohibit geographic adjustments from being applied to Physician Quality Reporting Initiative payments. Resolution 211 asks that our AMA lobby Congress and the Centers for Medicare & Medicaid Services to prohibit geographic adjustments for E-prescribing payments. Resolution 212 asks that at our AMA advocate that Congress: (1) immediately eliminate the inaccurate Geographic Practice Cost Index (GPCI) adjustment for the technical component of imaging studies; and (2) bring about a 1.0 floor for all GPCI practice expense adjustments.

The intent of these resolutions is to eliminate physician payment inequities due to unwarranted geographic area adjustments. Existing AMA policy covers both the intent and requests of Resolutions 210, 211, and 212. D-400.985 directs that our AMA will: (1) use the AMA Physician Practice Information Survey to determine actual differences in rural vs. urban practice expenses; (2) seek Congressional authorization of a detailed study of the way rents are reflected in the Geographic Practice Cost Index (GPCI); and (3) advocate that payments under physician quality improvement initiatives not be subject to existing geographic variation adjustments (i.e., GPCIs). H-400.972 states that it is the
policy of the AMA to: (1) take all necessary legal, legislative, and other action to redress the inequities in the implementation of the RBRVS, including, but not limited to . . . . (c) defects in the Geographic Practice Cost Indices and area designations; (d) inappropriate Resource-Based Relative Value Units; . . . . (8) support further study of refinements in the practice cost component of the RBRVS to ensure better reflection of both absolute and relative costs associated with individual services, physician practices, and medical specialties, considering such issues as data adequacy, equity, and the degree of disruption likely to be associated with any policy change; . . . . (10) support the concepts of HR 4393 (the Medicare Geographic Data Accuracy Act of 1992), S 2680 (the Medicare Geographic Data Accuracy Act of 1992), and S 2683 (Medicare Geographic Data Accuracy Act) for improving the accuracy of the Medicare geographic practice costs indices (GPCIs) and work with CMS and the Congress to assure that GPCIs are updated in as timely a manner as feasible and reflect actual physician costs, including gross receipt taxes; (11) request that CMS refine relative values for particular services on the basis of valid and reliable data and that CMS rely upon the work of the AMA/Specialty Society RVS Updating Committee (RUC) for assignment of relative work values to new or revised CPT codes and any other tasks for which the RUC can provide credible recommendations. . . .

D-400.989 addresses “Equal Pay for Equal Work” and states that our AMA: . . . . (2) shall seek enactment of legislation directing the General Accounting Office to develop and recommend to Congress policy options for reducing any unjustified geographic disparities in Medicare physician payment rates and improving physician recruitment and retention in underserved rural areas. . . .

H-400.988 states that our AMA reaffirms its policy that geographic variations under a Medicare payment schedule should reflect only valid and demonstrable differences in physician practice costs, especially liability premiums, with further adjustments as needed to remedy demonstrable access problems in specific geographic areas.

H-390.945 states that our AMA believes that: (1) current geographic inequities in Medicare payments for physician services pose a serious threat to access to care for many Medicare beneficiaries; and; (2) such payment inequities must be addressed and remedied in a timely manner, without awaiting implementation of a new Medicare indemnity physician payment system. H-400.952 states that our AMA will continue to petition CMS to improve the accuracy of the Geographic Practice Cost Indices (GPCIs) through the use of accurate practice costs and timely data; and will petition CMS and, if necessary, the Congress to retain as distinct Medicare localities, cities where recent inclusion in state-wide localities by CMS is based on criteria that do not allow for appropriate recognition of the higher costs associated with practice in these areas. H-400.990 states that our AMA . . . . (2) supports reasonable attempts to remedy geographic Medicare physician payment inequities that do not substantially interfere with the AMA’s support for an RBRVS-based indemnity payment system. . . .

D-390.989 addresses “Equal Pay for Equal Work” and states that our AMA will work to eliminate the unfairness inherent in the current wide geographic disparity in physician Medicare reimbursement. H-400.984 states that our AMA will work to ensure that the most current, valid and reliable data are collected and applied in calculating accurate geographic practice cost indices (GPCIs) and in determining geographic payment areas for use in the new Medicare physician payment system, with data collected from rural practice sites for this purpose. Since existing policy covers the intent and requests of Resolutions 210, 211, and 212, they have been placed on the Reaffirmation Calendar.


Resolution 213 – Stricter Fines for Violating Direct-to-Consumer Advertisements

Resolution 213 asks that the AMA lobby the U.S. Food and Drug Administration for stricter sanctions and monetary fines against pharmaceutical companies that flout the guidelines regarding direct-to-consumer advertisements. Existing AMA policy covers this request, along with AMA advocacy activities. D-105.998 states that our AMA will request the appropriate federal agency to enforce the direct-to-consumer advertising guidelines and regulations. Since existing policy and advocacy activities cover the request of Resolution 213, it has been placed on the Reaffirmation Calendar.

D-105.998 should be reaffirmed.
In addition, attached is AMA testimony from May 8, 2008, before the House Energy and Commerce Oversight and Investigation Subcommittee regarding “Direct-to-Consumer Advertising: Marketing, Education or Deception?” Our testimony advocates that DTCA must comply with all other applicable FDA regulations, policies, and guidelines. (Following this hearing, PhRMA modified its guidance to its members concerning DTCA to bring it into line with AMA policy.)

Resolution 215 – Insurance Companies Use of Contractors to Recover Payments

The intent of Resolution 215 is to place limitations on health insurers’ ability to request payment back on paid claims, define acceptable processes for physicians to dispute attempts by health insurers to get payment back, require insurers to adhere to pricing and reviewing guidelines, and ensure that these limitations and requirements are not preempted by ERISA. H-70.926 states that our AMA policy is that post-payment audits, post-payment downcodes and other similar requests for recoupment by third party payers be made within one year of the date the claim is submitted or within the same amount of time permitted for submission of the claim, whichever is less; . . . D-285.968 states that our AMA will: 1. develop a Health Insurer "Code of Conduct" setting forth clear and concise principles addressing both medical care policies and payment issues; 2. seek concurrence among health insurers in complying with this "Code of Conduct;" and 4. widely disseminate information regarding this "Code of Conduct," and health insurer compliance, to physicians and consumers; . . . H-285.915 states that our AMA will seek, through amendment of the ERISA statute, through enactment of separate federal patient protection legislation, through enactment of similar state patient protection legislation that is uniform across states, and through targeted elimination of the ERISA preemption of self-insured health benefits plans from state regulation, to require that such self-insured plans: . . . (3) Be regulated in regard to plan policies and practices regarding utilization management, claims submission and review, and appeals and grievance procedures; . . . H-285.946 states that our AMA will develop national (state) standards and model legislation for fair managed care/physician contracts, thereby requiring full disclosure in plain English of important information, including but not limited to: (1) disclosure of reimbursement amounts, conversion factors for dthe RBRVS system or other formulas if applicable, global follow-up times, multiple procedure reimbursement policies, and all other payment policies; . . . (3) grievance and appeal mechanisms; . . . and D-285.971 states that our AMA will: (1) study the issue of rental (silent) network PPO "repricers," and report back to the House of Delegates at the 2007 Interim Meeting; (2) educate physicians regarding the onerous practice of network "repricing" or silent rental networks; and (3) distribute our model state legislation for state regulation of the secondary discount market or rental (silent) networks. Since existing policy and AMA advocacy activities cover the requests of Resolution 219, it has been placed on the Reaffirmation Calendar.


In addition, attached are AMA advocacy documents, including model state legislation to “Prevent Retrospective Denial of Payment For Any Previously Authorized or Paid Claim” along with talking points and other advocacy materials for “Advancing a Counterattack on Managed Care Payment Practices: Retrospective Audits.”

Resolution 218 – Open Source Code Electronic Medical Records (EMRs)

Resolution 218 is asking the AMA to support law and public policy that would make available to physicians at nominal cost, an electronic medical record system (EMR) based on open source code, that would meet the certification and “meaningful use” requirements specified in the “American Recovery and Reinvestment Act of 2009” (ARRA). The AMA has significant policy that covers Resolution 218. It supports initiatives for assisting physicians with the adoption of health information technology (HIT), including EMRs, that meet national, uniform standards; calls for positive incentives for physicians to acquire HIT; and calls on the AMA to provide physicians with HIT purchasing guidance. H-478.995 calls on our AMA to support the development, adoption, and implementation of national health information technology standards. D-478.994 supports initiatives that provide positive incentives for physicians to acquire health information technology (HIT)...and initiatives to ensure interoperability
among all HIT systems, and D-478.992 calls on the AMA to help educate physicians via the AMA website and appropriate AMA publications about issues to consider when purchasing health information technology (HIT) systems. Although current AMA policy does not specifically address supporting an open source code electronic medical record system (EMR), AMA policy is broad enough to cover supporting qualifying HIT such as open source code EMRs as well as other options. In addition, through AMA advocacy efforts, the recently enacted “American Recovery and Reinvestment Act of 2009” (ARRA) authorizes the federal government to make available a qualifying EHR system to health care providers for a nominal fee and requires the federal government to study and report on open source HIT systems. Given that existing AMA policy and advocacy activities cover the request of Resolution 218, it has been placed on the Reaffirmation Calendar.

H-478.995, D-478.994, and D-478.992 should be reaffirmed.

In addition, attached are AMA letters to Congress supporting an acceleration of the transition to a connected, nationwide HIT infrastructure and the use of HIT.

Resolution 219 – Out-of-Network Payments

The intent of Resolution 219 is to support and encourage increased transparency from health insurers regarding patient financial responsibility. AMA policy and advocacy activities support educating and informing patients of their financial responsibilities so that they can make informed health care choices. H-165.846 states that mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services: . . . . D-180.985 states that our AMA will: (1) continue to closely monitor any new "transparency" programs unveiled by health plans to determine the impact on physicians; (2) communicate to health plans, employers and patients our concerns about current "transparency" programs, and educate them about "true transparency"; and (3) continue to educate physicians about the complexities of claims adjudication and payment processes to enable them to more efficiently manage their practices. Since existing policy and advocacy activities cover the requests of Resolution 219, it has been placed on the Reaffirmation Calendar.

H-165.846 and D-180.985 should be reaffirmed.

In addition, attached are AMA documents advocating for health plan transparency for patient financial responsibility, including testimony before the House Ways and Means Health Subcommittee regarding “Price Transparency in the Health Care Sector,” July 18, 2006, along with AMA model state legislation.
Whereas, Six to seven out of every ten American adults are overweight or obese; and

Whereas, One out of four children under the age of four is now classified as obese; and

Whereas, Eighty percent of type II diabetes mellitus is due to obesity at a cost of over $140 billion dollars per year; and

Whereas, Seventy percent of cardiovascular disease is obesity related; and

Whereas, Obesity is listed as the number one cause of death in the United States; and

Whereas, Only 13% of adult Americans get the recommended exercise weekly; and

Whereas, Only 30% of patients receive any information concerning diet and exercise at their patient visits; and

Whereas, The current economic decline is global; and

Whereas, Individual responsibility seems to be at an all-time low; and

Whereas, The AMA has numerous policies including: H-440.902, H-150.953, D-60.990, D-440.971, D-440.980, D-425.994 and D-440.954 that direct the AMA to work with involved organizations, pursue measures to treat obesity, use AMA materials in the education of patients, and urge physicians as well as managed care organizations and other third party payers to recognize obesity as a complex disorder; therefore be it

RESOLVED, That our American Medical Association make improving health through increased activity and proper diet a priority (Directive to Take Action); and be it further

RESOLVED, That our AMA propose legislation calling on the federal government and state governments to develop new and innovative programs in partnership with the private sector that encourage personal responsibility for proper dietary habits and physical activity of individual Americans (Directive to Take Action); and be it further

RESOLVED, That our AMA continue to work in conjunction with the American College of Sports Medicine, American Heart Association, US Department of Health and Human Services and any other concerned organizations to provide educational materials that encourage a healthier America through increased physical activity and improved dietary habits. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $6,120.

Received: 05/06/09
H-440.902 Obesity as a Major Health Concern
The AMA: (1) recognizes obesity in children and adults as a major public health problem; (2) will study the medical, psychological and socioeconomic issues associated with obesity, including reimbursement for evaluation and management of obese patients; (3) will work with other professional medical organizations, and other public and private organizations to develop evidence-based recommendations regarding education, prevention, and treatment of obesity; (4) recognizes that racial and ethnic disparities exist in the prevalence of obesity and diet-related diseases such as coronary heart disease, cancer, stroke, and diabetes and recommends that physicians use culturally responsive care to improve the treatment and management of obesity and diet-related diseases in minority populations; and (5) supports the use of cultural and socioeconomic considerations in all nutritional and dietary research and guidelines in order to treat overweight and obese patients. (Res. 423, A-98; Reaffirmed and Appended: BOT Rep. 6, A-04)

H-150.953 Obesity as a Major Public Health Program
Our AMA will: (1) urge physicians as well as managed care organizations and other third-party payors to recognize obesity as a complex disorder involving appetite regulation and energy metabolism that is associated with a variety of comorbid conditions; (2) work with appropriate federal agencies, medical specialty societies, and public health organizations to educate physicians about the prevention and management of overweight and obesity in children and adults, including education in basic principles and practices of physical activity and nutrition counseling; such training should be included in undergraduate and graduate medical education and through accredited continuing medical education programs; (3) urge federal support of research to determine: (a) the causes and mechanisms of overweight and obesity, including biological, social, and epidemiological influences on weight gain, weight loss, and weight maintenance; (b) the long-term safety and efficacy of voluntary weight maintenance and weight loss practices and therapies, including surgery; (c) effective interventions to prevent obesity in children and adults; and (d) the effectiveness of weight loss counseling by physicians; (4) encourage national efforts to educate the public about the health risks of being overweight and obese and provide information about how to achieve and maintain a preferred healthy weight; (5) urge physicians to assess their patients for overweight and obesity during routine medical examinations and discuss with at-risk patients the health consequences of further weight gain; if treatment is indicated, physicians should encourage and facilitate weight maintenance or reduction efforts in their patients or refer them to a physician with special interest and expertise in the clinical management of obesity; (6) urge all physicians and patients to maintain a desired weight and prevent inappropriate weight gain; (7) encourage physicians to become knowledgeable of community resources and referral services that can assist with the management of overweight and obese patients; and (8) urge the appropriate federal agencies to work with organized medicine and the health insurance industry to develop coding and payment mechanisms for the evaluation and management of obesity. (CSA Rep. 6, A-99)

D-440.954 Addressing Obesity
Our AMA will: (1) assume a leadership role in collaborating with other interested organizations, including national medical specialty societies, the American Public Health Association, the Center for Science in the Public Interest, and the AMA Alliance, to discuss ways to finance a comprehensive national program for the study, prevention, and treatment of obesity, as well as public health and medical programs that serve vulnerable populations; (2) encourage state medical societies to collaborate with interested state and local organizations to discuss ways to finance a comprehensive program for the study, prevention, and treatment of obesity, as well as public health and medical programs that serve vulnerable populations; and (3) continue to monitor and support state and national policies and regulations that encourage healthy lifestyles and promote obesity prevention. (BOT Rep. 11, I-06)

D-440.971 Recommendations for Physician and Community Collaboration on the Management of Obesity
Our AMA will: (1) work with the Centers for Disease Control and Prevention to convene relevant stakeholders to evaluate the issue of obesity as a disease, using a systematic, evidence-based approach; (2) continue to actively pursue measures to treat obesity as an urgent chronic condition, raise the public’s awareness of the significance of obesity and its related disorders, and encourage health industries to make appropriate care available for the prevention and treatment of obese patients, as well as those who have
co-morbid disorders; (3) encourage physicians to incorporate body mass index (BMI) and waist circumference as a component measurement in the routine adult physical examination, and BMI percentiles in children recognizing ethnic sensitivities and its relationship to stature, and the need to implement appropriate treatment or preventive measures; (4) promote use of our Roadmaps for Clinical Practice: Assessment and Management of Adult Obesity primer in physician education and the clinical management of adult obesity; (5) develop a school health advocacy agenda that includes funding for school health programs, physical education and physical activity with limits on declining participation, alternative policies for vending machines that promote healthier diets, and standards for healthy a la carte meal offerings. Our AMA will work with a broad partnership to implement this agenda; and (6) collaborate with the CDC, the Department of Education, and other appropriate agencies and organizations to consider the feasibility of convening school health education, nutrition, and exercise representatives, parents, teachers and education organizations, as well as other national experts to review existing frameworks for school health, identify basic tenets for promoting school nutrition and physical activity (using a coordinated school health model), and create recommendations for a certificate program to recognize schools that meet a minimum of the tenants. (CSA Rep. 4, A-05; Reaffirmation A-07; Reaffirmation I-07; Reaffirmed: CSAPH Rep. 1, A-08)

D-440.980 Recognizing and Taking Action in Response to the Obesity Crisis
Our AMA will: (1) collaborate with appropriate agencies and organizations to commission a multidisciplinary task force to review the public health impact of obesity and recommend measures to better recognize and treat obesity as a chronic disease; (2) actively pursue, in collaboration and coordination with programs and activities of appropriate agencies and organizations, the creation of a "National Obesity Awareness Month"; (3) strongly encourage through a media campaign the re-establishment of meaningful physical education programs in primary and secondary education as well as family-oriented education programs on obesity prevention; (4) promote the inclusion of education on obesity prevention and the medical complications of obesity in medical school and appropriate residency curricula; and (5) provide a progress report on the above efforts to the House of Delegates by the 2004 Annual Meeting. (Res. 405, A-03; Reaffirmation A-04; Reaffirmation A-07)

H-170.995 Healthful Lifestyles
The AMA believes that consumers should be encouraged and assisted to learn healthful practices by: (1) educating and motivating the consumers to adopt more healthful lifestyles; (2) exploring methods of utilizing public communication more effectively in health education efforts directed towards motivating consumers to adopt healthful lifestyles; (3) encouraging consumers, in appropriate risk groups, to utilize professional preventive health care services which would permit the early detection and treatment, or the prevention, of illness; and physicians demonstrating these practices through personal examples of health lifestyles. (BOT Rep. A, NCCMC Rec. 48, A-78; Reaffirmed: CLRPD Rep. C, A-89; Res. 402, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: BOT Rep. 8, I-06)

H-170.963 Reward-Based Incentive Programs for Healthy Lifestyles
Our AMA: (1) Supports an integrated approach to encouraging the adoption of healthy lifestyles, involving coordinated efforts by physicians, other health care providers, insurers, employers, unions, and government. (2) Policy is that reward-based incentive programs that are developed to promote healthy lifestyles should be guided by the following principles: (a) Incentive programs should be designed with input from physicians. (b) Incentive programs should reward behaviors, not health status. (c) Programs should be designed to assess and address risk factors as well as current health status. (d) Program participation should allow for at least some level of individual assessment and feedback. (e) Confidentiality of program participants must be maintained, possibly through use of a third-party vendor to track individual participation. (f) Incentives should be integrated into an ongoing risk-reduction and behavior change program to encourage and support long-term changes in habits and behaviors. (g) To the extent possible, efforts should be made to ensure that other policies, resources, and activities support and facilitate participation in healthy behaviors. (Joint CMS and CSAPH Rep., A-06; Reaffirmation A-07; Reaffirmed: BOT Rep. 9, A-07)
D-60.990 Exercise and Healthy Eating for Children
Our AMA shall: (1) seek legislation that would require the development and implementation of evidence-based nutrition standards for all food served in K-12 schools irrespective of food vendor or provider; and (2) work with the US Public Health Service and other federal agencies, the Federation, and others in a coordinated campaign to educate the public on the epidemic of childhood obesity and enhance the K-12 curriculum by addressing the benefits of exercise, physical fitness, and healthful diets for children. (Res. 423, A-02; Reaffirmation A-04; Reaffirmation A-07; Reaffirmation I-07)

H-60.979 Physician-Based Physical Activity and Exercise Counseling Protocols for Youth and Adolescents
It is the policy of the AMA, in collaboration with appropriate agencies, to assist in the development of physician-based physical activity assessment and counseling protocols for youth and adolescents, including the development of training materials to instruct physicians in the use of these protocols. (Res. 186, I-90; Reaffirmed: Sunset Report, I-00)

H-470.961 Requirement for Daily Free Play in Schools
Our AMA recommends that elementary schools maintain at least thirty minutes of daily free play or physical education that is consistent with CDC guidelines. (Res. 409, A-04; Reaffirmation A-07)

D-470.994 Requirement for Daily Free Play in Schools
Our AMA will work with other interested medical societies to urge the Department of Education and state and national legislatures to enact regulatory and legislative provisions that ensure at least thirty minutes of daily free play for elementary school students. (Res. 409, A-04)

H-470.990 Promotion of Exercise Within Medicine and Society
Our AMA supports (1) education of the profession on exercise, including instruction on the role of exercise prescription in medical practice in its continuing education courses and conferences, whenever feasible and appropriate; (2) medical student instruction on the prescription of exercise; (3) physical education instruction in the school system; and (4) education of the public on the benefits of exercise, through its public relations program. (Res. 56, I-78; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmation I-98; Reaffirmation A-07)

H-470.997 Exercise and Physical Fitness
The AMA encourages all physicians to utilize the health potentialities of exercise for their patients as a most important part of health promotion and rehabilitation, and urges state and local medical societies to emphasize through all available channels the need for physical activity for all age groups and both sexes. The AMA encourages other organizations and agencies to join with the Association in promoting physical fitness through all appropriate means. (BOT Rep. K, A-66; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Modified and Reaffirmed: CSAPH Rep. 2, A-08)

H-440.917 Increased Physical Activity for Most US Adults
The AMA endorses, in principle, the movement calling for every adult to accumulate in the course of each day 30 or more minutes of physical activity of moderate intensity; and urges physicians to review the consensus statement of the Centers for Disease Control and Prevention and the American College of Sports Medicine which extends the traditional concept of physical fitness to include intermittent cumulative physical activity and the scientific evidence on which this advice rests. (Res. 408, A-95; Reaffirmed: CSA Rep. 8, A-05)

H-425.993 Health Promotion and Disease Prevention
The AMA (1) reaffirms its current policy pertaining to the health hazards of tobacco, alcohol, accidental injuries, unhealthy lifestyles, and all forms of preventable illness; (2) advocates intensified leadership to promote better health through prevention; (3) believes that preventable illness is a major deterrent to good health and accounts for a major portion of our country's total health care expenditures; (4) actively supports appropriate scientific, educational and legislative activities that have as their goals: (a) prevention of smoking and its associated health hazards; (b) avoidance of alcohol abuse, particularly that
which leads to accidental injury and death; (c) reduction of death and injury from vehicular and other accidents; and (d) encouragement of healthful lifestyles and personal living habits; and (5) strongly emphasizes the important opportunity for savings in health care expenditures through prevention.


**H-170.986 Health Information and Education**

(1) Individuals should seek out and act upon information that promotes appropriate use of the health care system and that promotes a healthy lifestyle for themselves, their families and others for whom they are responsible. Individuals should seek informed opinions from health care professionals regarding health information delivered by the mass media self-help and mutual aid groups are important components of health promotion/disease and injury prevention, and their development and maintenance should be promoted. (2) Employers should provide and employees should participate in programs on health awareness, safety and the use of health care benefit packages. (3) Employers should provide a safe workplace and should contribute to a safe community environment. Further, they should promptly inform employees and the community when they know that hazardous substances are being used or produced at the worksite. (4) Government, business and industry should cooperatively develop effective worksite programs for health promotion and disease and injury prevention, with special emphasis on substance abuse. (5) Federal and state governments should provide funds and allocate resources for health promotion and disease and injury prevention activities. (6) Public and private agencies should increase their efforts to identify and curtail false and misleading information on health and health care. (7) Health care professionals and providers should provide information on disease processes, healthy lifestyles and the use of the health care delivery system to their patients and to the local community. (8) Information on health and health care should be presented in an accurate and objective manner. (9) Educational programs for health professionals at all levels should incorporate an appropriate emphasis on health promotion/disease and injury prevention and patient education in their curricula. (10) Third party payers should provide options in benefit plans that enable employers and individuals to select plans that encourage healthy lifestyles and are most appropriate for their particular needs. They should also continue to develop and disseminate information on the appropriate utilization of health care services for the plans they market. (11) State and local educational agencies should incorporate comprehensive health education programs into their curricula, with minimum standards for sex education, sexual responsibility, and substance abuse education. Teachers should be qualified and competent to instruct in health education programs. (12) Private organizations should continue to support health promotion/disease and injury prevention activities by coordinating these activities, adequately funding them, and increasing public awareness of such services. (13) Basic information is needed about those channels of communication used by the public to gather health information. Studies should be conducted on how well research news is disseminated by the media to the public. Evaluation should be undertaken to determine the effectiveness of health information and education efforts. When available, the results of evaluation studies should guide the selection of health education programs. (BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmation A-07)
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Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report

Sarah E. Barlow, MD, MPH and the Expert Committee

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ABSTRACT

To revise 1998 recommendations on childhood obesity, an Expert Committee, comprised of representatives from 15 professional organizations, appointed experienced scientists and clinicians to 3 writing groups to review the literature and recommend approaches to prevention, assessment, and treatment. Because effective strategies remain poorly defined, the writing groups used both available evidence and expert opinion to develop the recommendations. Primary care providers should universally assess children for obesity risk to improve early identification of elevated BMI, medical risks, and unhealthy eating and physical activity habits. Providers can provide obesity prevention messages for most children and suggest weight control interventions for those with excess weight. The writing groups also recommend changing office systems so that they support efforts to address the problem. BMI should be calculated and plotted at least annually, and the classification should be integrated with other information such as growth pattern, familial obesity, and medical risks to assess the child’s obesity risk. For prevention, the recommendations include both specific eating and physical activity behaviors, which are likely to promote maintenance of healthy weight, but also the use of patient-centered counseling techniques such as motivational interviewing, which helps families identify their own motivation for making change. For assessment, the recommendations include methods to screen for current medical conditions and for future risks, and methods to assess diet and physical activity behaviors. For treatment, the recommendations propose 4 stages of obesity care; the first is brief counseling that can be delivered in a health care office, and subsequent stages require more time and resources. The appropriateness of higher stages is influenced by a patient’s age and degree of excess weight. These recommendations recognize the importance of social and environmental change to reduce the obesity epidemic but also identify ways healthcare providers and health care systems can be part of broader efforts.
In 1997, when the Department of Health and Human Services Health Resources and Service Administration convened the first expert committee to develop recommendations on the evaluation and treatment of child and youth obesity, few studies of this problem had been conducted to provide evidence for the recommendations. Since then, increasing scientific attention has resulted in an expanded body of literature on the causes, comorbidities, and treatment of this problem. The condition remains frustrating and difficult to treat but, with more-current scientific information available, in 2005 the American Medical Association, in collaboration with the Health Resources and Service Administration and the Centers for Disease Control and Prevention (CDC), convened a new expert committee that was charged with providing revised recommendations. These new recommendations use current, evidence-based data, as well as clinical experience when evidence does not exist, to provide updated practical guidance to practitioners (see Appendix for the complete recommendations).

Representatives from 15 national health care organizations formed the expert committee. The steering committee, composed of representatives from the American Medical Association, the Health Resources and Service Administration, and the CDC, invited these member organizations because they serve children at high risk of obesity, they represent experts in obesity-related conditions, or they represent experts in aspects of obesity treatment. The representatives from the 15 member organizations submitted nominations for the experts who would compose the 3 writing groups and work on the following 3 areas of focus: prevention, assessment, and treatment of childhood overweight and obesity. Special care was taken both to ensure that a broad range of disciplines, including medicine, nutrition, nursing, psychology, and epidemiology, was represented and to capture the interests of diverse cultural groups. The experts in these groups reviewed the scientific information that forms the basis of the expert committee recommendations. Their work is referred to throughout this report according to the area of review (prevention, assessment, or treatment), and their reports accompany this article.1-3

Each multidisciplinary writing group reviewed the current literature to develop the recommendations. Because the science continues to lag behind the obesity epidemic, many gaps in evidence-based recommendations remain. With few exceptions, randomized, controlled, intervention trials have not been performed to prove or to disprove the effect of a particular behavior on weight control in obese children. The available studies often examine associations between health behaviors and weight or between health behaviors and energy balance. Even less evidence exists about the process of addressing obesity in a primary care setting. The purpose of the expert committee was to offer practical guidance to clinicians by providing recommendations in all areas of obesity care, including those that lack the best possible evidence. When evidence of an effect on obesity was not available, the writing groups considered the literature, clinical experience, the likelihood of other health benefits, the possible harm, and the feasibility of implementing a particular strategy before including it. Although a thorough evidence-based review was beyond the scope of this project, the writing groups provided a broad rating of the evidence, so that readers can appreciate the limitations of these recommendations and watch for new studies that will refine them. The rating categories were as follows:

1. recommends with consistent evidence (CE), that is, multiple studies generally show a consistent association between the recommended behavior and either obesity risk or energy balance;
2. recommends with mixed evidence (ME), that is, some studies demonstrated evidence for weight or energy balance benefit but others did not show significant associations, or studies were few in number or small in sample size;
3. suggests, that is, studies have not examined the association of the recommendation with weight or energy balance, or studies are few, small in number, and/or without clear findings; however, the expert committee thinks that these recommendations could support the achievement of healthy weight and, if future studies disprove such an effect, then these recommendations are likely to have other benefits and are unlikely to cause harm.

The report provides qualitative ratings of evidence for the recommended lifestyle behaviors. The summary report recommends assessment of the lifestyle behaviors that are targets for change but does not rate evidence for the assessment process; the literature in this area, cited in the assessment report,2 is sparse and has limited applicability to an office setting. The writing groups also addressed the implementation of clinical care for obesity. At the level of the family, the writing groups suggested strategies to encourage and to support a patient or family that chooses to change eating or physical activity behaviors. At the level of the provider office, the committee suggested ways in which the office system can change to track overweight and obese children and to support family management of this chronic condition. The scarcity of studies about the process of obesity treatment precluded an evidence review. The recommendations represent a consensus based on the best available information. Ongoing research will eventually provide the best possible evidence for childhood obesity care, and future recommendations will reflect new knowledge. In the meantime, clinicians, who routinely make clinical
decisions in the absence of the best possible evidence, will find updated guidance for this pervasive condition.

The writing groups presented their recommendations to the expert committee for discussion and revision in May 2006. Once consensus was reached, the committee members then presented the recommendations to their member organizations for endorsement (see “Acknowledgments” for expert committee and writing group participants).

**EPIDEMIOLOGIC FEATURES**

**Childhood Obesity Epidemic**

The rapid increase in the prevalence of childhood obesity has alarmed public health agencies, health care clinicians, health care researchers, and the general public. On the basis of measured heights and weights from nationally representative samples of US children assessed approximately every 5 years, obesity prevalence has increased from ~5% in 1963 to 1970 to 17% in 2003 to 2004. Clinicians are faced with addressing this problem with a steadily increasing number of patients.

Obesity and overweight are defined on the basis of age- and gender-specific BMI normative values that were established when the distribution of BMI values was constant. The increase in obesity prevalence is therefore measured against a stable cutoff point, the 95th percentile BMI for gender and age.

**Demographic Features**

The obesity epidemic has disproportionately affected some racial/ethnic groups. In 2003–2004, the prevalence rates were particularly high among black girls (24%) and among Mexican American boys (22%). Rates have also increased among Native American and Asian American youths. Overall, poverty has been associated with greater obesity prevalence among adolescents; however, subgroups have differed. In 1 report, for example, obesity prevalence among younger black male adolescents was higher in nonpoor families than in poor families but prevalence among older black male adolescents was higher in poor families. Higher family socioeconomic status is associated with lower obesity prevalence among white girls but not among black girls.

**Causes**

Both genes and environment contribute to obesity risk. Twin studies have clearly demonstrated a genetic risk, and the discovery of leptin, ghrelin, adiponectin, and other hormones that influence appetite, satiety, and fat distribution provides insight into metabolic mechanisms for physiologic risk. With multiple substances and multiple gene sites associated with obesity, the system is complex, redundant, and likely not amenable to a simple pharmaceutical intervention. However, genes are not destiny. Just as behavior and environment strongly influence a person’s risk of developing skin cancer, behavior and environment influence the development of obesity in genetically at-risk people. At a population level, the increase in prevalence is too rapid to be explained by a genetic shift; rather, it must result from changes in eating and physical activity behaviors that have shifted the balance of energy intake and energy expenditure.

The influence of specific behavior changes on energy balance is difficult to determine. Many cross-sectional studies and some longitudinal studies have examined the relationships between specific behaviors (for instance, intake of sugar-sweetened beverages or participation in daily physical education classes) and obesity. Interventional studies that examine prospectively the impact of a behavior on weight or BMI are rare. Each of the writing groups reviewed the literature for evidence of the influence of behaviors on either energy balance or BMI. The review found evidence for only a few behaviors. One important limitation of these studies is measurement validity. For assessment of energy intake under normal, free-living circumstances, subjects must report the food they consume, through either recall or a food diary. These methods are inaccurate and subject to underreporting. Measuring physical activity is somewhat less problematic, with improved accelerometers and the capacity to measure accurately the total energy expenditure through labeled-water techniques. Probably a bigger challenge in this scientific area is the large number of possible eating and activity behaviors that may contribute to energy imbalance. If greater sugar-sweetened beverage intake, larger portion sizes at all meals and snacks, more-frequent snacks, more ready-to-eat foods, more restaurant eating, more television viewing, fewer physical education classes, less walking to and from school, less outside play at home, more escalators, elevators, and automatic doors, and so forth, all coexist, then the impact of any one of those behaviors on obesity prevalence may be unmeasurable.

Scientists continue to study obesity but, given its complex causes, years or decades may pass before the most effective intervention or prevention strategies are identified. The recommendations presented here are evidence based where evidence is available; where evidence is not available or is incomplete, the expert committee has combined data with clinical judgment, including selected interventions when such interventions are reasonable and are unlikely to cause harm. An example is the recommendation to increase fiber intake. Although studies have not demonstrated that increased fiber intake leads to improved weight, foods that are high in fiber have lower energy density and could displace other foods, resulting in overall reduced energy intake. This diet change, even if unproven, has other nutritional benefits and is unlikely to cause harm. As discussed above, this summary report includes a general
assessment of the quality of evidence for each behavior. The prevention, assessment, and treatment reports provide detailed descriptions of studies for each topic. 1-3

DEFINITIONS AND TERMINOLOGY

Measurement of Body Fat
High levels of body fat are associated with increasing health risks. However, no single body fat value, whether measured as fat mass or as percentage of body weight, clearly distinguishes health from disease or risk of disease. Even if body fat level could be measured easily, other factors such as fat distribution, genetics, and fitness, contribute to the health assessment.

BMI, a measure of body weight adjusted for height, is a useful tool to assess body fat. BMI is defined as weight (in kilograms) divided by the square of height (in meters). BMI levels correlate with body fat13,14 and also correlate with concurrent health risks, especially cardiovascular risk factors. 15 High BMI predicts future adiposity, as well as future morbidity and death.16 The sensitivity of BMI of >85th percentile for identifying the fattest children is good,17 and, in contrast to more-precise measures of body fat (such as dual-energy x-ray absorptiometry), health care providers can assess weight and height routinely. Although BMI does not measure body fat directly and therefore may lead to imprecise assessment of adiposity, it is feasible and has acceptable clinical validity if used thoughtfully. Another practical benefit of BMI use for children is the continuity with recommended assessments of adult body weight.

For children, the distribution of BMI changes with age, just as weight and height distributions change. As a result, although absolute BMI is appropriate to define body weight in adults, percentiles specific for age and gender define underweight, healthy weight, overweight, and obesity in children.

The validity of BMI depends in part on the cutoff points used. Like body fat levels, BMI and BMI percentiles are continuous, and any cutoff point will be imperfect in distinguishing those with health risks from those without. When a high cutoff point is selected, patients with “normal” BMI despite high body fat levels will be misclassified as healthy. When the cutoff point is low, patients with high BMI despite normal body fat levels (for example, muscular athletes) will be misclassified as unhealthy. The cutoff point selection must balance overdiagnosis and underdiagnosis. Because body fat levels and health risks are continuous, clinicians should rely on BMI as a useful tool that triggers concern and assessment, but they should recognize that other clinical information influences the need for intervention.

Pediatric Cutoff Points and Terminology: Same Cutoff Points, New Terms
The use of 2 cutoff points, namely, BMI of 95th percentile and 85th percentile, captures varying risk levels and minimizes both overdiagnosis and underdiagnosis. When BMI is <85th percentile, body fat levels are likely to pose little risk. When BMI is ≥95th percentile, body fat levels are likely to be high. BMI of 85th to 94th percentile indicates health risks that vary depending on body composition, BMI trajectory, family history, and other factors. These cutoff points are unchanged from the 1998 expert committee recommendations18 and CDC19 and Institute of Medicine19 recommendations.

The expert committee recommends different terminology. The committee suggests that, when BMI is ≥95th percentile, the term “obesity” should replace “overweight” and, when BMI is 85th to 94th percentile, “overweight” should replace “at risk of overweight.” The compelling reasons for this revision are clinical. The term obesity denotes excess body fat more accurately and reflects the associated serious health risks more clearly than does the term overweight, which is not recognized as a clinical term for high adiposity. Overweight denotes high weight from high lean body mass as well as from high body fat levels and so is appropriate for the 85th to 94th percentile category, which includes children with excess body fat as well as children with high lean body mass and minimal health risks. These terms provide continuity with adult definitions and avoid the vagueness of “at risk of overweight,” which has been confusing to patients and health care providers. Because the recommended cutoff points have not changed, these terms will not affect the prevalence rates of the BMI categories.

Exceptions to the use of 85th and 95th percentile BMI values as cutoff points occur for older and younger children. For older adolescents, BMI of 95th percentile is higher than BMI of 30 kg/m², the adult obesity cutoff point. The committee therefore recommends that obesity in youths be defined as BMI of 95th percentile or BMI of ≥30 kg/m², whichever is lower. For children <2 years of age, BMI normative values are not available. Weight-for-height values above the 95th percentile in this age group can be categorized as overweight.

Stigmatization associated with the term obesity has been one reason for the use of the term overweight. The negative connotation of obesity results from pervasive social prejudice and deserves attention. 20-22 However, the committee recommends that clinicians address this concern through supportive demeanor and language in the clinical encounter. The terminology and cutoff points for both adults and children have been debated, but several groups have weighed the advantages and disadvantages and made similar recommendations (Table 1).

Calculators, wheels, tables, and nomograms are some of the tools used to calculate absolute BMI, which then is plotted on current growth charts available on-line from the CDC. Personal digital assistant devices and Internet-based programs can calculate BMI and also report percentiles; to monitor a child’s growth pattern over...
time, however, clinicians must plot BMI values on a BMI curve. Electronic health record programs can calculate BMI values, report percentiles, and automatically plot a child’s BMI values over time on a BMI curve (Table 2). For children <2 years of age, providers should plot weight-for-height values over time.

Once a child’s BMI is measured, clinicians must exercise judgment, first in assessing the child’s health and then in choosing language to inform the child and family. Especially for a child with BMI in the overweight category (85th–94th percentile), a clinician may decide that the health risk is low, but he or she should make that decision with knowledge of the BMI category, rather than a visual impression of normal weight, and with a deliberate review or update of the patient’s family and medical history, a review of the BMI trajectory, and an assessment of body fat distribution, diet and activity habits, and appropriate laboratory tests. The clinician may conclude that the overweight child is not “overfat” and can safely reinforce the obesity prevention messages that are appropriate for children with healthy BMI values. Future scientific data on the risk of obesity and the risk of medical problems may improve clinicians’ ability to predict which children need early intervention; current, however, primary health care providers must use clinical judgment and must regularly review the child’s BMI and reassess health risks. Rarely, children with BMI of >95th percentile are also deemed healthy, although this is less likely to be the case the farther values are above the 95th percentile curve, and some children with BMI somewhat below the 85th percentile may have fat-related health risks. The BMI is an important screening tool, but it must be integrated with other information in the health assessment.

Much legitimate concern exists about stigmatization of overweight and obese children.21,23 Public concern followed decisions to assess BMI in schools, because of the potential harm of labeling a child with a condition that is a target of prejudice.24 Health care visits are generally a good place to identify excess weight, because the setting frames the condition as a health problem and because the visit is private. Therefore, clinicians must take responsibility for identification but must approach the subject sensitively, to minimize embarrassment or harm to self-esteem. Consistent with the 1998 recommendations,18 the expert committee urges clinicians to be supportive, empathetic, and nonjudgmental. A careful choice of words will convey an empathetic attitude. Adult patients have identified “fatness,” “excess fat,” and “obesity” as derogatory terms,25 and obese adolescents prefer the term “overweight.”26 Younger children and their families may respond similarly, and clinicians should discuss the problem with individual families by using more-neutral terms, such as “weight,” “excess weight,” and “BMI.” Therefore, the expert committee recommends the use of the clinical terms overweight and obesity for documentation and risk assessment but the use of different terms in the clinician’s office, to avoid an inference of judgment or repugnance.

Recognition of the need for a third cutoff point to define severe obesity in childhood obesity seems to be evolving. An adolescent weighing 180 pounds and another weighing 250 pounds are in the same BMI category (>95th percentile) but face markedly different social and medical effects. New data indicate that extreme obesity in children is increasing in prevalence, and these children are at high risk for multiple cardiovascular disease risk factors.27 A definition of severe childhood obesity would help identify these children so that their particular risks and treatment needs can be established. The expert committee proposes recognition of the 99th percentile BMI, which is BMI of ~30 to 32 kg/m² for youths 10 to 12 years of age and ≥34 kg/m² for youths 14 to 16 years of age. The marked increase in risk factor prevalence at this percentile provides clinical justification for this additional cutoff point. Although much additional study with larger and more-diverse samples is needed to characterize the medical and social risks of this category, the committee recommends that clinicians recognize this BMI cutoff point and ensure that best efforts are made to provide treatment to these youths and their families. Because the 97th percentile is the highest curve

### Table 1: Terminology for BMI Categories

<table>
<thead>
<tr>
<th>BMI Category</th>
<th>Former Terminology</th>
<th>Recommended Terminology</th>
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<tbody>
<tr>
<td>&lt;5th percentile</td>
<td>Underweight</td>
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</tr>
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<td>5th–84th percentile</td>
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</tr>
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<td>85th–94th percentile</td>
<td>At risk of overweight</td>
<td>Overweight</td>
</tr>
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<td>≥95th percentile</td>
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### Table 2: BMI Tools

<table>
<thead>
<tr>
<th>Tools</th>
<th>BMI Calculation</th>
<th>BMI Percentile Classification</th>
<th>BMI Percentile Plotting</th>
<th>BMI z Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard calculatorab</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>BMI wheel</td>
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<tr>
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<td>X</td>
<td>X</td>
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<tr>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Personal digital assistant programc</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Electronic health record</td>
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<tr>
<td>b CDC recommendations, 2002.2</td>
</tr>
<tr>
<td>c International Obesity Task Force, 2000.6</td>
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<td>d Institute of Medicine, 2005.9</td>
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<tr>
<td>e Potential application; not currently available.</td>
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available on the growth charts, Table 3 provides 99th percentile cutoff points according to age and gender.

### Table 3: Cutoff Points for 99th Percentile BMI According to Age and Gender

<table>
<thead>
<tr>
<th>Age, ya</th>
<th>Boys</th>
<th>Girls</th>
</tr>
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<tbody>
<tr>
<td>5</td>
<td>20.1</td>
<td>21.5</td>
</tr>
<tr>
<td>6</td>
<td>21.6</td>
<td>23.0</td>
</tr>
<tr>
<td>7</td>
<td>23.6</td>
<td>24.6</td>
</tr>
<tr>
<td>8</td>
<td>25.6</td>
<td>26.4</td>
</tr>
<tr>
<td>9</td>
<td>27.6</td>
<td>28.2</td>
</tr>
<tr>
<td>10</td>
<td>29.3</td>
<td>29.9</td>
</tr>
<tr>
<td>11</td>
<td>30.7</td>
<td>31.5</td>
</tr>
<tr>
<td>12</td>
<td>31.8</td>
<td>33.1</td>
</tr>
<tr>
<td>13</td>
<td>32.6</td>
<td>34.6</td>
</tr>
<tr>
<td>14</td>
<td>33.2</td>
<td>36.0</td>
</tr>
<tr>
<td>15</td>
<td>33.6</td>
<td>37.5</td>
</tr>
<tr>
<td>16</td>
<td>33.9</td>
<td>39.1</td>
</tr>
<tr>
<td>17</td>
<td>34.4</td>
<td>40.8</td>
</tr>
</tbody>
</table>

The data were derived from ~500 children in each year from 5 through 11 years of age and ~850 children in each year from 12 through 17 years of age (adapted from Freedman et al, with permission).

Cutoff points are at the midpoint of the child's year (eg, 5.5 years).

### OVERVIEW OF PROVIDER OFFICE PROCESS

#### Universal Assessment of Obesity Risk

These recommendations support a shift from simple identification of obesity, which often occurs when the condition is obvious and intractable, to universal assessment, universal preventive health messages, and early intervention. If primary care providers are to have an impact on the childhood obesity epidemic, then their best approach is assessment of obesity risk for all patients, with anticipatory guidance on healthy behaviors to minimize that risk. The work of the expert committee and writing groups addresses all stages of care, from normal-weight, low-risk children to severely obese children. Figure 1 presents an overview of the process to assess obesity risk.

Although it is not a precise measure of body fat or health risk, BMI is the initial screen that should be calculated at each well-child visit and should serve as the starting point for classification of health risks. Children in the healthy-weight category (BMI of 5th–84th percentile) have lower risks, although parental obesity, family medical history, and current diet and physical activity behaviors may alter that assessment. These children and their families should receive support in maintaining or establishing healthy lifestyle (prevention) behaviors. The likelihood of health risks increases in the 85th to 94th percentile (overweight) category and again is influenced by parental obesity, family medical history, and current lifestyle habits, as well as BMI trajectory and current cardiovascular risk factors. Some of these children should receive prevention counseling, whereas others should receive more-active intervention. Children with a BMI above the 95th percentile (obese) are very likely to have obesity-related health risks, and most should be encouraged to focus on weight control practices. Providers must use clinical judgment in assessing

---

**FIGURE 1**

Universal assessment of obesity risk and steps to prevention and treatment. DM indicates diabetes mellitus.
health risks, because no formula exists that can integrate BMI pattern, family background, and health behaviors to determine future weight and health. Clinicians use similar information to evaluate overweight children for failure to thrive. Because ideally the children will return to the same provider, the assessment can be revised and the approach adjusted.

**Chronic Care Model**

The expert committee recommendations are comprehensive and ambitious. Health care-centered efforts alone cannot effect change, but they can complement and potentially enhance evolving public health efforts, such as school wellness policies, parks and recreation programs, and shifts in child-targeted food advertisements. In addition, health care provider offices and health care systems will need to change, in many cases, to implement these recommendations. These recommendations can serve as guides that will improve as new information becomes available.

The traditional office visit model works best for acute problems, such as otitis media or joint injury; the clinician assesses the single problem, orders additional testing as needed, and presents a treatment plan (generally short-term) to the patient. However, the complexity of chronic problems, such as diabetes mellitus or obesity, and their requirement for patient education about self-management often overwhelm both the patient and the clinician during an office visit. The chronic care model envisions a new structure that integrates community resources, health care, and patient self-management to provide more-comprehensive and more-useful care. This paradigm envisions offices linked to community resources, such as exercise programs; support for self-management, which requires educating patients and families about assessment and monitoring; an expanded practice team that supports patient self-management and monitors adherence to evidence-based care pathways; and clinical information systems that can remind the team of routine tests and treatments and can monitor the practice’s adherence to goals. Changes in office procedure require deliberate planning and evaluation, and the rapid-cycle quality improvement method may be a useful approach for continuous quality improvement. In this model, practices plan a change and a method to measure that change, implement the change, and then examine the measure of change. The plan is modified depending on how well the goals are met. The cycle is repeated until the practice is satisfied with the change. For example, a practice could plan to include the BMI category next to the vital signs on the patient’s chart for well-child visits. After 3 months, the practice would measure the percentage of charts that included the BMI category. If only 60% of charts included the BMI category, then staff members would discuss barriers and propose a new plan, such as readily available BMI calculators or the need for the office secretary to add growth charts with BMI curves to records of established patients with weight-for-height curves. With the new routine in place, progress toward the goal would again be measured.

The chronic care model has obvious applications in childhood obesity, and several large health maintenance organizations have initiated some of these approaches. Kaiser Permanente has trained staff members to use motivational interviewing, and Wellpoint has distributed parental toolkits in primary care clinics, to help educate office personnel about children’s development and appropriate nutrition and physical activity. Several programs have linked to community efforts, such as community-based exercise programs. The care model for obesity recognizes the importance of changes in the school, worksite, and community. Figure 2 shows how the environment and the medical system support the patient and the family in their management of the condition.

Providers have reported that lack of reimbursement often is a barrier to obesity care. Currently, insurance carriers may exclude obesity treatment from the benefits packages they offer. The American Academy of Pediatrics has a fact sheet about appropriate coding (www.aap.org/healthtopics/overweight.cfm) and can answer specific coding questions through electronic mail (aapcodinghotline@aap.org). The prevention report includes tables with billing codes for obesity-related preventive care, as well as diagnostic codes. Currently, health maintenance organizations may invest in preventive care more willingly than traditional fee-for-service insurance.

**Obesity Care and Cultural Values of Patients**

Beliefs about what is an attractive weight or a healthy weight, what foods are desirable or appropriate for parents to provide children, how families should share meals, the importance or enjoyment of physical activity, and the authority parents have over children at different ages, as well as many other attitudes that affect lifestyle habits, are influenced by cultural values and beliefs. Some studies have examined differences between iden-
tified racial, ethnic, or cultural groups, such as the observation that black girls are more satisfied with heavier bodies than are white girls. Low-income mothers may recognize obesity as a problem, not on the basis of growth curves but when they perceive that high weight restricts their child’s tolerance for physical activity. A study of low-income minority parents of preschool-aged children showed that Hispanic parents had indulgent feeding styles more often than did low-income black parents. Population studies indicate that levels of vigorous physical activity differ according to age and racial group. However, studies in these areas are incomplete. Barriers to behavior change may be related to community circumstances, such as lack of safe recreation areas, rather than values and preferences. Clinicians should inform themselves about the values or circumstances that may be common in the population they serve, especially if that population differs from their own. However, a clinician’s knowledge of an individual family’s personal values and circumstances, which are not dictated by the family’s ethnic, racial, or economic group, may be most helpful in tailoring recommendations.

PREVENTION

Importance
Given the difficulty of behavior-based weight loss and subsequent weight maintenance and the expense and potential harm of medication and surgery, obesity prevention should be a public health focus. Efforts must begin early in life, because obesity in childhood, especially among older children and those with more-severe obesity, is likely to persist into adulthood. Therefore, childhood represents an important opportunity to establish healthy eating and activity behaviors that can protect children against future obesity. Pediatric providers are accustomed to addressing health behaviors, such as car seat use, tobacco avoidance, and avoidance of risky sexual behavior, and they provide guidance on nutrition in early childhood routinely. In addition, they know the family’s medical history and social and behavioral interactions. They are well positioned to guide families in the areas of eating and activity.

The targets of obesity prevention should be all children, starting at birth. Lifestyle behaviors to prevent obesity, rather than intervention to improve weight, should be aimed at children with healthy BMIs (5th–84th percentile) and some children with BMIs in the overweight category (85th–94th percentile), depending on their growth pattern and risk factors. Clinicians should be aware of the increased risk of obesity for children with obese parents and those whose mothers had diabetes mellitus during the child’s gestation. Indeed, young children with 1 or 2 obese parents are at high risk of obesity in young adulthood, even if their current weight is normal.

Target Behaviors
The expert committee recommends that clinicians advise patients and their families to adopt and to maintain the following specific eating, physical activity, and sedentary behaviors. These healthy habits may help prevent excessive weight gain and also are unlikely to cause harm, on the basis of current knowledge. The level of evidence is indicated, and the prevention report provides references.

Evidence supports the following:
1. limiting consumption of sugar-sweetened beverages (CE);
2. encouraging consumption of diets with recommended quantities of fruits and vegetables; the current recommendations from the US Department of Agriculture (USDA) (www.mypyramid.gov) are for 9 servings per day, with serving sizes varying with age (ME);
3. limiting television and other screen time (the American Academy of Pediatrics recommends no television viewing before 2 years of age and thereafter no more than 2 hours of television viewing per day), by allowing a maximum of 2 hours of screen time per day (CE) and removing televisions and other screens from children’s primary sleeping area (CE) (although a relationship between obesity and screen time other than television viewing, such as computer games, has not been established, limitation of all screen time may promote more calorie expenditure);
4. eating breakfast daily (CE);
5. limiting eating out at restaurants, particularly fast food restaurants (CE) (frequent patronage of fast food restaurants may be a risk factor for obesity in children, and families should also limit meals at other kinds of restaurants that serve large portions of energy-dense foods);
6. encouraging family meals in which parents and children eat together (CE) (family meals are associated with a higher-quality diet and with lower obesity prevalence, as well as with other psychosocial benefits); and
7. limiting portion size (CE) (the USDA provides recommendations about portions, which may differ from serving sizes on nutrition labels, and a product package may contain >1 serving size).

The prevention writing group also suggests, on the basis of analysis of available data and expertise, the following behaviors:
1. eating a diet rich in calcium (the USDA provides recommendations about serving size and daily number of dairy product servings);
2. eating a diet high in fiber;
3. eating a diet with balanced macronutrients (energy from fat, carbohydrates, and protein in proportions for age, as recommended by Dietary Reference Intakes)\(^39\);
4. encouraging exclusive breastfeeding to 6 months of age and maintenance of breastfeeding after introduction of solid food to 12 months of age and beyond, consistent with American Academy of Pediatrics recommendations\(^40,41\);
5. promoting moderate to vigorous physical activity for at least 60 minutes each day\(^42\); and
6. limiting consumption of energy-dense foods.

**Implementation**

The complexity of obesity prevention lies less in the identification of target health behaviors and much more in the process of influencing families to change behaviors when habits, culture, and environment promote less physical activity and more energy intake. Handing families a list of recommended eating and activity habits as if it were an antibiotic prescription fits into traditional medical training and the structure of the office visit, but such an approach is rarely effective. The prevention writing group has provided suggestions on how to interact with families to promote target behaviors and how to create office systems that support the clinician’s ongoing commitment to obesity prevention. The appendix of the prevention report presents an example of office visit structure, interaction between provider and patient, and specific language to illustrate this approach.\(^1\)

**The Role of the Family**

Several studies of obesity treatment in children have demonstrated the importance of parents’ participation in weight control programs.\(^43–45\) The commitment of parents and other caregivers to helping the child develop healthy habits to prevent obesity is likely to be very important. Parents can serve as role models, authority figures, and behavioralists to mold their children’s eating and activity habits. Clinicians can influence children’s habits indirectly by teaching and motivating parents to use their authority effectively. For very young children, clinicians should focus the discussion on parenting behavior. The greater independence of adolescents means that clinicians should discuss health behaviors directly with them, although clinicians should encourage parents to make the home environment as healthy as possible.

Parenting actions that support the target behaviors differ with the age of the child, and clinicians can provide appropriate material to assist parents. For instance, clinicians can discuss or provide information about encouraging free safe movement for infants, appropriate food portions for toddlers, limited stroller use for preschoolers, and easy breakfast alternatives for teenagers. The prevention report contains a list of age-specific parenting actions.\(^1\)

Clinicians function as counselors in obesity prevention and obesity care. Briefly presented below are some counseling techniques that can be used to encourage parents and patients to improve healthy behaviors. Short courses at local or national meetings can give clinicians greater opportunities to learn counseling techniques, which are generally not taught as part of the usual health care education.

**Patient-Centered Communication**

The theories that follow assume that a clinician’s instruction to change a behavior will be effective only if the parent or family recognizes a potential problem and wants to address or to prevent that problem. Therefore, part of the clinician’s task is to help motivate families. Counseling techniques are presented here as ways to encourage obesity prevention behaviors, but the same approach has applications in obesity treatment behaviors.

The stages of change theory describes several cognitive stages that precede actual behavior change.\(^46\) According to this theory, a person may initially be unaware of a problem, then move to awareness of the problem but have no plans to address it, then plan a new behavior, and finally actually begin the new behavior. A clinician can help patients and families move along these stages, rather than prescribing a new behavior to those who are not ready. Recent work indicates that parents of overweight and obese children are often unaware of the condition.\(^47\)

The technique of motivational interviewing, which also takes into account patients’ readiness to change, uses nonjudgmental questions and reflective listening to uncover the beliefs and values of a parent or patient. By eliciting the concerns of patients, the clinician can evoke motivation, rather than try to impose it, and then help patients formulate a plan that is consistent with their own values. This approach avoids the defensiveness created by a more-directive style.

1. nondirective questions about the parent’s or patient’s attitude should be used (“Your child’s BMI is above the 95th percentile. What concerns, if any, do you have about her weight?”) The clinician’s next steps depend on the parent’s response. This approach differs from a directive style, in which the clinician informs the family of the seriousness of the condition (“Your child’s BMI is very high, and it is important that your child gets control of her weight before it becomes a bigger problem.”);
2. reflective listening, in which the clinician summarizes the parent’s comments without judging them, should
**TABLE 4**  Fifteen-Minute Obesity Prevention Protocol

<table>
<thead>
<tr>
<th>Step</th>
<th>Sample Language</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1. Assess</strong></td>
<td>We checked your child’s BMI, which is a way of looking at weight and taking into consideration how tall someone is. Your child’s BMI is in the range where we start to be concerned about extra weight causing health problems.</td>
</tr>
<tr>
<td>Assess weight and height and convert to BMI</td>
<td>Elicit parent’s concerns. What concerns, if any, do you have about your child’s weight? “He did jump 2 sizes this year. Do you think he might get diabetes someday?”</td>
</tr>
<tr>
<td>Provide BMI information</td>
<td>Reflect/probe. So you’ve noticed a big change in his size and you are concerned about diabetes down the road. What makes you concerned about diabetes in particular?</td>
</tr>
<tr>
<td><strong>Step 2. Set agenda</strong></td>
<td>(Use verbal questions or brief questionnaires to assess key behaviors) Example: About how many times a day does your child drink soda, sports drinks, or powdered drinks like Kool-Aid?</td>
</tr>
<tr>
<td>Query which, if any, of the target behaviors the parent/child/adolescent may be interested in changing or which might be easiest to change</td>
<td>Provide/elicit. You are doing well with sugared drinks. “I know it’s not healthy. He used to drink a lot of soda, but now I try to give him water whenever possible. I think we are down to just a few sodas a week.” So, you have been able to make a change without too much stress.</td>
</tr>
<tr>
<td>Agree on possible target behavior</td>
<td>Provide neutral feedback for behavior(s) not in optimal range; elicit response; reflect/probe. Your child watches 4 hours of television on school days. What do you think about that? “I know it’s a lot, but he gets bored otherwise and starts picking an argument with his little sister.” So, watching TV keeps the household calm.</td>
</tr>
<tr>
<td><strong>Step 3. Assess motivation and confidence</strong></td>
<td>We’ve talked about eating too often at fast food restaurants, and how television viewing is more hours than you’d like. Which of these, if either of them, do you think you and your child could change? “Well, I think fast food is somewhere we could do better. I don’t know what he would do if he couldn’t watch television. Maybe we could cut back on fast food to once a week.” That sounds like a good plan.</td>
</tr>
<tr>
<td>Assess willingness/importance</td>
<td>On a scale of 0 to 10, with 10 being very important, how important is it for you to reduce the amount of fast food he eats? On a scale of 0 to 10, with 10 being very confident, assuming you decided to change the amount of fast food he eats, how confident are you that you could succeed?</td>
</tr>
<tr>
<td>Explore importance and confidence ratings with the following probes:</td>
<td><strong>Benefits</strong></td>
</tr>
<tr>
<td>Barriers</td>
<td>You chose 6. Why did you not choose a higher number? “It’s quick and cheap and he loves it, especially the toys and fries.” Reflection: So there are benefits for both you and him.</td>
</tr>
<tr>
<td><strong>Solutions</strong></td>
<td>What would it take you to move to an 8? “Well, I really want him to avoid diabetes. My mother died of diabetes, and it wasn’t pretty; maybe if he started showing signs of it; maybe if I could get into cooking a bit more.”</td>
</tr>
<tr>
<td><strong>Step 4. Summarize and probe possible changes</strong></td>
<td>So where does that leave you? Or from what you mentioned, it sounds like eating less fast food may be a good first step, or How are you feeling about making a change?</td>
</tr>
<tr>
<td>Query possible next steps</td>
<td><strong>Probe plan of attack</strong></td>
</tr>
<tr>
<td><strong>Summarize change plan; provide positive feedback</strong></td>
<td>Involving child in cooking or meal preparation, ordering healthier foods at fast food restaurants, and trying some new recipes at home.</td>
</tr>
<tr>
<td><strong>Step 5. Schedule follow-up visit</strong></td>
<td>Let’s schedule a visit in the next few weeks/months to see how things went. Sounds like you aren’t quite ready to commit to making any changes now. How about we follow up with this at your child’s next visit? Or Although you don’t sound ready to make any changes, between now and our next visit you might want to think about your child’s weight gain and lowering his diabetes risk.</td>
</tr>
<tr>
<td>Agree to follow-up visit within x weeks/months</td>
<td>If no plan is made</td>
</tr>
</tbody>
</table>

be used (“If I heard you correctly, you are concerned about how much television your child is watching, but you know your child is safe and happy watching television when he is home alone.”) Reflections help build rapport and allow the patient to understand and to resolve ambivalence;

3. values and current health practices should be compared; if a parent values her child being healthy and a good student, then the clinician can help the parent examine how activities other than television could improve the child’s health and academic performance;
4. importance/confidence rulers should be used (“On a scale from 0 to 10, with 10 being the highest, how important is it to you to change your child’s television viewing?” “On a scale from 0 to 10, with 10 being the highest, how confident are you that you could decrease his television viewing to 2 hours a day?”) The number the parent gives leads the clinician to ask, “What would it take to get you to a higher number?” The clinician should thus help the parent think of solutions to the problem.

Table 4 presents an example of an interchange during an office visit that focuses on obesity prevention and incorporates motivational interviewing techniques.

Cognitive and behavioral techniques can help patients and families who are prepared to modify behaviors to achieve these changes. Providers can encourage goal setting, monitoring of behaviors targeted for change, and use of positive reinforcement. Initial goals should be easily achievable, such as engaging in 15 minutes of physical activity or having only 1 serving of a sugar-sweetened beverage each day. Reinforcement by parents should be given for behavior goals rather than weight change and can take the form of verbal praise or an extra privilege but not food. Providers should expect imperfect adherence and should communicate to parents and patients that they are making progress even if they do not achieve their goals every day. Providers and parents should focus on successes and not failures.

The Role of the Provider’s Office

The provider’s office system can enhance or undermine the clinician’s efforts to address obesity prevention consistently. The expert committee endorses the following office practices.

1. routine documentation of BMI. Although clinicians visually recognize obesity in many children without seeing the plotted BMI values, they may overlook excess body fat in children in the overweight (85th–94th percentile BMI) category and miss an opportunity to guide the family toward healthier behaviors. To document BMI consistently and accurately, offices need reliable scales for infants and children, recumbent infant length boards, and wall-mounted stadiometers. This equipment needs regular calibration. Staff members must know how to measure weight and height accurately, how to calculate BMI, and how to plot the measures on the growth curves;

2. establishment of procedures to deliver obesity prevention messages to all children. When the patient’s individual risk of obesity is low, these messages can promote appropriate general health or wellness, rather than weight control. One example from collaborative efforts in Maine and Massachusetts is the 5 2 1 0 message, which reminds families to eat ≥5 fruits and vegetables, spend no more than 2 hours on screen time, include 1 hour of physical activity or active play, and consume little or no sugar-sweetened beverages. Clinicians remind families of these goals at all health supervision visits and have posters in the office and handouts that reinforce these recommendations. Although the specific content of such messages may vary until research establishes the best approach, simple memorable guidelines, presented early and repeated regularly, can be delivered efficiently in the office and are likely to be effective teaching tools;

3. establishment of procedures to address children who are overweight (85th–94th percentile BMI) and obese (≥95th percentile BMI). For instance, when a child is overweight, a practice may plan to review the family history, child’s blood pressure, child’s cholesterol level, and BMI percentile over time and then assess health risks on the basis of that information. Offices should flag charts of overweight and obese children, so that all providers at all visits are aware and can monitor growth, risk factors, and social/emotional issues;

4. involvement and training of interdisciplinary teams, including nurses, physicians, and administrative staff members, regarding their respective responsibilities and skills;

5. chart audits to establish baseline practices, to help set goals for practice improvement, and then to measure the improvement over time. Offices can use the techniques for continuous quality improvement from the rapid-cycle improvement method described above.

The Roles of the School and the Community

These recommendations focus on the office visit and the opportunity to influence the family routine and home environment, but the child’s school and community environments can either support or impede obesity prevention behaviors. Clinicians can support school and community programs that help prevent obesity through local, state, or national advocacy, and they can encourage patients’ families to voice their preference to their schools through parent-teacher organizations or school board meetings or directly to principals, teachers, and after-care program directors. The Institute of Medicine report on obesity prevention provides a model for school policies.19 It recommends adequate physical education and recess periods and the establishment of nutritional standards for all foods served at school, including foods from vending machines and other competitive foods. To improve the community environment, providers can advocate for the establishment and maintenance of safe parks and recreation centers, and they can urge local grocery stores to offer healthy, low-cost food that is
consistent with the most common cultures of the community members.

**ASSESSMENT**

**Risks**
When a child’s BMI is above the 85th percentile, the clinician should assess medical and behavioral risks before initiating any intervention. Medical risks include risk of future or persistent obesity, risk of future obesity-related medical conditions, and identification of current obesity-related medical conditions. Behavioral risks include current eating habits, physical activity, and sedentary behaviors that promote energy imbalance. These evaluations must precede behavior-based treatment.

**Medical Assessment**

**Responsibility**
Screening children for obesity-related medical problems falls squarely in the purview of health care providers, especially primary care providers. Providers are responsible for considering any current obesity-associated medical conditions, such as hyperlipidemia, risks of future conditions associated with obesity and ameliorated by weight control, and rare conditions that cause obesity, such as primary Cushing syndrome or Prader-Willi syndrome. Because weight control alone may not treat many conditions adequately, diagnosis must be followed by appropriate treatment.

**Body Fat Assessment**
The BMI percentile, although imperfect, is the recommended screen for body fat in routine office practice. Offices should use the 2000 CDC BMI charts, rather than the International Obesity Task Force standards, because the CDC charts provide the full array of percentile levels (which makes them more appropriate for assessment of individual children), whereas the International Obesity Task Force charts provide only overweight and obesity categories.5-48

Skinfold thickness measurements are not recommended. Although these measurements provide information about body fat and risks of medical conditions,49 they are not feasible in routine clinical care, because they are difficult to perform accurately without careful training and experience and reference data are not readily available.

Similarly, waist circumference measurements are not recommended currently. Waist circumference measurements can provide indirect information about visceral adiposity, which tracks with cardiovascular and metabolic risk factors, and are more easily performed than skinfold thickness measurements,50-52 but reference values for children that identify risk over and above the risk from BMI category are not available. In the future, cutoff points that provide additional information and can influence evaluation or treatment may make waist circumference measurement a useful clinical tool.

BMI percentile categories guide assessment of medical risk; 5th to 85th percentile is healthy weight, 85th to 94th percentile is overweight, and ≥95th percentile is obese, with >99th percentile being an emerging category that suggests a high likelihood of immediate medical problems. Because no objective assessment to distinguish high body fat from high lean body mass is clinically practical, clinicians must also consider the family history of obesity and medical problems, the child’s past BMI pattern, and the child’s current medical conditions and current health behaviors as they decide whether to recommend intervention.

**Parental Obesity**
Parental obesity is a strong risk factor for a child’s obesity persisting into adulthood, especially for young children.37 Genetic vulnerability plays an important role in the development of obesity. Although it is currently not possible to test for specific genotypes or to adapt therapy on the basis of genetic information, knowledge of strong familial risks for obesity, especially parental obesity, should lead to greater efforts to establish or to improve healthy behaviors.

**Family Medical History**
Several obesity-related medical conditions are familial. Family history predicts type 2 diabetes mellitus or insu-
lin resistance, and the prevalence of childhood diabetes is especially high among several ethnic and racial backgrounds common in the United States, including Hispanic, black, and North American Indian.53 Cardiovascular disease and cardiovascular disease risk factors (hyperlipidemia and hypertension) are also more common when family history is positive.54 Offices should review and regularly update the family history regarding first- and second-degree relatives.

**Evaluation of Weight-Related Problems**

**Screening**

Obesity-related medical conditions affect almost every organ system in the body. A review of systems and a physical examination represent an inexpensive way to screen for many of these conditions, although some conditions are without symptoms or signs. Summarized below are important weight-related medical conditions, with their common symptoms and appropriate screening tests. Tables 5 and 6 present a review of systems and physical examination findings in the order typically followed in an office visit.

**Respiratory Problems**

Obstructive sleep apnea can lead to right ventricular hypertrophy and pulmonary hypertension. In addition, the disturbed sleep leads to poor attention, poor academic performance, and enuresis. This condition is one of the most serious problems that can occur and is more common among children who are severely obese. Prevalence is higher among obese children55,56 and may be ≥50% among adolescents with severe obesity.57 Symptoms that parents may notice are loud snoring with pauses in breathing, restless sleep, and daytime somnolence. On physical examination, children may have tonsillar hypertrophy, although obstructive sleep apnea can occur in the absence of tonsillar hypertrophy or after removal of tonsils and adenoids. Diagnosis is made through polysomnography. Treatment should include removal of tonsils and adenoids if they are enlarged. If this approach is ineffective or not indicated, then a pulmonologist should evaluate the patient for continuous positive airway pressure therapy during sleep.

In obesity hypoventilation syndrome, the weight of fat on the chest and abdomen impairs ventilation; these patients are severely obese. Symptoms are similar to those of obstructive sleep apnea, and diagnosis is made through polysomnography, which demonstrates elevated carbon dioxide levels. These patients may have elevated hemoglobin and hematocrit levels. They require continuous positive airway pressure therapy until substantial weight loss relieves the condition.

**Sleep Problems**

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**Table 5**

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<tr>
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<th>Findings</th>
<th>Possible Explanations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anthropometric features</td>
<td>High BMI percentile</td>
<td>Overweight or obesity</td>
</tr>
<tr>
<td></td>
<td>Short stature</td>
<td>Underlying endocrine or genetic condition</td>
</tr>
<tr>
<td>Vital signs</td>
<td>Elevated blood pressure</td>
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<td>Skin</td>
<td>Acanthosis nigricans</td>
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<tr>
<td></td>
<td>Excessive acne, hirsutism</td>
<td>Polycystic ovary syndrome</td>
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<td></td>
<td>Irritation, inflammation</td>
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</tr>
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<td></td>
<td>Violaceous striae</td>
<td>Cushing syndrome</td>
</tr>
<tr>
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<td>Papilledema, cranial nerve VI paralysis</td>
<td>Pseudotumor cerebri</td>
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<td>Tonsillar hypertrophy</td>
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<td></td>
<td>Undescended testes</td>
<td>Prader-Willi syndrome</td>
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</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td>Small hands and feet, polydactyly</td>
<td>Some genetic syndromes</td>
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* These conditions are usually without signs.

**Table 6**

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* These conditions are usually without signs.
Obese patients with asthma may need guidance about asthma management during physical activity or outdoor play, to minimize the limitations on exercise.

Gastrointestinal Problems
Nonalcoholic fatty liver disease (NAFLD) is a condition of increasing concern because of the increasing prevalence of obesity and diabetes, which are important risk factors. The term NAFLD includes simple steatosis, steatohepatitis, fibrosis, and cirrhosis resulting from fatty liver. Knowledge of prevalence, natural history, and effective management is incomplete, although studies are ongoing. NAFLD generally causes no symptoms, although some patients have right upper quadrant abdominal pain or tenderness or mild hepatomegaly. Serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels, which are usually elevated, are reasonably good screens. Ultrasonography and other imaging methods can demonstrate changes consistent with nonalcoholic steatohepatitis but cannot indicate the degree of inflammation or fibrosis. Liver biopsy is the standard method for diagnosis. Weight loss leads to improved liver test results and histologic features, and studies of medications are ongoing.95 When and how often to perform ALT and AST testing have not been determined; pending evidence-based recommendations, the expert committee suggests biannual screening starting at 10 years of age for children with BMI of ≥95th percentile and those with BMI of 85th to 94th percentile who have other risk factors. This schedule coincides with diabetes screening recommendations.60 ALT or AST results 2 times normal levels should prompt consultation with a pediatric hepatologist.

Gallstones are more prevalent among overweight and obese children.61 In addition, rapid weight loss increases the risk of gallstones.62 Intermittent episodes of intense colicky pain in the right upper quadrant of the abdomen are classic symptoms, but milder pain and epigastric pain can occur. On physical examination, the right upper quadrant may be tender. Ultrasonography can identify gallstones and cholecystitis.

Several common pediatric gastrointestinal problems, including gastroesophageal reflux disease and constipation, are exacerbated by obesity.63,64 Symptoms, signs, and management are the same as for children of normal weight, but clinicians should be aware of the increased likelihood of these conditions and should provide appropriate medical and behavioral treatment in addition to weight control.

Endocrine Disorders
Type 2 diabetes mellitus is one of the most serious complications of childhood obesity. As many as 45% of children with newly diagnosed diabetes mellitus have type 2 rather than type 1 disease.53 Patients may not have symptoms such as polyuria and polydipsia; consequently, identification requires laboratory screening for children at risk. Risk factors are BMI of ≥85th percentile; family history of diabetes; black, Hispanic, or Native American background; and other related conditions, such as polycystic ovary syndrome, acanthosis nigricans, or cardiovascular risk factors. The American Diabetes Association currently recommends screening with a fasting glucose test when a child is overweight and has 2 additional risk factors. Screening should begin at puberty or 10 years of age and should be performed every 2 years. A fasting glucose level of ≥126 mg/dL or a casual glucose level of ≥200 mg/dL indicates diabetes and requires referral to a pediatric endocrinologist. Fasting glucose levels of ≥100 mg/dL are considered prediabetes, indicating future risk for diabetes.60

Polycystic ovary syndrome occurs in ≥8% of young women 18 to 25 years of age, with prevalence depending on the definition used. Women with polycystic ovary syndrome are more likely to be obese.65 Infrequent menses (<9 cycles per year) is the most important finding that should lead to additional evaluation. Physical examination findings that are common but not diagnostic for polycystic ovary syndrome are hirsutism, excessive acne, and acanthosis nigricans. Women with polycystic ovary syndrome often have insulin resistance or type 2 diabetes and may have metabolic syndrome. Reproductive hormone laboratory tests can diagnose the condition but generally require interpretation by a subspecialist, such as an endocrinologist, gynecologist, or adolescent physician (see the assessment report); these specialists can initiate and monitor treatment to protect fertility.

Hypothyroidism is a frequent concern of parents, but this condition does not usually cause severe obesity. The prevalence is ~1 case per 1000.66 Symptoms include fatigue and decline in academic performance. Cessation of linear growth is an important sign, and a goiter may be present. Thyroid function tests are generally unnecessary when a child has normal linear growth velocity and no other symptoms of hypothyroidism.

Primary Cushing syndrome is extremely rare. The population incidence is probably ~2 cases per 1 000 000 annually, with onset in adulthood being more common than onset in childhood.67 Because the condition is treatable, clinicians should be aware of the physical examination findings, which include “moon facies” and “buffalo hump,” although exogenous obesity can also lead to this distribution of adipose tissue. Primary Cushing syndrome generally leads to short stature and therefore is extremely unlikely in a tall obese child. The striae found in Cushing syndrome are violaceous in color and thus differ from the commonly seen striae resulting from rapid weight gain. If Cushing syndrome is suspected, then the child should be referred to an endocrinologist for appropriate testing.

Evaluation of puberty in obese children requires careful attention to physical examination findings and
Nervous System Disorders
Pseudotumor cerebri is an extremely rare condition (incidence estimates for children are 1 case per 100,000 annually), but obesity is one of several risk factors and, untreated, the condition can lead to vision loss. Patients describe severe headaches with photophobia. Patients may have double vision if they have impairment of cranial nerve VI. Optic disks are blurred. When suspected, this condition requires urgent referral to the neurology service.

Cardiovascular Risk Factors
Approximately 13% of overweight children have elevated systolic blood pressure, and ~9% have elevated diastolic blood pressure. Blood pressure should be assessed at all health supervision visits, and offices should have large cuffs, including thigh cuffs, which allow accurate assessment of blood pressure for severely obese youths. The National Heart, Lung, and Blood Institute has updated tables defining elevated blood pressure levels according to age, gender, and height percentile, which offices should have available for easy reference.

Three or more readings above the 95th percentile for either systolic or diastolic blood pressure indicate hypertension. Information on the National Heart, Lung, and Blood Institute Web site (www.nhlbi.nih.gov/health/prof/heart/hbp/hbp_ped.htm) includes recommendations for evaluation, which may include ambulatory blood pressure monitoring to identify “white coat” hypertension or abnormal diurnal blood pressure patterns. Primary care providers can follow these detailed recommendations for evaluation and treatment or can refer patients to a specialist.

Lipid level abnormalities are among the most common obesity-related medical conditions. Because of the high prevalence, a fasting lipid profile should be obtained when BMI is ≥85th percentile, even in the absence of other risk factors. Total cholesterol levels of <170 mg/dL are acceptable, levels of 170 to 199 mg/dL are in the borderline category, and levels of ≥200 mg/dL are high. Low-density lipoprotein levels of <110 mg/dL are acceptable, levels of 110 to 129 mg/dL are borderline, and levels of ≥130 mg/dL are high. Dietitians can guide patients and families regarding the reduced-fat and reduced-cholesterol diets recommended by the National Cholesterol Education Panel. If levels are highly elevated and do not respond to diet changes, then a pediatric cardiologist or lipid specialist can assess the benefits and risks of medication use. Abnormal triglyceride levels, defined by the National Cholesterol Education Panel as ≥110 mg/dL for adolescents, and abnormal high-density lipoprotein levels, defined as ≤40 mg/dL, respond to increased physical activity.

Psychiatric Disorders
The effects of obesity on quality of life can be severe. Depression, an important comorbidity of obesity, may precede or result from obesity. Clinicians should look for flat affect, anxiety, body dissatisfaction, excess eating, fatigue, and difficulty sleeping. Sexual and physical abuse may increase the risk of severe obesity. Youths with binge eating or purging behavior should be evaluated for eating disorders.

Orthopedic Disorders
Blount disease (tibia vara) occurs more often among obese children, and onset generally occurs after 8 years of age. Often painless, Blount disease presents as visible bowing of the lower extremity and is diagnosed with anteroposterior radiographic views of the affected knee obtained while the patient is standing. An orthopedic surgeon can determine how to treat this condition, to correct bowing and to prevent progression.

Slipped capital femoral epiphysis occurs between 9 and 16 years of age, affects boys more than girls, and has an incidence estimated at ~11 cases per 100,000 children. It occurs more frequently when a child is obese. These children have hip or knee pain and pain with walking. On examination, hip range of motion is impaired. Bilateral frog-leg radiographic views of the hips should be obtained, and the child should be referred to the orthopedic surgery service.

A recent study revealed that overweight children and adolescents reported more fractures and musculoskeletal discomfort. Because injury and pain interfere with physical activity, early intervention (including physical therapy, when indicated) may reduce weight gain in these children.

Skin Conditions
Acanthosis nigricans is present in ~10% of obese white children and 50% of obese black children. Although it is associated with hyperinsulinemia, acanthosis nigricans is associated more strongly with high BMI. The prominence of acanthosis nigricans diminishes with weight loss.
Severely obese children can have chronic irritation and infection in the folds of the skin, especially in the lower abdomen and axilla. This intertrigo and furunculosis requires good hygiene, use of topical antibiotic and antifungal ointments, and sometimes systemic antibiotic therapy.

**Genetic Syndromes**

Well-defined genetic syndromes that cause obesity, such as Prader-Willi syndrome, are very rare. The assessment report lists some of these syndromes and their presentations. Clinicians should consider referral for genetic testing, especially when the obese child is short and has developmental delay. Unfortunately, diagnosis of these genetic syndromes does not modify treatment options.

**Laboratory Testing**

History and physical examination cannot effectively screen for abnormal cholesterol levels, NAFLD, and type 2 diabetes mellitus. Therefore, these conditions must be identified with laboratory tests. The expert committee recommends that children with BMI of 85th to 94th percentile should undergo lipid panel testing and, if risk factors are present, then fasting glucose, ALT, and AST levels should be measured every 2 years for individuals ≥10 years of age. For children with BMI of ≥95th percentile, the committee suggests that fasting glucose, ALT, and AST levels be measured every 2 years starting at 10 years of age, regardless of other risk factors. Elevation of ALT or AST levels above 60 U/L on 2 occasions may indicate the need for additional evaluation, probably with guidance from pediatric gastroenterology/hepatology experts.

The results of the primary care provider’s history, physical examination, and screening laboratory tests may indicate the need for additional diagnostic tests. A table of more-specialized diagnostic testing to be performed after initial positive screening is presented in the assessment report. Table 7 summarizes the medical assessment according to BMI category.

**Implementation of Medical Assessment**

Many practices develop checklists of symptoms and family history for patients or parents to complete. Clinicians can include weight-related symptoms and conditions on the list and then review these with families. Forms in the chart may help trigger the recommended evaluation once the BMI category of the child is flagged.

**Behavior Assessment**

**Goals**

The purpose of the behavior assessment is twofold. The first goal is to identify the child’s dietary and physical activity behaviors that may promote energy imbalance and that are modifiable. The second goal is to assess the capacity of the patient and/or the patient’s family to change some or all of these behaviors. Families must have both the means and the motivation to make changes. For instance, a child may benefit from increased outdoor play but, if no safe play area exists or if the parents do not perceive the benefit of this behavior change, then no change will occur and the child will “fail treatment.” The clinician should work with the family to target behavior changes that are appropriate and possible.

**Dietary and Physical Activity Assessments**

Because comprehensive dietary and physical activity assessments, such as diet or physical activity diaries, are impractical in a typical office setting, the expert committee recommends a focused assessment of behaviors that have the strongest evidence for association with energy balance and that are modifiable. It should be noted that current evidence generally reveals an association between specific behaviors and energy consumption or expenditure or between a behavior and weight status, leaving the direction of the relationship unknown.

For eating behavior assessment, the following behaviors should be addressed:

- frequency of eating food prepared outside the home, including food in restaurants, school and work cafeterias, and fast food establishments and food purchased for “take out”;
- ounces, cups, or cans of sugar-sweetened beverages consumed each day;
- portions that are large for age (qualitative assessment);
- ounces or cups of 100% fruit juice consumed each day;
- frequency and quality of breakfast;
- consumption of foods that are high in energy density, such as high-fat foods;
- number of fruit and vegetable servings consumed each day; and
- number of meals and snacks consumed each day and quality of snacks.

For physical activity assessment, the following behaviors should be addressed:

- time spent in moderate physical activity each day (including organized physical activity and unstructured activity, including play), to estimate whether the goal of 60 minutes of moderately vigorous activity each day is achieved;
- routine activity patterns, such as walking to school or performing yard work;
- sedentary behavior, including hours of television, videotape/DVD, and video game viewing and computer
<table>
<thead>
<tr>
<th>BMI Percentile</th>
<th>Recent History</th>
<th>Medication Use</th>
<th>Review of Symptoms</th>
<th>Family History (First- and Second-Degree Relatives)</th>
<th>Physical Examination</th>
<th>Laboratory Tests</th>
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<tr>
<td>5th–84th</td>
<td>BMI percentile change</td>
<td>Medications that may affect weight gain (eg, neuropsychiatric medications)</td>
<td>Obesity, type 2 diabetes, hypertension, lipid level abnormalities, heart disease</td>
<td>Blood pressure (correct cuff)</td>
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<td>85th–94th</td>
<td>BMI percentile change</td>
<td>Medications that may affect weight gain (eg, neuropsychiatric medications)</td>
<td>Obesity, type 2 diabetes, hypertension, lipid level abnormalities, heart disease</td>
<td>Blood pressure (correct cuff), acanthosis nigricans, tonsils, goiter, tender abdomen, liver, bowing of legs, limited hip range of motion, optic discs if headaches, acne and hirsutism</td>
<td>Fasting lipid profile; if age 10 y and other risk factors, fasting glucose level biannually; ALT and AST levels biannually</td>
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<td>95th–99th</td>
<td>BMI percentile change</td>
<td>Medications that may affect weight gain (eg, neuropsychiatric medications)</td>
<td>Obesity, type 2 diabetes, hypertension, lipid level abnormalities, heart disease</td>
<td>Blood pressure (correct cuff), acanthosis nigricans, tonsils, goiter, tender abdomen, liver, bowing of legs, limited hip range of motion, optic discs if headaches, acne and hirsutism</td>
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<td>&gt;99th</td>
<td>BMI change</td>
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<td>Obesity, type 2 diabetes, hypertension, lipid levels abnormalities, heart disease</td>
<td>Blood pressure (correct cuff), acanthosis nigricans, tonsils, goiter, tender abdomen, liver, bowing of legs, limited hip range of motion, optic discs if headaches, acne and hirsutism, skin inflammation</td>
<td>Fasting lipid profile; if age 10 y and other risk factors, fasting glucose level biannually; ALT and AST levels biannually</td>
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use, to determine whether viewing is >2 hours per day.

Implementation of Behavior Assessment
Standardized instruments simplify assessment of usual diet and activity behaviors, and several are available (see the assessment report2). None assesses all of the targeted behaviors comprehensively, and none has been tested for reliability and validity in a clinical setting. Additional research in this area is urgently needed.

Targeting of realistic behavior changes requires an assessment of practical resources and barriers. Neighborhood parks, grocery stores, recreation centers, and neighborhood children with whom to play can all support a healthier lifestyle. Clinical offices can maintain a list of nearby community resources. Within the household, finances, time, and caregivers other than parents may affect behavior changes. A family’s cultural values, which are influenced by ethnicity, religion, educational background, and many other factors, often affect the family’s perception of appropriate physical activity or customary food and eating practices. Clinicians who become familiar with attitudes common among the patients they serve and who pay attention to the specific values of individual families will be able to tailor recommendations. For example, if a family prefers a traditional Mexican diet, then the clinician might suggest that the family members learn to prepare the foods with less fat and more whole grains; if a family places a high priority on religious worship and family time on Sundays, then the clinician might suggest that the family members develop a tradition of walking, biking, or bowling together. Offices should provide educational material appropriate for the particular patient population. For example, an office that serves Cambodian patients should offer information about a healthy Cambodian diet, in the appropriate language.

Because behavior change requires sustained commitment by the patient and family members, their motivation is the most important but most challenging aspect of obesity care. Motivational interviewing, as discussed above, is a technique that merges assessment and intervention and provides a framework for communicating physical and laboratory findings. The clinician helps the patient and family members determine their priorities, consider how current behaviors support or undermine those priorities, and assess the resources and barriers in their family and environment that may influence their capacity to improve behaviors. For example, a family may decide to improve portion sizes but not to add fruits and vegetables, or a family may want to explore other possible resources before choosing a behavior change. Through the process of behavior assessment, the clinician and family members together identify treatment goals.

Whether the child or the parent is the target of behavior changes depends on the age of the child. When the child is young, the parents and caregivers should take responsibility for providing a healthy diet, limiting the amount of television and screen time, and creating opportunities for active play. Parents should not expect the child to choose between soda and water or to turn off the television at the end of 2 hours. Therefore, clinicians should address concerns and motivation with parents when children are young. However, adolescents generally have many opportunities away from home to make eating and physical activity choices. Although parents can support an adolescent’s efforts by making the home environment healthy, the adolescent’s own concerns and motivation are paramount in any weight control efforts and should be the focus of the clinician’s assessment.

TREATMENT

Goals
The primary goal of obesity treatment is improvement of long-term physical health through permanent healthy lifestyle habits. Implementation of these habits alone will lead to improved weight (weight loss or weight maintenance during linear growth) for some children, but other children and youths may need additional focused efforts to achieve negative energy balance. Others may need additional help with behavior modification strategies to develop and to sustain healthy habits. Emotional health (good self-esteem and appropriate attitudes toward food and body) is also an important outcome. To achieve these goals, the treatment writing group recommended that providers present a staged approach, with 4 treatment stages of increasing intensity. Patients can begin at the least-intensive stage and advance depending on responses to treatment, age, degree of obesity, health risks, and motivation. Providers may identify some obese youths who are motivated to begin behavior change at a more-intensive stage. This approach may lead to greater success when obesity is more severe, as long as the patient is motivated.

Outcomes
The establishment of permanent healthy lifestyle habits is a good outcome, regardless of weight change, because of the long-term health benefits of these behaviors. Improvement in medical conditions is also an important sign of long-term health benefits. The metric for improved weight is BMI percentile, generally to <85th percentile, although some children are healthy in the overweight category (85th–94th percentile). Although improvement in BMI percentile is the goal, monitoring this metric in the short-term with BMI curves may be difficult. Serial weight measurements can reflect energy balance in the short-term. Weight maintenance leads to reductions in absolute BMI because of ongoing linear
growth, and even slow weight gain can result in lower BMI percentiles because the BMI for a given percentile curve increases with age. In general, younger and more mildly obese children should change weight more gradually than older and severely obese youths. When a patient’s weight or BMI percentile does not improve as desired over 3 to 6 months of planned treatment, the provider and family should consider advancing to the next, more-intensive stage of treatment.

Staged Treatment
The expert committee’s proposed systematic approach integrates aspects of treatment that have evidence to support them, although the approach as a whole is untested. This approach promotes brief, office-based intervention for the greatest number of overweight and obese children and then a systematic intensification of efforts, tailored to the capacity of the clinical office, the motivation of the family, and the degree of obesity, with the most aggressive treatment stage being considered only for those who have not responded to other interventions.

Providers’ offices need to prepare by implementing a system for evaluation; by identifying resources, such as pediatric dietitians or behavioralists, or training staff members for diet and activity assessments; and by identifying community resources and referral centers, if available. Referral centers may emerge in response to the needs of area practices. For each stage of obesity treatment, the expert committee has recommended a process for implementation, suggesting how the primary care provider can provide this care or identify support beyond the office.

Stages of Obesity Treatment

Stage 1: Prevention Plus
As a first step, overweight and obese patients and their families could focus on basic healthy lifestyle eating and activity habits that form the obesity prevention strategies. However, the outcome would be improved BMI status rather than maintained healthy BMI, and the provider would offer more-frequent monitoring to motivated patients and families.

Specific healthy eating and activity habits are as follows.

1. consume ≥5 servings of fruits and vegetables every day (ME). Families may subsequently increase to 9 servings per day, as recommended by the USDA. The USDA Web site (www.mypyramid.gov) recommends the number of cups of fruits and vegetables per day according to age, ranging from 2 cups per day for 2-year-old children to 4.5 cups per day for 17- and 18-year-old youths;
2. minimize sugar-sweetened beverages, such as soda, sports drinks, and punches (ME). Ideally, these beverages will be eliminated from a child’s diet, although children who consume large amounts will benefit from reduction to 1 serving per day;
3. decrease television viewing (and other forms of screen time) to ≤2 hours per day (CE). If the child is <2 years of age, then no television viewing should be the goal. To assist with this change, the television should be removed from the room where the child sleeps;
4. be physically active ≥1 hour each day (ME). Unstructured play is most appropriate for young children. Older children should find physical activities that they enjoy, which may include sports, dance, martial arts, bike riding, and walking. Activity can be structured, such as a dance class, or unstructured, such as dancing to music at home, and children can perform several shorter periods of activity over the day;
5. prepare more meals at home rather than purchasing restaurant food (ME);
6. eat at the table as a family at least 5 or 6 times per week (ME);
7. consume a healthy breakfast every day (ME);
8. involve the whole family in lifestyle changes (CE);
9. allow the child to self-regulate his or her meals and avoid overly restrictive feeding behaviors (CE for children <12 years of age);
10. help families tailor behavior recommendations to their cultural values (suggest).

For implementation of Prevention Plus, the following points should be noted.

1. families and providers can work together to identify the behaviors that are appropriate to target. Considerations include current behaviors that most contribute to energy imbalance, the family’s cultural values and preferences, the family’s specific financial situation, neighborhood, and schedule, and the motivation of the child and family to make particular changes. By using motivational interviewing techniques, the provider allows the child and family to determine the priority behaviors, which naturally integrates the family situation and values;
2. patients may need to achieve the target behaviors in steps. For example, obese children may need to begin with 15 minutes of physical activity per day and work up to 60 minutes, or a family may choose 3 goals at the beginning and expand the number of targeted behaviors over time;
3. follow-up visit frequency should be tailored to the individual family, and motivational interviewing techniques may be useful to set the frequency;

4. the Prevention Plus stage of obesity treatment can take place in the office setting;

5. physicians, advanced practice nurses, physician assistants, and office nurses, with appropriate training, can provide this level of treatment;

6. after 3 to 6 months, if the child has not made appropriate improvement, the provider can offer the next level of obesity care, that is, structured weight management.

**Stage 2: Structured Weight Management**

This level of obesity treatment is distinguished from Prevention Plus less by differences in the targeted behaviors and more by the support and structure provided to the child to achieve those behaviors. Specific eating and activity goals in addition to the goals in Prevention Plus are as follows:

1. a planned diet or daily eating plan with balanced macronutrients, in proportions consistent with Dietary Reference Intake recommendations, emphasizing foods low in energy density (such as those with high fiber or water content) (suggest);

2. structured daily meals and planned snacks (breakfast, lunch, dinner, and 1 or 2 scheduled snacks, with no food or calorie-containing beverages at other times, may reduce excess intake) (suggest);

3. additional reduction of television and other screen time to ≤ 1 hour per day (suggest);

4. planned, supervised, physical activity or active play for 60 minutes per day (ME);

5. monitoring of these behaviors through use of logs (for example, the patient or family members can record the minutes spent watching television and can keep a 3-day recording of food and beverages consumed) (CE); and

6. planned reinforcement for achieving targeted behaviors (suggest).

For implementation of structured weight management, the following points should be noted.

1. the eating plan requires a dietitian or a clinician who has received additional training in creating this kind of eating plan for children;

2. office staff members who have some training in motivational interviewing and in teaching of monitoring and reinforcement techniques can establish initial goals with families and see them for follow-up care;

3. some families need a counselor for help with parenting skills, resolution of family conflict, or motivation;

4. depending on the child and family, referral to a physical therapist or exercise therapist can help the child and family develop physical activity habits;

5. monthly office visits are probably most appropriate at this level;

6. a provider’s office staff can provide much of this treatment, with some additional training;

7. some practices may find group sessions to be effective and efficient.

**Stage 3: Comprehensive Multidisciplinary Intervention**

This approach increases the intensity of behavior changes, the frequency of visits, and the specialists involved, to maximize support for behavior changes. Generally, this type of program would exceed the capacity of a primary care office to offer within the typical visit structure. However, an office or several offices could organize specialists to offer this kind of a program. Eating and activity goals are generally those of the structured weight management stage.

For implementation of comprehensive multidisciplinary intervention, the following points should be noted.

1. a structured program in behavior modification should include, at a minimum, food monitoring, short-term diet and physical activity goal setting, and contingency management (CE);

2. negative energy balance resulting from structured dietary and physical activity changes is planned (ME);

3. parental participation in behavior modification techniques is needed for children < 12 years of age (CE). Parental involvement would be progressively less with older youths;

4. parents should be trained regarding improvement of the home environment (suggest);

5. systematic evaluation of body measurements, diet, and physical activity should be performed at baseline and at specified intervals throughout the program (suggest);

6. a multidisciplinary team with experience in childhood obesity, including a behavioral counselor (for example, social worker, psychologist, other mental health care provider, or trained nurse practitioner), registered dietitian, exercise specialist (physical therapist or other team member with training or a community program prepared to assist obese children), and primary care provider who continues to monitor medical issues and maintains a supportive alliance with the families, should be involved;

7. frequent office visits should be scheduled; weekly visits for a minimum of 8 to 12 weeks seem to be
most efficacious\(^80\) (CE). Subsequently, monthly visits can help maintain new behaviors;

8. group visits may be more cost-effective and have therapeutic benefit\(^80,81\) (ME);

9. an established pediatric weight management program may be best suited to provide this type of intervention, although such programs are sparse and often are not covered by insurance plans;

10. commercial weight management programs can be considered, but the primary care provider’s office needs to screen the programs to ensure that the approach is healthy and appropriate for the age of the child. Information to guide this evaluation is included in the treatment report.\(^3\)

Stage 4: Tertiary Care Intervention

Interventions

The intensive interventions in this category may be offered to some severely obese youths. These interventions move beyond the goal of balanced healthy eating and activity habits that are the core of the other stages. Candidates for consideration should have attempted weight control in the comprehensive multidisciplinary intervention stage, should have the maturity to understand possible risks, and should be willing to maintain physical activity and, if consistent with the additional intervention, a healthy diet with appropriate behavior monitoring. However, lack of success with the comprehensive multidisciplinary intervention is not by itself an indication to move to this level of treatment.

The interventions listed below have been used for adolescents, and some patients may be candidates for one of these interventions. Consideration of each of these interventions depends on the patient and the resources in the geographic area.

Medications

Two medications have been used for adolescents.\(^82\) Sibutramine is a serotonin reuptake inhibitor that increased weight loss for adolescents who were in a diet and exercise program, compared with diet and exercise alone. Adolescents who received medication lost more than did those in the control group.\(^83,84\) In 1 study, use of orlistat, which causes fat malabsorption through inhibition of enteric lipase, led to less weight gain, compared with diet and exercise alone, among adolescents.\(^85\) The effect of these medications (always studied in conjunction with diet and exercise) has been modest. The Food and Drug Administration has approved sibutramine for patients \(\geq 16\) years of age and orlistat for patients \(\geq 12\) years of age.

Very Low-Calorie Diet

There are few reports on the use of highly restrictive diets for children or adolescents. A restrictive diet was used as the first step in a childhood weight management
program, followed by a mildly restrictive diet. Long-term outcome data have not been reported.

**Weight Control Surgery**

Because of the increasing number of youths with severe obesity that is not responsive to behavioral intervention, a few centers offer bariatric surgery, either gastric bypass or gastric banding. This treatment generally leads to substantial weight loss and improvement in medical conditions. However, perioperative risks, postprocedure nutritional risks, and the necessity of lifelong commitment to altered eating make this approach unattractive or inappropriate for many. Selection criteria proposed by Inge et al include BMI of ≥40 kg/m² with a medical condition or ≥50 kg/m²; physical maturity (generally 13 years of age for girls and ≥15 years of age for boys); emotional and cognitive maturity; and weight loss efforts for ≥6 months in a behavior-based treatment program. Those investigators also recommended strongly that bariatric surgery centers maintain databases, so that these criteria can be modified as appropriate on the basis of outcomes. Furthermore, adolescents who undergo such procedures need careful evaluation before surgery and prolonged nutritional and psychological support after surgery, and many youths who might otherwise qualify live too far from an adolescent bariatric center.

**Implementation**

For implementation of tertiary care intervention, the following points should be noted.

1. these interventions should occur in pediatric weight management centers with comprehensive services;
2. the multidisciplinary team should have expertise in childhood obesity and its comorbidities, with patient care provided by a physician or nurse practitioner, registered dietitian, behavioral counselor, and exercise specialist. Standard clinical protocols for patient selection should evaluate patient age, degree of obesity, motivation and emotional readiness, previous efforts to control weight, and family support. Standard clinical protocols should be in place for evaluation before, during, and after intervention. These evaluations should focus on the physical and emotional effects of the treatment. These protocols should be established by a physician, dietitian, and behavioralist;
3. some patients who are appropriate candidates for one of these interventions may not have access because programs are not available in their geographic area or insurance does not cover the treatment.

**Staged Approach for Individual Patients**

When a clinician identifies health risks resulting from excess fat (most patients with BMI of ≥95th percentile and many patients with BMI of 85th–94th percentile), the provider can first offer Prevention Plus. If the child and family are already attempting these behaviors as part of prevention efforts or if 3 to 6 months of Prevention Plus do not lead to expected improvement, then the patient can move on to structured weight management. Similarly, after 3 to 6 months in a structured weight management program, some patients who have not achieved goals can move on to a comprehensive multidisciplinary intervention. The timing of these stages should be adapted to individual families and the availability of programs. For instance, providers may suggest a comprehensive program immediately when youths are motivated to begin such treatment, especially if they have urgent medical issues. If families must wait for an opening in a comprehensive program, then clinicians could provide Prevention Plus or structured weight management in the interim. Suggested weight goals and highest treatment stage recommended according to age and BMI category are presented in Table 8.

Patients <2 years of age require different evaluation and intervention approaches. Measurement and plotting of weight and height are unchanged but, because the growth curves do not include BMI percentiles, weight-for-height values should be plotted; children with weight-for-height values above the 95th percentile are classified as overweight. Risk of excess body fat increases as weight-for-height values increase above the 95th percentile, although no cutoff points currently define obesity. At this age, parental weight status is very important in assessing future obesity risk and predicts obesity in young adulthood more accurately than does the toddler’s current weight status. Therefore, an 18-month-old child with 2 obese parents is at very high risk, even if the toddler’s weight-for-height value is <95th percentile.

Until normative values for individual longitudinal growth are well established, energy restrictions designed to reduce weight are not recommended for this age group. However, providers should discuss the potential long-term risks and should encourage parents to establish obesity prevention strategies. For infants 0 to 12 months of age, pediatric providers can encourage exclusive breastfeeding until 6 months of age and continued breastfeeding to 12 months of age and beyond, after introduction of solid foods. Parents can be encouraged to offer new foods repeatedly and to avoid sugar-sweetened beverages (such as soda) and snack foods (such as French fries and potato chips). Providers can recommend that televisions not be in the infant’s sleeping room. Caregivers other than the parents should follow the same “parenting” strategies. When providers identify overweight toddlers 12 to 24 months of age, the providers should recommend age-appropriate obesity prevention strategies, such as avoidance of sugar-sweetened beverages and excessive juice intake and avoidance of excessive milk intake (>16–24 oz of milk per day may
add extra energy or displace other nutrients). Providers can encourage establishment of 3 meals per day eaten at the table with other family members, with the television off. Families should not restrict how much their children eat at meals and snacks but should be sure that all of the food available is healthy, with plenty of fruits and vegetables. At this age, children frequently consume 2 snacks in addition to their meals but, between meals and snacks, parents can offer water when children are thirsty, rather than providing constant access to caloric beverages such as juice. Children should have ample opportunity for active play, with limitation of television and DVD viewing and no televisions in their bedrooms. When weight is extremely high, the infant or toddler may have a genetic condition, especially if height is low or development is delayed.

Severe obesity combined with low motivation or lack of concern creates a distressing situation for clinicians, especially when the child has urgent medical conditions such as sleep apnea or diabetes. Particularly challenging are situations in which the child is young and the parents, on whom the child relies for healthy eating and physical activity structure, are unwilling to make changes. Providers can use empathy and persistence; they should maintain their relationship with the family and encourage change without scolding. Scolding or a sense of failure may lead the family to seek care elsewhere. If providers search for the source of resistance, then they may find ways to address it. A social worker could help address financial limitations, an adult psychiatrist could help a parent who is depressed, family therapy could help a family cope with a divorce, and Big Brother/Big Sister programs could offer a weekly outing that is physically active. Offices should actively keep these families engaged (eg, encouraging follow-up appointments to evaluate weight, rather than waiting for the next well-child check). Office staff members can check with the family by telephone after missed appointments. When families agree to meet with a specialist, such as a dietitian, office staff members can inform the specialist of the situation, to ensure that the appointment goes smoothly, and also can address practical problems, such as transportation issues. These strategies communicate the clinician’s concern about the child’s health but also the desire to support the family.

Although providers often feel overwhelmed by obesity care in the face of the environmental forces that promote it, increasing public concern, increasing attention directed at school and community policies, and refined understanding of the most-effective interventions will eventually come together to meet this challenge successfully. Meanwhile, health care providers have the potential to improve outcomes by performing early identification, by helping individual families create the best possible home environment, and by providing more-structured guidance to overweight and obese children and their families.

APPENDIX: EXPERT COMMITTEE RECOMMENDATIONS ON THE ASSESSMENT, PREVENTION, AND TREATMENT OF CHILD AND ADOLESCENT OVERWEIGHT AND OBESITY

Assessment Recommendations

1. The expert committee recommends that physicians and allied health care providers perform, at a minimum, a yearly assessment of weight status for all children and that this assessment include calculation of height, weight (measured appropriately), and BMI for age and plotting of those measures on standard growth charts.

2. With regard to classification, the expert committee recommends that individuals 2 to 18 years of age with BMI of ≥95th percentile for age and gender or BMI of >30 (whichever is smaller) should be considered obese and individuals with BMI of ≥85th percentile but <95th percentile for age and gender should be considered overweight; this term replaces “at risk of overweight.”

3. The expert committee recommends the use of 99th percentile BMI values for age as cutoff points (indicated by using a table with cutoff points for the 99th percentile BMI according to age and gender), to allow for improved accessibility of the data in the clinical setting and for additional study.

4. The expert committee recommends against the routine clinical use of skinfold thickness measurements in the assessment of obesity in children.

5. The expert committee was unable to recommend waist circumference measurements for routine clinical use at the present time, because of incomplete information and the lack of specific guidance for clinical application.

6. The expert committee recommends that qualitative assessment of dietary patterns for all pediatric patients be conducted, at a minimum, at each well-child visit for anticipatory guidance and that assessment include self-efficacy and readiness to change and identification of the following specific dietary practices, which may be targets for change: frequency of eating outside the home at restaurants or fast food establishments, excessive consumption of sweetened beverages, and consumption of excessive portion sizes for age. Additional practices to be considered for evaluation during the qualitative dietary assessment include excessive consumption of 100% fruit juices, breakfast consumption (frequency and quantity), excessive consumption of foods that are high in energy density, low consumption of fruits
and vegetables, and meal frequency and snacking patterns (including quality).

7. The expert committee recommends that assessment of levels of physical activity and sedentary behaviors should be performed for all pediatric patients, at a minimum, at each well-child visit for anticipatory guidance and should include the general areas of (a) self-efficacy and readiness to change, (b) environment and social support and barriers to physical activity, (c) whether the child is meeting recommendations of 60 minutes of at least moderate physical activity per day, and (d) levels of sedentary behavior (including hours of behaviors such as watching television and/or DVDs, playing video games, and using the computer, in comparison with a baseline value of <2 hours per day).

8. The expert committee recommends that physicians and allied health care providers obtain a focused family history for obesity, type 2 diabetes mellitus, cardiovascular disease (particularly hypertension), and early deaths resulting from heart disease or stroke, to assess the risks of current or future comorbidities associated with a child’s overweight or obese status.

9. The expert committee recommends that a thorough physical examination be performed and that, for a child identified as overweight or obese, the following measurements be included, in addition to the aforementioned recommendations on BMI: (a) pulse, measured in the standard pediatric manner; (b) blood pressure, measured with a cuff large enough that 80% of the arm is covered by the bladder of the cuff; and (c) signs associated with comorbidities of overweight and obesity (see the assessment report).2 Waist circumference is not recommended for routine use. Although high waist circumference can indicate insulin resistance and other comorbidities of obesity and may be useful to characterize risks for obese children, measurement is difficult and appropriate cutoff values are uncertain.

10. The expert committee recommends that the following laboratory tests be considered in the evaluation of a child identified as overweight or obese. If the BMI is 85th to 94th percentile for age and gender with no risk factors, then a fasting lipid profile should be obtained. If the BMI is 85th to 94th percentile for age and gender with risk factors in the history or physical examination, then AST, ALT, and fasting glucose levels should also be measured. If the BMI is >95th percentile for age and gender, even in the absence of risk factors, then all of the tests listed for 85th to 94th percentile BMI with risk factors should be performed. Guidelines for laboratory assessment and testing for more-detailed evaluation, typically performed and interpreted by subspecialists, are also provided (see assessment report).2

Treatment Recommendations

1. The expert committee recommends that all physicians and health care providers address weight management and lifestyle issues with all patients, regardless of presenting weight, at least each year.

2. The expert committee recommends that all children between 2 and 18 years of age with BMI values between the 5th and 84th percentile follow the recommendations for prevention outlined in the prevention report.3

3. The expert committee recommends that the treatment of overweight children be approached with a staged method based on the child’s age, BMI, related comorbidities, parents’ weight status, and progress in treatment and that the child’s primary caregivers and family be involved in the process.

4. The expert committee recommends the following staged approach for children between the ages of 2 and 19 years whose BMI is >85th percentile. Stage 1 is the Prevention Plus protocol. These recommendations can be implemented by the primary care physician or an allied health care provider who has some training in pediatric weight management or behavioral counseling. Stage 1 recommendations include the following. (a) Consume ≥5 servings of fruits and vegetables per day (ME). (b) Minimize or eliminate sugar-sweetened beverages (ME). (c) Limit screen time to ≤2 hours per day, with no television in the room where the child sleeps (CE). (d) Engage in ≥1 hour of daily physical activity (ME). The patient and the family of the patient should be counseled to facilitate the following eating behaviors: (a) eating a daily breakfast (ME); (b) limiting meals outside the home (ME); (c) eating family meals at least 5 or 6 times per week (ME); and (d) allowing the child to self-regulate his or her meals and avoiding overly restrictive behaviors (CE for children <12 years of age and suggested for children >12 years of age). Providers should acknowledge cultural differences and help families to adapt recommendations to meet these differences (suggest). Within this category, the goal should be weight maintenance, with growth resulting in decreasing BMI as age increases. Monthly follow-up assessment should be performed. After 3 to 6 months, if no improvement in BMI or weight status has been noted, then advancement to stage 2 is indicated, on the basis of patient/family readiness to change. Stage 2 is a structured weight management protocol. These recommendations can be implemented by a primary care physician or an allied
the health care provider who is highly trained in weight management. Stage 2 recommendations include the following: (a) development of a plan for use of a balanced macronutrient diet, emphasizing small amounts of energy-dense foods (suggest); (b) provision of structured daily meals and snacks (breakfast, lunch, dinner, and 1 or 2 snacks per day) (suggest); (c) supervised active play of ≥60 minutes per day (ME); (d) screen time of ≤1 hour per day (suggest; CE for ≤2 hours); (e) increased monitoring (eg, screen time, physical activity, dietary intake, and restaurant logs) by provider, patient, and/or family (CE); and (f) reinforcement for achieving targeted behavior goals (not weight goals) (suggest). Within this category, the goal should be weight maintenance that results in decreasing BMI as age and height increase; however, weight loss should not exceed 1 lb/month for children 2 to 11 years of age or an average of 2 lb/week for older overweight/obese children and adolescents. If there is no improvement in BMI or weight status after 3 to 6 months, then the patient should advance to stage 3. Stage 3 is a comprehensive multidisciplinary intervention. At this level of intervention, optimally the patient should be referred to a multidisciplinary obesity care team. Eating and activity goals are the same as in stage 2. Activities within this category should also include the following: (a) planned negative energy balance achieved through structured diet and physical activity (ME); (b) structured behavioral modification program, including food and activity monitoring and development of short-term diet and physical activity goals (CE); (c) involvement of primary caregivers/family members for behavioral modification for children <12 years of age (CE); (d) provision of training for all families to improve the home environment (suggest); and (e) frequent office visits. Weekly visits for a minimum of 8 to 12 weeks seem to be most efficacious (CE), and subsequent monthly visits help maintain new behaviors. Group visits may be more cost-effective and have therapeutic benefit (ME). Systematic evaluation of body measurements, dietary intake, and physical activity should be conducted at baseline and at specific intervals throughout the program. Within this category, the goal should be weight maintenance or gradual weight loss until BMI is <85th percentile. Weight loss should not exceed 1 lb/month for children 2 to 5 years of age or 2 lb/week for older obese children and adolescents.

5. The expert committee recommends stage 4 for children >11 years of age with BMI of >95th percentile who have significant comorbidities and who have not been successful in stages 1 to 3 or children with BMI of >99th percentile who have shown no improvement in stage 3 (comprehensive multidisciplinary intervention). Stage 4 is a tertiary care protocol, that is, referral to a pediatric tertiary weight management center with access to a multidisciplinary team with expertise in childhood obesity, operating under a designed protocol. This protocol should include continued diet and activity counseling and the consideration of such additions as meal replacement, very low-calorie diet, medication, and surgery (suggest).

6. The expert committee recommends that the following weight loss targets be considered when the staged treatment plan is implemented; the recommendations are based on clinical recommendations and judgment because of the limited amount of evidence: age 2 to 5 years: BMI of 85th to 94th percentile: weight maintenance until BMI is <85th percentile or slowing of weight gain is indicated by a downward deflection in the BMI curve; BMI of ≥95th percentile: weight maintenance until BMI is <85th percentile; however, if weight loss occurs with a healthy adequate diet, then it should not exceed 1 lb/month (if greater loss is noted, then the patient should be monitored for causes of excessive weight loss); BMI of >21 or 22 kg/m² (rare, very high): gradual weight loss, not to exceed 1 lb/month (if greater loss occurs, then the patient should be monitored for causes of excessive weight loss); age 6 to 11 years: BMI of 85th to 94th percentile: weight maintenance until BMI is <85th percentile or slowing of weight gain is indicated by a downward deflection in the BMI curve; BMI of 95th to 98th percentile: weight maintenance until BMI is <85th or gradual weight loss of ~1 lb/month (if greater loss is noted, then the patient should be monitored for causes of excessive weight loss); BMI of ≥99th percentile: weight loss not to exceed an average of 2 lb/week (if greater loss is noted, then the patient should be monitored for causes of excessive weight loss); age 12 to 18 years: BMI of 85th to 94th percentile: weight maintenance until BMI is <85th percentile or slowing of weight gain is indicated by a downward deflection in the BMI curve; BMI of 95th to 98th percentile: weight maintenance until BMI is <85th or gradual weight loss of ~1 lb/month (if greater loss is noted, then the patient should be monitored for causes of excessive weight loss); BMI of ≥99th percentile: weight loss not to exceed an average of 2 lb/week (if greater loss is noted, then the patient should be monitored for causes of excessive weight loss).

7. The expert committee recommends that, for children 12 to 18 years of age with BMI of >99th percentile, primary care physicians and allied health care providers may begin treatment at stage 1, 2, or 3, as indicated by the patient’s and family’s readiness to change.
Prevention Recommendations

Patient-Level Interventions

1. The expert committee recommends that physicians and allied health care providers counsel the following for children 2 to 18 years of age whose BMI is 5th to 84th percentile: (a) limiting consumption of sugar-sweetened beverages (CE); (b) encouraging diets with recommended quantities of fruits and vegetables (ME); (c) limiting television and other screen time by allowing no more than 2 hours per day, as advised by the American Academy of Pediatrics (CE), and removing television and computer screens from children’s primary sleeping areas (CE); (d) eating breakfast daily (CE); (e) limiting eating at restaurants, particularly fast food restaurants (CE); (f) encouraging family meals in which parents and children eat together (CE); and (g) limiting portion sizes (CE).

2. The expert committee also suggests that providers counsel families to engage in the following behaviors: (a) eating a diet rich in calcium; (b) eating a diet high in fiber; (c) eating a diet with balanced macronutrients (energy from fat, carbohydrates, and protein in proportions appropriate for age, as recommended by Dietary Reference Intakes); (d) initiating and maintaining breastfeeding; (e) participating in 60 minutes of moderate to vigorous physical activity per day for children of healthy weight (the 60 minutes can be accumulated throughout the day, rather than in single or long bouts; ideally, such activity should be enjoyable to the child); and (f) limiting consumption of energy-dense foods.

Practice- and Community-Level Interventions

1. The expert committee recommends that physicians, allied health care professionals, and professional organizations (a) advocate for the federal government to increase physical activity at schools through intervention programs from grade 1 through the end of high school and college and through the creation of school environments that support physical activity in general and (b) support efforts to preserve and to enhance parks as areas for physical activity, inform local development initiatives regarding the inclusion of walking and bicycle paths, and promote families’ use of local physical options by making information and suggestions about physical activity alternatives available in doctors’ offices.

2. The expert committee recommends the use of the following techniques to aid physicians and allied health care providers who may wish to support obesity prevention in clinical, school, and community settings: (a) actively engaging families with parental obesity or maternal diabetes, because these children are at increased risk for developing obesity even if they currently have normal BMI; (b) encouraging an authoritative parenting style in support of increased physical activity and reduced sedentary behavior (authoritative parents are both demanding and responsive, providing tangible and motivational support for children); (c) discouraging a restrictive parenting style (restrictive parenting involves heavy monitoring and controlling of a child’s behavior) regarding child eating; (d) encouraging parents to model healthy diets and portions sizes, physical activity, and limited television time; and (e) promoting physical activity at school and in child care settings (including after-school programs) by asking children and parents about activity in these settings during routine office visits.

ACKNOWLEDGMENTS

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in children. Those documents expedited preparation of this report.

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**Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report**

Sarah E. Barlow and and the Expert Committee

*Pediatrics* 2007;120;S164-S192

DOI: 10.1542/peds.2007-2329C

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AMA mission: To promote the art and science of medicine and the betterment of public health.

The AMA supports a wide range of policies and activities regarding public health issues, including the promotion of healthy lifestyles (healthy eating, physical activity, not using tobacco, and avoiding excess or risky use of alcohol), the elimination of health disparities, violence prevention, geriatric and adolescent health, and combating obesity.

Specific to childhood obesity, AMA policy supports:

**Healthy Eating**
- Evidence-based nutrition standards for all food (including a la carte, snack bar, and vending machine offerings) served and sold in K-12 schools
- Provision of vegetables, fruits, legumes, grains, vegetarian foods, and healthful beverages in school lunch programs
- Banning food commercials aimed at children

**Adequate Physical Activity**
- Meaningful and mandatory physical education programs for all children, including the handicapped, in K-12 schools, conducted by qualified personnel
- At least 30 minutes of daily free play or physical education in elementary school
- Family-oriented education about the benefits of physical activity

**Health Education in Schools**
- Comprehensive programs and activities in elementary and secondary schools to help young people develop the skills needed to choose healthy dietary patterns and adequate physical activity

**Public Education**
- Educating the public about obesity, including the benefits of healthy eating and physical activity to prevent and limit the health consequences of obesity

**Physician Education***
- Educating physicians about the prevention and management of overweight and obesity in children, including physical activity and nutrition assessment and counseling methods
- Routine determination of body mass index (BMI) percentiles in children

**Research**
- More research on the relative efficacy of clinical and public health interventions to prevent, diagnose, treat, and manage overweight and obesity

*The AMA, in collaboration with the U.S. Department of Health and Human Services’ Health Resources and Services Administration and the Centers for Disease Control and Prevention, convened an expert committee to develop recommendations on the assessment, prevention, and treatment of child and adolescent overweight and obesity, recently published in the journal *Pediatrics* (December 2007).
March 27, 2008

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Salt and Sodium; Petition to Revise the Regulatory Status of Salt and Establish Food Labeling Requirements Regarding Salt and Sodium [Docket No. 2005P-0450]

The American Medical Association (AMA) commends the Food and Drug Administration (FDA) for holding a public hearing on FDA’s policies regarding salt (sodium chloride) and sodium in food, and its willingness to reexamine this issue. This is especially important because of the relationship between salt intake and cardiovascular disease. The AMA is pleased to submit these comments as a follow-up to our oral testimony presented at the November 29, 2007 hearing.

Sodium Intake and Cardiovascular Disease (CVD)

Across populations, the progressive increase in blood pressure and the prevalence of hypertension with age are directly related to sodium intake. Numerous observational studies, randomized controlled trials, and meta analyses document that high sodium intake increases blood pressure.\textsuperscript{1-11} The public health focus usually has been on reducing hypertension, defined as systolic blood pressure (SBP) of 140 mm Hg or higher, diastolic blood pressure (DBP) of 90 mm Hg or higher, and/or use of antihypertensive medications. However, it is important to emphasize that the risks of developing cardiovascular disease increase as the blood pressure rises progressively over 115/75 mm Hg.\textsuperscript{12-14} This fact further reinforces the need to address risk factors that increase blood pressure, including sodium intake. The current average adult daily sodium intake in the United States approximates 4000 mg/2000 kcal.\textsuperscript{15} Secular trends show a 55 percent increase in sodium intake from the early 1970s to 2008; simultaneously, the age-adjusted prevalence of hypertension has increased by 50 percent.\textsuperscript{16}

Excessive sodium intake has harmful cardiovascular effects independent of its effect on blood pressure. Sodium intake is an independent predictor of left ventricular mass.\textsuperscript{17-19} Additionally, platelet reactivity increases with high dietary sodium intake, and platelet
function is linked to systemic sodium-potassium homeostasis.\textsuperscript{20} A lower-salt diet reduces aortic stiffness, independent of its effect on blood pressure, and studies show that salt intake is linked to arterial compliance.\textsuperscript{21,22} Excess sodium consumption increases calcium excretion and also increases caloric consumption by increasing fluid intake.

In summary, the evidence is overwhelming that excessive sodium intake causes increased morbidity and mortality from cardiovascular disease.\textsuperscript{23-26}

**Recommended Sodium Intake.** A sodium intake of less than 2400 mg/day has been a cornerstone of the National Heart, Lung, and Blood Institute’s National High Blood Pressure Education Program (NHBPEP) recommendations to prevent and manage hypertension since 1993.\textsuperscript{27} In 1998, the American Heart Association adopted a similar recommendation.\textsuperscript{28} In 2002, the United States Department of Health and Human Services established an objective for 2010 that at least 65 percent of the population should consume less than 2400 mg/day of sodium.\textsuperscript{29} Currently, only 20 percent of the population meets that objective.

Results of the DASH-Sodium Trial showed that the most substantial reduction of systolic blood pressure occurred when sodium intake decreased from 2300 mg/day to 1500 mg/day.\textsuperscript{30} Furthermore, the virtual absence of either hypertension or a progressive rise in blood pressure with advancing age in populations with an average sodium ingestion of less than 1400 mg/day supports the concept of a threshold above which the risk of harmful cardiovascular disease consequences begins to increase.\textsuperscript{31}

**Sources of Dietary Sodium.** In the typical U.S. diet, 77 percent of sodium comes from processed and restaurant foods, 12 percent occurs naturally in foods, 6 percent is added at the table, and 5 percent is added during cooking.\textsuperscript{32} Many processed foods contain 1000 mg or more per serving, while typical restaurant meals contain 2300 to 4600 mg of sodium. Although physicians can and should educate patients about reducing sodium intake, even highly motivated individuals find this task difficult because most dietary sodium is derived from salt added by food processors and restaurants. Therefore, any meaningful approach to reducing the population intake of salt and the burden of cardiovascular disease must include a substantial reduction in the sodium content of these foods. A reasonable interim target is a 50 percent reduction in sodium in processed foods, fast foods, and restaurant meals over the next decade. The Healthy People 2010 objective on sodium consumption cannot be met without such action.

**AMA Policies on Dietary Sodium**

The AMA has longstanding policies supporting: 1) the education of the public about foods high in sodium and the relationship of sodium intake to hypertension; 2) efforts by the food industry and restaurants to reduce the sodium content of foods, without compromising safety or nutrition; and 3) the labeling of sodium content of food items offered by fast food proprietors and chain restaurants.
However, excessive sodium consumption by the U.S. population and its profound negative impact on cardiovascular health continues unabated. Furthermore, voluntary efforts to reduce the amount of sodium in processed foods, fast foods, or restaurant meals have been minimal. Therefore, the AMA is convinced that more drastic measures are necessary, and in June 2007 the AMA House of Delegates adopted additional policies that: 1) support a stepwise (gradual), minimum 50 percent reduction in sodium in processed foods, fast food products, and restaurant meals to be achieved over the next decade; 2) direct the AMA to engage the FDA and other partners to educate consumers about the benefits of long-term, moderate reductions in sodium intake, and to consider ways to improve food labeling so that consumers better understand the amount of sodium contained in processed food products, as well as identify food products with high sodium content; and 3) urge the FDA to revoke the “Generally Recognized As Safe” (GRAS) status of salt, and to develop regulatory measures to limit sodium in processed and restaurant foods.

FDA Request for Comments

In Docket No. 2005P-0450, the FDA invited general comments on a citizen petition submitted by the Center for Science in the Public Interest (CSPI) and identified two general issues, each with specific corresponding questions. These issues were: (1) the GRAS status of salt; and (2) food labeling as it relates to sodium. The AMA is pleased to supply the following comments and potential approaches to reducing the American dietary burden of sodium and the incidence of cardiovascular disease.

Issue 1: GRAS Status of Salt. In general, the AMA supports the objectives of the CSPI petition, including revocation of the GRAS status of salt. However, we recognize the complexities involved with this approach, as has been articulated by the FDA. More expedient approaches may be available to begin working to reduce the population burden of sodium in the U.S. immediately, as discussed below. However, absent a solid and immediate commitment from the food and restaurant industries to reduce the amounts of sodium in processed foods, fast foods, and restaurant meals, the AMA believes the FDA must revoke the GRAS status of salt. Clearly, the scientific evidence is overwhelming that current levels of salt added to these products, i.e., as a food additive, are unsafe and increase morbidity and mortality from cardiovascular disease.

Question #2 seeks information on whether reducing the salt content of food, even in a modest way, would impact the safety or quality of various foods given the wide variety of technical functions for which salt is used in food. Although we are uncertain what FDA means by “modest reduction,” the experiences of the United Kingdom (U.K.) may be instructive. The U.K. began a campaign to reduce sodium intake, aimed at the food industry and the public, approximately five years ago. A large number of companies in the U.K. have voluntarily adopted a front-of-package red-yellow-green traffic light system. The sodium contents of fresh and frozen prepackaged meals sold in supermarkets have decreased by 45 percent over the past four years as a result of product reformulation. There is no evidence that either the
safety or the quality of the food supply in the U.K. has been adversely affected by lowering sodium content.

Issue 2: Food Labeling. Food labeling initiatives introduced by the FDA during the last 25 years have provided consumers with more information about the sodium content of foods. FDA regulations currently require declaration of sodium content in the Nutrition Facts panel, provide for health claims of low sodium diets, and stipulate the maximum sodium concentrations for foods that can be labeled “healthy.”

Question #5 asks how the effectiveness of such FDA regulations in reducing salt intake by the public would be described. Although such regulations have provided new information on the sodium content of foods, they have been ineffective in reducing salt intake, which increased more than 50 percent from the 1970s to 2000.16

We are unaware of any data on the potential for “label statements about the health effects of salt” alone to reduce salt intake (Question #6). However, Finland began a major campaign aimed at the food industry and the public to reduce sodium consumption more than 30 years ago. Finland utilizes front-of-package warning labels for foods high in salt and a heart-healthy symbol for foods low in salt. Sodium consumption decreased 40 percent in Finland during this period. Simultaneously, average blood pressures decreased by more than 8 mm Hg.16 Thus, a combination of appropriate food labeling and extensive education appears to have been effective in reducing both sodium consumption and blood pressure in the Finnish population and could be used as a model for the U.S.

Question #7 asks to what extent FDA’s labeling policies provide incentives to manufacturers to reduce the salt content of processed foods. We believe that a real opportunity exists through the use of labeling initiatives to better inform the public and to provide incentives for the food industry to reduce the amount of salt added to the food supply. We propose three alternatives for the FDA to consider in designing new labeling regulations for sodium.

The FDA could follow the lead of the U.K. which divided foods into 30 major categories and then recommended that companies’ products contain no more than the median levels then extant in such products. Coupling this approach with a front-of-package red-yellow-green traffic light system to differentiate high sodium from lower sodium products would assist consumers in making healthy choices. A complementary approach would be to designate any product containing more than 50 mg/ounce as high in sodium and require a front-of-product warning label. A third approach would be to require a five percent per year reduction in sodium for all products designated as high sodium. Each of these three approaches would lead to major reductions in sodium content by food manufacturers. It also would be necessary to embark upon an extensive consumer education campaign if any of these labeling approaches is adopted.
In conclusion, the AMA would be happy to work with the FDA and the food industry to develop appropriate recommendations to reduce the amount of salt added to the food supply, educate consumers, and reduce the population sodium intake.

Thank you for your attention to this important medical and public health issue.

Sincerely,

Michael D. Maves, MD, MBA

attachment
References


April 6, 2009

The Honorable Lynn Woolsey
U.S. House of Representatives
2263 Rayburn House Office Building
Washington, DC 20515

Dear Representative Woolsey:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our support for H.R. 1324, the “Child Nutrition Promotion and School Lunch Protection Act of 2009.” This bill would help confront the epidemic of child obesity by improving the nutritional quality of foods sold in schools outside federally-reimbursed school meal programs.

The prevalence of obesity has increased substantially over the last two decades, particularly among the nation’s children and adolescents. Experts in nutrition science have found that, since the 1970s, obesity rates have tripled among children aged 6 to 19. As a result, obesity-associated illnesses such as non-insulin-dependent diabetes and osteoarthritis are increasingly being observed in our youth. One-quarter of children ages 5 to 10 show early warning signs of heart disease, such as elevated blood cholesterol or high blood pressure.

The AMA strongly supports legislation, such as H.R. 1324, which would require the development and implementation of evidence-based nutrition standards for all food served in schools outside of federally-reimbursed school meals, including a la carte sales, vending machines, school stores, and snack bars. The regulations must apply to all foods made available on school grounds throughout the entire school day. The AMA believes that the battle against obesity cannot be fought on the clinical front alone but requires a collaborative and coordinated effort by many stakeholders, including government, the private sector, local communities, families, schools, physicians, and other health care professionals. The fight against obesity should focus on sites where children spend much of their time, such as schools.
We applaud you for your leadership on this critical public health issue. We look forward to working with you to raise public awareness of the seriousness of obesity and its related disorders, particularly in children, and to develop and implement strategies to help confront the obesity epidemic.

Sincerely,

Michael D. Maves, MD, MBA
October 8, 2008

The Honorable Elias A. Zerhouni, MD
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Zerhouni:

On behalf of the physician and medical student members of the American Medical Association (AMA), I want to share with you our concerns about gaps in the scientific knowledge regarding obesity screening and interventions related to healthy lifestyle behaviors such as healthy eating and regular physical activity. Despite the substantial literature supporting use of body mass index and waist circumference in adults as indicators of overweight and obesity, associations between these indicators and various adverse health outcomes often vary by age, gender, race/ethnicity, and socioeconomic status, which may reflect population-specific differences in body composition, fat distribution, causes of overweight, and genetic susceptibility. Thus, current definitions of normal weight, overweight, and obesity using these indicators may misclassify the health status of some individuals, and in turn, the most appropriate treatments. Intervention trials are needed on the efficacy of clinical screening programs for overweight and obesity to improve mortality, morbidity, and mental health.

Lifestyle behaviors such as unhealthy eating and physical inactivity are modifiable risk factors that may prevent, and reduce the consequences of, obesity and other health conditions and diseases. While healthy eating and physical activity are generally recommended for individuals of any size or body composition, the efficacy of routine dietary and activity counseling in all individuals in primary care settings has yet to be established.

Policy adopted by our House of Delegates supports additional research on the efficacy of screening for overweight and obesity, using different indicators of body fatness, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain. Our policy also supports more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks. These policies are based on a report by the AMA’s Council on Science and Public Health, a copy of which is enclosed.
The AMA commends the National Institutes of Health for its ongoing support of research on obesity and healthy lifestyle behaviors. Further research is essential to improve the clinical utility of obesity screening and clinical interventions to promote and support healthy lifestyle behaviors that may prevent, and limit the health consequences of, obesity and other adverse health outcomes.

Sincerely,

Michael D. Maves, MD, MBA

Enclosure
EXECUTIVE SUMMARY

Objective: To evaluate the clinical utility of measuring body mass index (BMI) and waist circumference in the diagnosis and management of overweight and obesity in adults.

Methods: Reports, statements, and/or guidelines on the measurement of overweight and obesity were obtained from the web sites of government and health professional organizations. The Cochrane Database of Systematic Reviews and the web site of the Agency for Healthcare Research and Quality were searched for reviews related to this topic. Literature searches were conducted in PubMed for English-language review articles published between July 1997 and December 2007 using the search terms “BMI,” “body mass index,” “waist circumference,” “waist hip ratio,” “overweight,” “obesity,” and “guidelines.” Additional articles were identified by reviewing the reference lists of pertinent publications.

Results: BMI is an indirect measure of body fatness that is widely recommended by several government and health professional organizations, including our American Medical Association, to screen for overweight and obesity in adults. Waist circumference measurement is also recommended to help identify individuals at high risk of adverse health outcomes, along with patient history and other clinical measurements. The risk of adverse health outcomes associated with BMI and waist circumference varies with age, gender, race/ethnicity, and socioeconomic status, and may reflect population-specific differences in body composition, fat distribution, causes of overweight, and genetic susceptibility. Thus, current BMI cut-points to define categories of normal weight, overweight, and obesity may misclassify the health status of some individuals. Concern also exists about inconsistent associations between BMI and certain health outcomes, particularly mortality. However, J- and U-shaped associations between BMI and mortality may be due to inadequate control of confounding and/or less aggressive preventive and treatment efforts in individuals classified as normal weight. The clinical utility of waist circumference remains uncertain, in part due to the lack of a standard approach for measurement in research studies. Despite concerns about misclassification of disease risk, BMI and waist circumference are believed to help clinicians and patients monitor changes in body size over time, and thus aid prevention and management efforts. Nevertheless, there is a lack of intervention trials on the efficacy of clinical screening programs for overweight and obesity to improve mortality, morbidity, or mental health.

Conclusions: BMI and waist circumference remain practical estimates of risk of obesity-related conditions and should be included in routine health assessments. However, physician education programs should more clearly highlight the risk differences among ethnic and age groups at varying levels of BMI. At the same time, more research is needed to determine the efficacy of screening programs, using different indicators of body fatness, in decreasing morbidity and mortality, and improving mental health and prevention of weight gain. Likewise, more research is needed on physician screening and interventions related to healthy lifestyle behaviors in all patients to improve health and minimize disease risks.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-A-08

Subject: The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity

Presented by: Mary Anne McCaffree, MD, Chair

Referred to: Reference Committee D
(Robert T. M. Phillips, MD, PhD, Chair)

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Board of Trustees Report 9-A-07 recommended, in part, that our American Medical Association (AMA) ask the Council on Science and Public Health (CSAPH) to critically evaluate the clinical utility of measuring body mass index (BMI) and/or waist circumference in the diagnosis and management of overweight and obesity, with input from leading researchers and key stakeholder organizations.

This report reviews the reports, statements, and/or guidelines of several government and health professional organizations on the measurement of overweight and obesity. It also reviews selected research that supports or challenges these guidelines and recommendations. The report focuses on the use of BMI and waist circumference in adults only, as the AMA recently convened an expert committee to address this issue in children and adolescents.

Current AMA Policy on Measurement of Overweight and Obesity

AMA policies related to measuring overweight and obesity include Policy D-440.971 (AMA Policy Database), which encourages physicians to routinely measure BMI and waist circumference in adults and BMI percentiles in children, while recognizing ethnic sensitivities and the relationship of BMI to stature, and Policy H-150.953, which urges physicians to assess their patients for overweight and obesity during routine medical examinations. See the Appendix for complete policy statements. In addition, recommendations emanating from our AMA’s National Obesity Summit in 2004 encouraged routine measurement of BMI and waist circumference.

Background

BMI is an estimate of body fatness expressed as weight in kilograms divided by height in meters squared (kg/m²). BMI has been widely recommended by several government and health professional organizations, including our AMA, as a useful tool to screen for overweight and obesity in adults. Waist circumference is an estimate of abdominal adiposity that is also recommended by many of these organizations, although it is less widely used clinically. BMI and waist circumference are intended to identify individuals at high risk of adverse health outcomes, along with patient history and other clinical measurements.¹

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Obesity and overweight are currently defined by the National Heart Lung Blood Institute (NHLBI), World Health Organization (WHO), and most health professional and governmental organizations using BMI cut-points, despite evidence that BMI may not correspond to the same degree of body fatness or disease risk in all populations. Some attempts have been made to recommend alternative cut-points or alternate measures of body fatness and/or disease risk. In general, it remains unclear whether the current BMI cut-points have helped clinicians improve patient morbidity and mortality. However, few effective interventions are available to clinicians to reduce BMI in their patients compared with comorbid conditions such as hypertension and diabetes.

Recent estimates indicate that approximately two-thirds of Americans aged 20 to 74 years are classified as overweight or obese based on BMI categories established by the National Institutes of Health. This compares to less than 50% of adults who were deemed overweight or obese before 1980 using the same measures. The increasing trend in overweight in the last 25 years reflects primarily an increase in the obese category (BMI ≥ 30 kg/m²) and a decrease in the percentage of adults in the normal (18.5-25 kg/m²) range. Similarly, abdominal adiposity, as measured by waist circumference, has significantly increased in adults over the last 20 years. The prevalence of obesity is increasing in the United States and throughout the world using either indicator of adiposity.

Categories of body size have research, policy, and clinical applications. While these categories may not be equally applicable across populations for all obesity-related conditions, any revisions to these widely used definitions of overweight and obesity must be carefully considered.

Methods

The web sites of government and health professional organizations were searched for reports, statements, and/or guidelines on the measurement of overweight and obesity. The Cochrane Database of Systematic Reviews and the web site of the Agency for Healthcare Research and Quality were searched for reviews related to this topic. PubMed was searched for English-language review articles published between July 1997 and December 2007 using the search terms “BMI,” “body mass index,” “waist circumference,” “waist hip ratio,” “overweight,” “obesity,” and “guidelines.” Additional articles were identified by reviewing the reference lists of pertinent publications.

Current Classifications of Weight Status

In 1993, the WHO’s Expert Committee on Physical Status recommended classifying overweight adults using BMI categories of 25.0 to 29.9 kg/m² for overweight grade 1, 30.0 to 39.9 kg/m² for overweight grade 2, and ≥ 40.0 kg/m² for overweight grade 3. The panel acknowledged that BMI does not directly measure fat mass or fat percentages, but believed that the possibility of misclassification would have minimal impact as part of an overall health risk assessment that includes abdominal adiposity, smoking and dietary habits, physical activity, blood pressure, serum lipids and glucose, and family history. In 1997, the WHO Consultation on Obesity recommended an additional cut-point at a BMI of 35 kg/m² as part of a three-tiered classification of obesity (Table 1).

In 1998, the NHLBI’s Obesity Education Initiative Expert Panel defined overweight and obesity in adults 18 years of age and older using the same BMI cut-points as the WHO (Table 2). The
NHLBI additionally recommended measuring waist circumference in individuals with BMIs below 35 kg/m², noting an increased relative risk of obesity-associated factors in women with waist circumference greater than 88 cm (35 inches) and in men with waist circumference greater than 102 cm (40 in). These guidelines have been endorsed by many government and professional organizations, including the National Cholesterol Education Program, the National High Blood Pressure Education Program, the North American Association for the Study of Obesity (NAAASO), the Centers for Disease Control and Prevention (CDC), the American Heart Association, the American College of Physicians (ACP), the American College of Preventive Medicine (ACPM), and the US Preventive Services Task Force (USPSTF) (Table 3).

Both the WHO and NHLBI guidelines recognize that current BMI cut-points are not ideal indicators of body size. The WHO expert committees regarded BMI as a crude population-level indicator of obesity and associated risks that does not necessarily coincide with the same degree of adiposity across populations. The 1997 WHO report recommended the development of sex-specific waist circumference cut-points for different populations to further aid in the classification of overweight and obesity, which the NHLBI report did define for the general American population. The WHO and NHLBI recommendations further recognized that BMI may misclassify some individuals on the basis of stature, such as those who are very muscular, less than 5 feet tall, or taller than 6 feet 3 inches. In addition, their recommendations to prevent further weight gain or to lose weight at a given BMI are not intended for pregnant or lactating women, individuals with serious psychiatric illness, or anyone with an illness that may be aggravated by caloric restriction. Moreover, adult BMI scores are not directly applicable to children or young teenagers.

In 2003, a WHO expert consultation recommended retaining the current classifications of overweight and obesity based on BMI, but with additional BMI cut-points of 23, 27.5, 32.5, and 37.5 kg/m² for public health action in many Asian populations. However, the committee failed to establish clear BMI cut-off points for overweight or obesity for all Asians, noting an onset of increased risk varying from 22 to 25 kg/m² across Asian populations, and of high risk varying from 26 to 31 kg/m². In addition, the expert consultation recommended the measurement of waist circumference, particularly in populations predisposed to central adiposity, but did not recommend specific waist circumference cut-points. The WHO has not recommended specific BMI or waist circumference cut-points for other populations, such as Africans or other populations not of European descent.

**Scientific Evidence for Indicators of Overweight and Obesity**

Although numerous governmental and health organizations, including the AMA, endorse the use of BMI and waist circumference to assess and monitor overweight and obesity, these measures, in fact, are screening tools, and are only qualified predictors of risk. BMI is significantly correlated with more accurate measures of body fatness, such as underwater weighing and dual-energy x-ray absorptiometry (DXA), but does not measure it directly. In adults, waist circumference is a measure of central adiposity, but also is not a direct measure. Waist circumference is most useful in further defining risk of overweight and obesity in individuals with a BMI below 35 kg/m²; for BMIs above this value, waist measurement adds little clinical information.

A large body of evidence supports the use of BMI and waist circumference in adults as indicators of underweight, overweight, and obesity. BMI has been the most frequently studied indicator,
and much of the scientific literature has found increased BMI to be associated with several diseases and conditions, including type 2 diabetes, coronary heart disease, high blood cholesterol, stroke, hypertension, gall bladder disease, osteoarthritis, sleep apnea, several cancers (notably endometrial, breast, prostate, and colon cancer), pregnancy complications, menstrual irregularities, stress incontinence, depression, and mortality. The nature of the relationships between BMI and these conditions is generally similar across population groups, although the specific level of risk at a given BMI may differ by age, gender, race/ethnicity, and/or socioeconomic status. These variations in specific risk are important to note, as they may reflect differences in body composition and fat distribution, as well as population-specific causes of overweight and genetic susceptibility to certain diseases.

Waist circumference also has been shown to be an independent predictor of disease risk, particularly of cardiovascular disease (CVD) and CVD risk factors such as hypertension, dyslipidemia, and type 2 diabetes. In fact, waist circumference is considered by some to be as good or better a predictor of CVD, type 2 diabetes, and mortality as BMI. As with BMI, ethnicity, gender, age may modify the specific level of risk associated with a given waist circumference.

**Concerns About Use of BMI and Waist Circumference**

Despite the substantial literature supporting use of BMI and waist circumference in adults, some investigations have not observed direct associations between BMI and waist circumference and various health outcomes, particularly mortality. As noted above, even direct associations between BMI, waist circumference, and health outcomes may vary by ethnicity, stature, and age. These variations in absolute and relative risks have led some researchers and clinicians to question the clinical utility of using BMI, particularly the current BMI cut-points, as clear indicators of overweight and obesity. Concerns are greatest in the normal and overweight classifications; there is less disagreement about the utility of these cut-points in the moderate to severely underweight (< 17 kg/m²) and obese categories.

**Population-Specific Variations in BMI and Health Risk.** Ethnicity, age, and athletic training may affect the relationship between BMI and various health outcomes. For example, some studies have found that risk of complications from overweight are not apparent in African Americans until they reach a BMI greater than 30 kg/m², which may be due to reduced body fatness in African Americans at a given BMI compared to Caucasians. However, other studies have not observed a different relationship between body fatness and BMI in African Americans as compared with Caucasians, and risk of mortality from CVD remains higher in African Americans than in Caucasians, due to part to higher rates of other CVD risk factors in African Americans, such as hypertension and diabetes. Waist circumference may be particularly helpful in clarifying disease risk in older African American women with BMIs in the normal and overweight ranges.

In contrast, the risk of obesity-related disorders has been reported to begin at a lower BMI in some Asian populations than in Caucasian populations. In general, many Asians have a higher percent body fatness than Caucasians of the same age, gender, and BMI. Likewise, the prevalence of Asians with risk factors for type 2 diabetes and CVD is higher than seen in Caucasian populations with BMIs below 25 kg/m². However, there is considerable variation in these associations between Asian populations. For example, a range of higher percentages of body fatness has been observed at low BMIs in Hong Kong Chinese, Singaporean Chinese, Malays,
Indians, Indonesians, and Japanese, as compared with Caucasians, while Polynesians have a lower proportion of body fat compared to Caucasians. However, despite their lower proportion of body fat, Polynesians still have a higher prevalence of diabetes. Similarly, the optimal BMI range for Australian Aboriginals appears to be 17 to 22 kg/m², with adverse metabolic consequences seen at BMI values greater than 22 kg/m². Nevertheless, there are no clear categories for overweight and obesity for all Asians. Research suggests that optimal cut-points for overweight range from 22 to 25 kg/m², and for obesity from 26 to 31 kg/m². Lower cut-points for populations in Hong Kong, Indonesia, and Singapore are not considered appropriate for those in northern China and Japan. A WHO expert consultation on the appropriate BMI categories for Asian populations noted that BMI categories serve merely as a “convenience” for public health and clinical use, and that in reality, increased health risks exist on a continuum with increasing BMI.

In older adults, changes in body composition (loss of fat-free mass, and gains in fat mass) and height alter the association between BMI and body fatness. At any given BMI, body composition changes seen with aging underestimate body fatness and height losses overestimate fatness. Despite these changes, risk of several conditions, including osteoarthritis, type 2 diabetes, sleep apnea, urinary incontinence, cataract, and some cancers are directly associated with BMI in older adults. Mortality risk is also related to BMI in older adults, although the relationship is more nuanced than in younger and middle-aged adults. As age increases, the relative risk of mortality associated with BMI decreases, leading some to argue that obesity is not as harmful in older adults as in younger and middle-aged adults. However, the absolute risk of mortality associated with BMI continues to increase with age, until approximately age 75 years; the apparent lack of association after age 75 years may be due to other competing risks or unique subgroup resistance to the adverse health effects of obesity.

Current BMI cut-points do not reflect the same level of body fatness in highly trained athletes, such as those participating in college sports or even former professional athletes. However, this does not apply to all athletes; for example, football linemen tend to have significantly higher BMIs than their fellow football players and other athletes, with correspondingly higher percent body fatness and greater risk for obesity-related conditions, such as high blood pressure and sleep apnea.

Such variation in risk has led to arguments that a BMI cutoff of 25 kg/m² to classify individuals as overweight is too conservative in certain populations and may stigmatize some individuals unnecessarily. In contrast, others argue that current cut-points result in lost opportunities to prevent or treat obesity-related conditions in some individuals currently classified as “normal” weight. Therefore, based on the above considerations, the current cut points for BMI probably misclassify some individuals, but the extent of such misclassification is unknown, as is the real impact of any stigmatization that may be associated with being classified as overweight or obese based on BMI alone.

Concerns About Waist Circumference. Waist circumference is not universally accepted as an optimal measure of abdominal adiposity, as some studies have found waist-to-hip ratio or waist-to-height ratio to be better predictors of cardiovascular risk. As noted above, ethnicity, age, and gender may modify the specific level of risk associated with a given waist circumference, although ethnicity and age-specific cut-points are still lacking. Furthermore, a consensus panel convened in 2006 by NAASO—the Obesity Society; the American Diabetes Association; and Shaping America’s Health: Association for Weight Management and Obesity Prevention—
concluded that a standardized approach for measuring waist circumference in research studies does not exist, as the optimal site at which waist circumference is most strongly correlated with abdominal adipose tissue is variable and the concomitant disease risk has not been established.\textsuperscript{10} The panel concluded that there was not sufficient evidence that waist circumference provided enough additional information beyond BMI, blood pressure, and blood glucose and lipid levels to warrant its use clinically.\textsuperscript{10} In addition, waist circumference has not as been as well-studied with many health outcomes other than CVD and its risk factors.

Reasons for Inconsistent Associations between BMI and Mortality. Perhaps the most controversy over the use of body size classifications has revolved around the association between BMI and mortality. Some concern focuses on the usefulness of BMI categories, as a number of studies have found that BMI values in the overweight range (25.0-29.9 kg/m\textsuperscript{2}) are not strongly associated with mortality as compared with BMI values in the normal range (18.5-24.9 kg/m\textsuperscript{2}).\textsuperscript{32-35} Of even greater concern are observed differences in the shape of the relationship between BMI and mortality. While many studies have reported direct, linear associations between BMI and mortality,\textsuperscript{36-40} other studies observed J- or U-shaped associations\textsuperscript{18,41,42} between BMI and mortality.\textsuperscript{33,41,42} However, the causes of death at low and high BMIs differ. At low BMIs, mortality is more likely due to digestive and pulmonary disease than at higher BMIs, where mortality is often due to CVD, diabetes, and gallbladder disease.\textsuperscript{4}

It has been argued that J- or U-shaped associations between BMI and mortality reflect inadequate control of confounding variables.\textsuperscript{1,4,37} A significant confounder is smoking, or inadequate measurement of smoking status. Early mortality due to pre-existing clinical or subclinical illness could also increase mortality risk at low BMIs. In addition, inappropriate adjustment for risk factors in the causal pathway, such as hypertension, hyperlipidemia, and diabetes, may result in underestimation of risks associated with overweight.\textsuperscript{4}

While these potential confounders are widely known, they continue to be inadequately controlled for in study designs or analyses. For example, a recent study analyzed smoking status only as “current” or “not current,”\textsuperscript{53,34} while another study did not include smoking at all in statistical models.\textsuperscript{43} Some studies also fail to account for interactions between BMI and smoking.\textsuperscript{41,42} Other studies have not accounted for pre-existing disease\textsuperscript{34} or early deaths.\textsuperscript{42} Some argue that excluding people with early deaths may not reduce bias and may have little impact on the association between BMI and mortality.\textsuperscript{44} However, the lack of impact may be due, in part, to a loss of statistical power that comes from sample size reductions.\textsuperscript{37} A recent analysis systematically demonstrated how potential sources of bias are not carefully and comprehensively accounted for in study design and statistical analyses.\textsuperscript{37} Unfortunately, it can be difficult to judge the thoroughness of statistical analyses from the limited information provided in the methods sections of many published articles; in other words, merely “adjusting for smoking” may not be sufficient to adequately address potential bias and confounding due to smoking.

J- or U-shaped associations may also reflect the possibility that people in the “normal” weight range are not as aggressively screened or treated for additional cardiovascular or other risk factors.

\textsuperscript{1} J- and U-shaped associations reflect increased mortality at both lower and higher ranges of BMI values. Thus, the lowest risk of mortality is observed in the normal, overweight, and/or obesity class I categories of BMI.
A comparison of relative risks of mortality associated with different levels of BMI across National Health and Nutrition Examination Surveys (NHANES) I (1971-1975), II (1976-1980), and III (1988-1994) found that the impact of obesity on mortality appeared to decrease over time, possibly due to improved medical care, particularly for CVD. Indeed, other analyses have found significantly greater decreases in total cholesterol levels and blood pressure in individuals classified as overweight and obese compared to those classified as normal weight. These decreases paralleled significant increases in the use of cholesterol and blood pressure medications, with the most marked increases seen among overweight and obese adults.

Advantages of Using BMI and Waist Circumference

Direct measures of body fatness, such as in vivo neutron inactivation analysis (IVNAA), are expensive and uncommon. Indirect methods, such as densitometry and DXA, are more accurate than the doubly indirect methods of BMI, waist circumference, and bioelectrical impedance, but are still relatively expensive and time consuming. Because they are simple, rapid, and inexpensive, BMI and waist circumference are more practical for use in clinical settings than other measures of body fatness.

Both BMI and waist circumference are believed to help both clinicians and patients monitor changes in body size over time, which may aid efforts to prevent and manage obesity-related diseases. In obese adults with obesity-related diseases, modest weight loss of 5% to 10% of body weight may improve health. In adults who are classified as overweight or obese without obesity-related comorbid conditions, lifestyle interventions may decrease the risk of developing these conditions and prevent further weight gain. BMI can also help screen for conditions related to underweight, including anorexia nervosa.

Waist circumference provides an estimate of abdominal adiposity, which can predict risk of cardiometabolic disease above and beyond BMI. Waist circumference may be easier for the public to understand than BMI, and may be a useful gauge of healthy lifestyle interventions in patients whose BMI is unchanging.

BMI in particular is an easy tool for monitoring obesity at the population level for public health and policy decisions. Cut-points inform policymakers of the percentage of the population at high risk of an adverse health outcome. Changing the cut-points would change the proportion of individuals receiving treatment, as well as the nature and extent of prevention efforts; this could in turn have both short- and long-term financial effects on government, health insurers, and individuals. BMI and waist circumference are also useful to assess the effect of interventions, as well as for estimating economic costs of obesity-related conditions.

Disadvantages of Using BMI and Waist Circumference

BMI and waist circumference measures are not intended to be the sole indicators of an individual’s disease risk. For example, normal-weight obese syndrome has been described in which individuals have a normal weight and BMI (<25 kg/m²), but have a fat mass > 30%. These individuals do not have metabolic syndrome, but do have higher plasma levels of proinflammatory cytokines, which may raise their risk of later developing obesity, metabolic syndrome, and/or CVD. In addition, people with BMIs below 25 kg/m² may present with insulin resistance, hyperinsulinemia, and dyslipidemia, while some individuals with BMIs greater than 30 kg/m² and...
excess body fat may be metabolically healthy (i.e., have high insulin sensitivity and normal blood pressure and lipid levels).\textsuperscript{48,49} Furthermore, weight gain in adulthood has been associated with increased morbidity and mortality, independent of baseline weight.\textsuperscript{4} Thus, monitoring changes in body weight throughout life, as well as monitoring other indicators of disease risk, such as hypertension and dyslipidemia, are necessary to assess an individual’s health status.

Categories of overweight and obesity using current cut-points may misclassify the health status of some individuals. As noted above, cut-points for BMI and waist circumference as indicators of overweight or obesity do not apply equally well across all populations. However, multiple cut-points for multiple populations could be confusing, particularly in locations where residents are of mixed cultural, ethnic, and racial heritage.\textsuperscript{7}

Specific to waist circumference, trained staff are needed to properly perform this measurement, making it less widely used.\textsuperscript{3} Like BMI, waist circumference may not be useful in very short (under 5 feet) individuals, nor does it appear to add additional risk information in those with a BMI \( \geq 35.0 \text{kg/m}^2 \). In addition, waist circumference has been correlated with fewer health outcomes than BMI. Also, there is currently no evidence that reducing either waist circumference or BMI through procedures such as liposuction will reduce risk of adverse health outcomes.\textsuperscript{50}

In addition, concern exists that overemphasis on BMI or body size alone, without appropriate counseling on healthy lifestyle behaviors, may contribute to unhealthy behaviors or eating disorders, although dieting has not been associated with increased risk of eating disorders in adults.\textsuperscript{51} Moreover, overattention to body size may detract from other modifiable risk factors, such as diet and physical activity, which are often independently associated with adverse health outcomes.\textsuperscript{16,52,53}

Furthermore, there is little evidence that obesity screening programs improve mortality or morbidity. A 2003 report by the USPSTF did not find any randomized controlled trials that tested the efficacy of obesity screening programs in improving mortality, morbidity, or mental health. Likewise, the report found only limited evidence on the effectiveness of weight loss on clinical outcomes.\textsuperscript{54} Another review also concluded that screening for obesity is unlikely to improve morbidity and mortality, due to misclassification of many individuals and lack of effective treatments for obesity.\textsuperscript{16}

Screening and Promotion of Healthy Diets and Physical Activity

Since BMI is not the only modifiable risk factor for most conditions, it is also important to monitor other indicators of risk, including high blood pressure and blood cholesterol levels, weight change, and physical inactivity. Healthy diets and physical activity are already recommended for the management of overweight and obesity by the ACP.\textsuperscript{55} Similarly, the USPSTF recommends high-intensity counseling about diet and/or physical activity, combined with other behavioral interventions, to promote sustained weight loss in obese adults.\textsuperscript{54} The USPSTF also recommends moderate to high intensity behavioral dietary counseling for adults with hyperlipidemia and/or other known risk factors for cardiovascular and other diet-related chronic diseases.\textsuperscript{56} However, the USPSTF found insufficient evidence to support moderate or low-intensity counseling and behavioral interventions in overweight and obese adults, as there is little direct evidence that these interventions lower mortality or morbidity related to obesity. Nevertheless, some organizations recommend healthy lifestyle counseling of varying degrees to individuals regardless of their BMI.
For example, the American Academy of Family Physicians (AAFP) recommends that all patients aged 2 years and older be advised to “maintain caloric balance.” The AAFP also developed a program called “Americans in Motion” (AIM) to encourage physical activity, healthy nutrition, and emotional well-being in all individuals, families, and communities. While healthy diets and physical activity have many health benefits beyond weight loss, and are recommended for healthy individuals of any size or body composition, the efficacy of routine dietary counseling in all individuals in primary care settings has yet to be established.

Summary and Conclusion

Overall, BMI and waist circumference are simple and affordable tools that help physicians identify changes in body size early, and that support efforts to maintain weight or achieve a modest weight reduction that will provide optimal health benefits to their patients. Both waist circumference and BMI are independent predictors of disease risk. Neither measure alone can predict a patient’s absolute disease risk; rather, clinicians should consider these values in conjunction with other information, such as the presence of other diseases, other disease risk factors, and family history. While BMI may inappropriately classify as overweight some individuals who are not at increased risk of disease, it is a useful tool that currently serves as a prompt to screen for other risk factors. However, individuals with normal BMIs should not be assumed to be risk-free, and should likewise be monitored for changes in body size and assessed for other disease risk factors.

The research, policy, and clinical effects of changing the current definitions for overweight and obesity must be carefully considered. BMI currently has wide acceptance as an indicator of overweight and obesity. The NHLBI and WHO reports are careful to point out that BMI is only one of several tools to use in assessing a patient’s risk of adverse health conditions, and concern exists about stigmatizing people at relatively low disease risk as overweight or obese. The benefit of measuring waist circumference on a regular basis in clinical settings appears unclear, as it requires additional training of staff and increased office visit time. Of great concern to some physicians and researchers is the differential association between BMI and disease risk across some populations. However, disease risk is not homogeneous even within ethnic or cultural groups, such as “Europeans,” “Asians,” and “Africans.” Multiple cut-points for multiple populations could be confusing, particularly in locations where people are of mixed cultural, ethnic, and racial heritage. Optimal BMI cut-points also may vary by health outcome.

At the present time, it appears more research is needed that specifically examines how health outcomes may vary across populations that are screened using different indicators of overweight and obesity. More research is also needed to address concerns such as patient stigma and utility of waist circumference vs. BMI in clinical settings. Research studies on mortality should carefully address confounding and bias, including the effect of treatment for comorbid conditions (such as medications for hypertension or high cholesterol) among overweight and obese individuals. Perhaps most important is the need for research on effective interventions, at both the individual- and population-level, to prevent and treat adverse health outcomes related to unhealthy body weight, regardless of how body weight is categorized.

In general, the relative risk of adverse health outcomes appears to increase with increasing body size. Thus, measurements of body size, however crude, should be done to monitor change in body size over time, as part of a comprehensive health examination. While more research is needed about the effectiveness of lifestyle counseling by physicians in all patients, there is evidence that
high risk individuals may benefit from such counseling. Prevention of weight gain in adulthood should be encouraged in most patients, outside of pregnancy, intense athletic training, or necessary weight restoration following starvation or illness.

RECOMMENDATIONS
The Council on Science and Public Health recommends that the following be adopted and the remainder of this report be filed:

1. That our American Medical Association (AMA) reaffirm Policy D-440.971, “Recommendations for Physician and Community Collaboration on the Management of Obesity,” which encourages physicians to incorporate body mass index (BMI) and waist circumference as a component measurement in the routine adult physical examination, recognizing ethnic sensitivities and its relationship to stature. (Reaffirm HOD Policy)

2. That our AMA support greater emphasis in physician educational programs on the risk differences among ethnic and age groups at varying levels of BMI and the importance of monitoring waist circumference in individuals with BMIs below 35 kg/m². (Directive to Take Action)

3. That our AMA support additional research on the efficacy of screening for overweight and obesity, using different indicators, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain. (Directive to Take Action)

4. That our AMA support more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks. (Directive to Take Action)

Fiscal Note: $1000
References


### TABLE 1. World Health Organization classification of adult weight by BMI$^{6,7}$

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
<th>Risk of comorbidities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
<td>Low (but risk of other clinical problems increased)</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.50-24.99</td>
<td>Average</td>
</tr>
<tr>
<td>Overweight</td>
<td>≥ 25.00</td>
<td></td>
</tr>
<tr>
<td>Preobese</td>
<td>25.00-29.99</td>
<td>Increased</td>
</tr>
<tr>
<td>Obesity</td>
<td>≥ 30.00</td>
<td></td>
</tr>
<tr>
<td>Obese class I</td>
<td>30.00-34.99</td>
<td>Moderate</td>
</tr>
<tr>
<td>Obese class II</td>
<td>35.00-39.99</td>
<td>Severe</td>
</tr>
<tr>
<td>Obese class III</td>
<td>≥ 40.00</td>
<td>Very severe</td>
</tr>
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</table>

### TABLE 2. National Heart Lung and Blood Institute classifications of overweight and obesity by BMI and waist circumference in adults$^1$

<table>
<thead>
<tr>
<th></th>
<th>Risk of type 2 diabetes, hypertension, and CVD relative to normal weight and waist circumference*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BMI (kg/m²)</td>
</tr>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
</tr>
<tr>
<td>Normal weight</td>
<td>18.5 – 24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25.0 – 29.9</td>
</tr>
<tr>
<td>Obesity (Class I)</td>
<td>30.0 – 34.9</td>
</tr>
<tr>
<td>Obesity (Class II)</td>
<td>35.0 – 39.9</td>
</tr>
<tr>
<td>Extreme obesity (Class III)</td>
<td>≥ 40</td>
</tr>
</tbody>
</table>

*NHLBI guidelines note that increased waist circumference can indicate increased disease risk even in individuals considered normal weight.
<table>
<thead>
<tr>
<th>Organization</th>
<th>Policy, recommendation, and/or guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMA</td>
<td>Encourages physicians to properly screen for overweight and obesity using BMI and waist circumference in adults, while recognizing ethnic sensitivities and their relationship to stature (also see Appendix). National Obesity Summit recommendations encourage routine measurement of BMI and waist circumference.</td>
</tr>
<tr>
<td>American Academy of Family Physicians (AAFP)</td>
<td>Recommends measuring height and weight periodically in all patients and uses CDC definitions of overweight and obesity. The AAFP has educational toolkits to help physicians measure BMI.</td>
</tr>
<tr>
<td>American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE)</td>
<td>Recommend assessing body fat via weight-for-height, BMI, waist-to-hip ratio, waist circumference, and “any other valid methods” as part of a comprehensive medical examination.</td>
</tr>
<tr>
<td>American College of Preventive Medicine (ACPM)</td>
<td>Recommends periodic measurement of BMI in all adults and endorses the NIH practical guidelines in advising overweight and obese patients.</td>
</tr>
<tr>
<td>American Heart Association and the American College of Cardiology Foundation</td>
<td>Recommend screening for both BMI and waist circumference, but note that some obese people classified as obese may have normal amounts of body fat and a large muscle mass and are not at increased risk of coronary heart disease (CHD), while some people with a normal BMI have high body fat and small muscle mass and are at increased risk of CHD.</td>
</tr>
<tr>
<td>Health Canada Guidelines for Body Weight Classification in Adults</td>
<td>Classify body weight using same BMI and waist circumference categories as WHO and NHLBI as part of overall health risk assessment.</td>
</tr>
<tr>
<td>The Endocrine Society and the Hormone Foundation</td>
<td>Overweight and obesity classified using NHLBI definitions.</td>
</tr>
<tr>
<td>National Heart, Lung, and Blood Institute (NHLBI) and the North American Association for the Study of Obesity (NAASO)</td>
<td>Body weight classified using categories of BMI (kg/m²) as defined in Table 2. Recommends measuring waist circumference in individuals with a BMI of 25-34.9 kg/m²</td>
</tr>
<tr>
<td>US Preventive Services Task Force (USPSTF)</td>
<td>Recommends screening for overweight and obesity using BMI²4</td>
</tr>
<tr>
<td>World Health Organization (WHO)</td>
<td>Body weight classified using categories of BMI (kg/m²) as defined in Table 1. Additional cut-points of 23, 27.5, 32.5, and 37.5 kg/m² are recommended for public health action in many Asian populations. Recommends measuring waist circumference but has not defined cut-points.</td>
</tr>
</tbody>
</table>
APPENDIX.

Relevant AMA policy related to obesity

Policy D-440.971 Recommendations for Physician and Community Collaboration on the Management of Obesity

Our AMA will: (1) work with the Centers for Disease Control and Prevention to convened relevant stakeholders to evaluate the issue of obesity as a disease, using a systematic, evidence-based approach; (2) continue to actively pursue measures to treat obesity as an urgent chronic condition, raise the public's awareness of the significance of obesity and its related disorders, and encourage health industries to make appropriate care available for the prevention and treatment of obese patients, as well as those who have co-morbid disorders; (3) encourage physicians to incorporate body mass index (BMI) and waist circumference as a component measurement in the routine adult physical examination, and BMI percentiles in children recognizing ethnic sensitivities and its relationship to stature, and the need to implement appropriate treatment or preventive measures; (4) promote use of our Roadmaps for Clinical Practice: Assessment and Management of Adult Obesity primer in physician education and the clinical management of adult obesity; (5) develop a school health advocacy agenda that includes funding for school health programs, physical education and physical activity with limits on declining participation, alternative policies for vending machines that promote healthier diets, and standards for healthy a la carte meal offerings. Our AMA will work with a broad partnership to implement this agenda; and (6) collaborate with the CDC, the Department of Education, and other appropriate agencies and organizations to consider the feasibility of convening school health education, nutrition, and exercise representatives, parents, teachers, and education organizations, as well as other national experts to review existing frameworks for school health, identify basic tenets for promoting school nutrition and physical activity (using a coordinated school health model), and create recommendations for a certificate program to recognize schools that meet a minimum of the tenants. (CSA Rep. 4, A-05)

H-150.953 Obesity as a Major Public Health Program

Our AMA will: (1) urge physicians as well as managed care organizations and other third party payers to recognize obesity as a complex disorder involving appetite regulation and energy metabolism that is associated with a variety of comorbid conditions; (2) work with appropriate federal agencies, medical specialty societies, and public health organizations to educate physicians about the prevention and management of overweight and obesity in children and adults, including education in basic principles and practices of physical activity and nutrition counseling; such training should be included in undergraduate and graduate medical education and through accredited continuing medical education programs; (3) urge federal support of research to determine: (a) the causes and mechanisms of overweight and obesity, including biological, social, and epidemiological influences on weight gain, weight loss, and weight maintenance; (b) the long-term safety and efficacy of voluntary weight maintenance and weight loss practices and therapies, including surgery; (c) effective interventions to prevent obesity in children and adults; and (d) the effectiveness of weight loss counseling by physicians; (4) encourage national efforts to educate the public about the health risks of being overweight and obese and provide information about how to achieve and maintain a preferred healthy weight; (5) urge physicians to assess their patients for overweight and obesity during routine medical examinations and discuss with at-risk patients the health consequences of further weight gain; if treatment is indicated, physicians should encourage and facilitate weight maintenance or reduction efforts in their patients or refer them to a physician
with special interest and expertise in the clinical management of obesity; (6) urge all physicians and patients to maintain a desired weight and prevent inappropriate weight gain; (7) encourage physicians to become knowledgeable of community resources and referral services that can assist with the management of overweight and obese patients; and (8) urge the appropriate federal agencies to work with organized medicine and the health insurance industry to develop coding and payment mechanisms for the evaluation and management of obesity. (CSA Rep. 6, A-99)
May 8, 2008

The Honorable Jeff Bingaman  
United States Senate  
703 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Bingaman:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express the AMA’s support for S. 866, the Health Promotion Funding Integrated Research, Synthesis, and Training (FIRST) Act.” This bill would encourage the federal government to build a more comprehensive and coordinated plan to develop the basic and applied science of health promotion, synthesize research results into practical guidelines, and disseminate findings to researchers, practitioners, and policy makers.

The Health Promotion FIRST Act is consistent with AMA policy strongly supporting health promotion and disease prevention initiatives, including research. AMA policy specifically supports funding and policy support for all aspects of biomedical science and research, including studies to assess implementation of health promotion and/or disease prevention activities. This legislation, by strengthening the scientific base of health promotion information in the United States, would help Americans lead healthier lives, which is a top priority of the AMA.

We are pleased to support S. 866, and look forward to working with you to advance through Congress this and similar legislation to promote healthier lifestyles for Americans.

Sincerely,

Michael D. Maves, MD, MBA
October 8, 2008

The Honorable Edward T. Schafer, MBA
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Ave., SW
Washington, DC 20250

Dear Secretary Schafer:

On behalf of the American Medical Association (AMA), I am writing to express the concerns of our member physicians about gaps in the scientific knowledge regarding high fructose corn syrup (HFCS) and the impact this may have on recommendations regarding its use in the food supply. Policy recently adopted by our House of Delegates supports the need for independent research, including epidemiological studies, on the health effects of HFCS and other sweeteners, and evaluation of the mechanism of action and relationship between fructose dose and response. This policy is based on a report by the AMA’s Council on Science and Public Health, a copy of which is enclosed.

The literature on HFCS consists mostly of ecological or small, short-term experimental studies, many of which have been industry-supported. While it appears unlikely that HFCS contributes more to adverse health outcomes than sucrose, few studies have evaluated the potentially differential effect of various sweeteners on chronic health conditions such as obesity, which develop over relatively long periods of time. Research is also lacking on the possible effects of different sweeteners in various subpopulations, including overweight and obese individuals, or those at risk of obesity. Improved nutrient and food composition databases are needed to analyze food consumption in epidemiological studies, as are more strongly designed experimental studies.

While AMA policy also recognizes that at the present time there is insufficient evidence to specifically restrict use of high fructose corn syrup in the food supply, we support the recommendation of the Dietary Guidelines for Americans that consumers limit the amount of all added caloric sweeteners in their diet.

The AMA commends the U.S. Department of Agriculture for its support of research on natural and artificial sweeteners. Further research is essential to improve our understanding of the effects of high fructose corn syrup and other sweeteners on health.

Sincerely,

Michael D. Maves, MD, MBA

Enclosure
REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-08)
The Health Effects of High Fructose Syrup
(Resolution 407, A-07)
(Reference Committee D)

EXECUTIVE SUMMARY

Objective: To review the chemical properties and health effects of high fructose corn syrup (HFCS) in comparison to other added caloric sweeteners and to evaluate the potential impact of restricting use of fructose-containing sweeteners, including the use of warning labels on foods containing high fructose syrups.

Methods: Literature searches for articles published through December 2007 were conducted in the PubMed database and the Cochrane Database of Systematic Reviews using the search terms “high fructose corn syrup” and “high fructose syrup.” Web sites managed by federal and world health agencies, and applicable professional and advocacy organizations, were also reviewed for relevant information. Additional articles were identified by reviewing the reference lists of pertinent publications.

Results: HFCS has been increasingly added to foods since its development in the late 1960s. The most commonly used types of HFCS (HFCS-42 and HFCS-55) are similar in composition to sucrose, consisting of roughly equal amounts of fructose and glucose. The primary difference is that these monosaccharides exist free in solution in HFCS, but in disaccharide form in sucrose. The disaccharide sucrose is easily cleaved in the small intestine, so free fructose and glucose are absorbed from both sucrose and HFCS. The advantage to food manufacturers is that the free monosaccharides in HFCS provide better flavor enhancement, stability, freshness, texture, color, pourability, and consistency in foods in comparison to sucrose. Concern about HFCS developed after ecological studies, using per capita estimates of HFCS consumption, found direct correlations between HFCS and obesity. In addition, human and animal studies have found direct associations between fructose and adverse health outcomes. However, the adverse health effects of HFCS, beyond those of other caloric sweeteners, most of which contain fructose, are not well established. Consumption of added caloric sweeteners in general has increased over the last 30 years, as has total calories. Likewise, rates of obesity have risen even in countries where little HFCS is consumed. Only a few small, short-term experimental studies have compared the effects of HFCS to sucrose, and most involved some form of industry support. Epidemiological studies on HFCS and health outcomes are unavailable, beyond ecological studies, because nutrient databases do not contain information on the HFCS content of foods and have only limited data on added sugars in general.

Conclusions: Because the composition of HFCS and sucrose are so similar, particularly on absorption by the body, it appears unlikely that HFCS contributes more to obesity or other conditions than sucrose. Nevertheless, few studies have evaluated the potentially differential effect of various sweeteners, particularly as they relate to health conditions such as obesity, which develop over relatively long periods of time. Improved nutrient databases are needed to analyze food consumption in epidemiological studies, as are more strongly designed experimental studies. At the present time, there is insufficient evidence to restrict use of HFCS or other fructose-containing sweeteners in the food supply or to require the use of warning labels on products containing HFCS.
Resolution 407 (A-07), introduced by the International Medical Graduates Section at the 2007
American Medical Association (AMA) Annual Meeting and referred to the Board of Trustees, asks:

That our AMA urge the US Food and Drug Administration (FDA) and the US Department of
Agriculture (USDA) to require the food industry to use non-fructose sweeteners and limit the
use of high fructose syrups in their products; and

That our AMA urge the FDA and USDA to require the food industry to clearly label products
containing high fructose syrups with an indication that “this product contains high fructose
syrup; excessive intake of high fructose syrup may lead to obesity.”

This report reviews the chemical properties and health effects of high fructose corn syrup (HFCS) in
comparison to other added caloric sweeteners and evaluates the potential impact of restricting the use
of fructose-containing sweeteners, including the use of warning labels on foods that contain high
fructose syrups.

Current AMA Policy on Food and Nutrition Labeling and Poor Nutritional Value of Added Sugars

AMA Policy H-150.971 (AMA Policy Database) on food labeling and advertising states that
“warning statements on food labels are not appropriate for ingredients that have been established as
safe for the general population.” This policy further states that the FDA has not defined descriptors
for foods that are relatively higher in sugar than other foods because there are no established scientific
data indicating the level at which sugars would become harmful in an individual food.

Other AMA policies encourage restaurants and schools to limit their use of added sugars. Policy
H-150.945 urges restaurants to improve the nutritional quality of menu items by using less added
sugars and sweeteners. Policies H-150.960 and D-150.987 support the replacement of sugar-added
products in schools with healthier alternatives. (See Appendix for complete policy statements.)

Methods
Literature searches for articles published though December 2007 were conducted in the PubMed database and the Cochrane Database of Systematic Reviews using the search terms “high fructose corn syrup” and “high fructose syrup.” Web sites managed by federal and world health agencies, and applicable professional and advocacy organizations, were also reviewed for relevant information, including the World Health Association, the USDA, and the Corn Refiners Association. Additional articles were identified by reviewing the reference lists of pertinent publications.

Background

High fructose syrups (HFS) are sweeteners produced from starches such as corn, rice, tapioca, wheat, potato, and cassava.\(^1\) Corn is the primary starch used to produce HFS in the United States, which manufactures more HFS than any other country;\(^2\) thus, HFCS is the most prevalent HFS.

HFCS is pervasive in the US food supply, found in many breakfast cereals, beverages, breads, sauces, spreads, salad dressings, canned fruits, snack foods, desserts, meat and fish products, condiments, dairy products, frozen dinners, soups, and other products.\(^3\) Rising rates of obesity since the early 1980s, shortly after HFCS was widely introduced into the US food supply, have fueled concerns about its potential adverse health effects. The adverse metabolic effects of fructose have likewise raised concerns about excessive amounts of fructose in the American diet.

Generally Recognized as Safe Status of HFCS

The FDA has affirmed (1983) and reaffirmed (1996)\(^4,5\) the generally recognized as safe (GRAS) status of HFCS. There is no limitation on its use beyond good manufacturing process.\(^5\)

Sweeteners in the Food Supply

Caloric sweeteners include sugar (sucrose), HFCS, honey, molasses, crystalline fructose, and fruit juice concentrates. As described below, most caloric sweeteners contain fructose and all provide 4 kcal per gram. The most commonly used sweeteners are refined sugars and HFCS, which account for 45% and 42%, respectively, of added caloric sweeteners in the US food supply.\(^6\) Corn-derived glucose (dextrose) and glucose syrups comprise an additional 12% of the added sweetener market, with honey and edible syrups (maple syrup, molasses, etc.) comprising the remaining 1%.\(^6\) The per capita availability of crystalline fructose and fruit juice as sweeteners is not tracked by the USDA’s Economic Research Service.

Low-calorie and non-nutritive sweeteners are increasingly used in food products,\(^7\) although the per capita use of these sweeteners is not available from the Economic Research Service. Sugar alcohols, also known as polyols, are not fully absorbed from the gastrointestinal tract, and provide an average of 2 kcal per gram (range: 0.2–3.0 kcal/g).\(^8,9\) These low-calorie sweeteners include sorbitol, mannitol, xylitol, erythritol, isomalt, lactitol, maltitol, and hydrogenated starch hydrolysates.\(^8,9\) Tagatose and trehalose are sugars that are similar to the sugar alcohols in function and provide 2 kcal and 4 kcal per gram, respectively.\(^9\) Non-nutritive sweeteners include sucralose, neotame, aspartame, acesulfame potassium, and saccharin. The non-nutritive sweeteners do not contain any calories, except for aspartame, which has 4 kcal per gram. Due to their intense sweetness, very small quantities of these non-nutritive sweeteners are needed, making the amount of energy actually consumed even from aspartame negligible.\(^8\)
Since 1966, the amount of added caloric sweeteners in the US food supply increased 27%, from 113 pounds per person per year to 143 pounds per person per year in 2005. Increased consumption of soft drinks and fruit drinks contributed to more than half of this increase in added sugar intake. The availability of HFCS in the food supply grew more than 100-fold since its introduction in 1967. Meanwhile, availability of sucrose (from refined cane and beet sugars) decreased 33%. HFCS, at a cost of 14 cents per pound, is half the price of sugar (sucrose), which cost 30 cents per pound in 2005. However, use of HFCS appears to have leveled off, after peaking in 1999 at 64 pounds per person, with 59 pounds per person in 2005. This appears to be due to the increased use of non-caloric sweeteners, as reflected by the increased availability of diet soft drinks and bottled water, and declines in consumption of regular soft drinks. Increased corn prices in response to ethanol production are expected to have little impact on the price of HFCS, raising the price of soft drinks by an expected 1%. Chemical Properties of HFCS Compared with Sugar

The term “high fructose corn syrup” implies that the syrup is primarily comprised of fructose. However, the types of HFCS used in most food products are only high in fructose as compared with regular corn syrup, which does not contain any fructose. Regular corn syrup is mainly used as a non-sweet thickener and consists of pure glucose and sucrose polymers. HFCS was developed in 1967 through the partial enzymatic isomerization of glucose to fructose, resulting in HFCS-42, which contains 42% fructose, 53% glucose, and 5% higher saccharides (Table). In the 1970s, HFCS-90 was developed (90% fructose) and combined with HFCS-42 to create HFCS-55 (55% fructose).

The monosaccharide content of HFCS-42 and HFCS-55 is similar to sucrose (table sugar), which is a disaccharide composed of 50% fructose and 50% glucose. In contrast to sucrose, the monosaccharides fructose and glucose exist free in solution in HFCS. In addition, HFCS-42 and HFCS-55 have significantly higher moisture contents than sucrose (29% and 23% versus 5%, respectively).

Other caloric sweeteners (with the exception of pure glucose) contain similar or even higher amounts of fructose. Honey has a molecular composition similar to sucrose and HFCS, as does molasses, which is the least refined form of sugar (Table). Fruit juices also contain similar amounts of fructose, although the exact composition varies by type. For example, orange and grape juices have equal amounts of fructose and glucose, while apple juice has about twice as much fructose as glucose (Table). Crystalline fructose, which can be made from HFCS as well as from sucrose, contains 98% to 100% fructose. Crystalline fructose is the sweetest monosaccharide, with a sweetness of 173 relative to crystalline sucrose, which as the standard has a reference value of 100 (glucose has a relative sweetness score of 74).

The different types of HFCS have distinct uses in food production. HFCS-55 was formulated to have the same level of sweetness as sucrose and is used primarily in carbonated soft drinks, other sweetened beverages, ice cream, and frozen desserts. HFCS-42 has less fructose than sucrose and is therefore slightly less sweet. HFCS-42 is used in baked goods, canned fruits, condiments, dairy products, and other products. HFCS-90 is used to produce HFCS-55, as well as in “light” foods, where only a small amount is needed due to its more intense sweetness.

HFCS has several advantages over sucrose in food manufacturing:
• Enhances other flavors because its sweetness is detected quickly and early by the taste buds, but does not linger, result in a clearer and crisper perception of other flavors.
• Maintains freshness and prolongs shelf life through improved moisture control and less microbial spoilage, resulting in firmer canned fruits and less freezer burn in frozen fruits.
• Maintains the soft texture of baked goods by retaining moisture and resisting crystallization.
• Provides better browning and flavor in baked goods, and better color retention in products such as ketchup and strawberry preserves.
• Maintains its structural stability over a range of temperatures and acidity levels.
• Maintains the pourability of frozen products due to its lower freezing point.
• Increases fermentability, which makes it more economical in producing breads.3,4

Many of the above noted advantages of HFCS are due to the colligative properties of the free fructose and glucose molecules, which depend on the concentration of the solute, not on their identity.1 For example, the smaller monosaccharides generate higher osmotic pressures and lower freezing points than the disaccharide sucrose. Likewise, free fructose and glucose in HFCS are “reducing sugars,” while sucrose is non-reducing; this provides better browning of baked goods and better retention of red colors.1 The properties of free fructose are particularly significant in enhancing the versatility of HFCS, such as its greater ability to adsorb and retain moisture compared with sucrose.1

In products sweetened with sucrose, the covalent bond between the fructose and glucose molecules breaks down in low acid environments, such as those found in soft drinks, as well as at high temperatures, such as during storage in hot climates.1,15 A recent study reported that the sucrose content of a cola beverage decreased from 36% of total sugars to only 10% of sugars three months after manufacture, and the free fructose content increased from 32% to 44% of total sugars.15 This creates variability in the taste profile of the product. In contrast, HFCS maintains its structural stability over a range of temperatures and acidic conditions.1

Fructose and Glucose in the Body

Since the hydrolysis of sucrose under low pH or high temperatures results in free fructose and glucose, as found in HFCS, beverages containing either sweetener should be absorbed similarly by the body. Even if sucrose is not hydrolyzed before consumption, the covalent bond between the fructose and glucose molecules in sucrose is easily cleaved by the enzyme sucrase in the brush-border cells of the small intestine.10,12,16 Thus, the body is absorbing free fructose and glucose molecules regardless of whether they originated as part of HFCS or sucrose. The only difference is the greater osmotic pressure generated by the smaller monosaccharides compared with the disaccharide sucrose, which affects the amount of fluid secreted in the stomach.16,17

Many of the concerns about HFCS are, in fact, concerns about the role of fructose in appetite and metabolism. Fructose is more quickly emptied from the stomach compared with other sugars, and is absorbed in the intestines more slowly and less completely than glucose.18,19 Unlike glucose, fructose intake does not stimulate insulin secretion, which is likely due to the lack of fructose transporters (Glut-5) in the β cells of the pancreas.10,20 Insulin is believed to directly and indirectly (though effects on leptin secretion) inhibit food intake.10 The brain and central nervous system also lack Glut-5 transporters, further inhibiting the ability of fructose to provide satiety signals.10,20 In addition, fructose can more easily be incorporated into phospholipids and triacylglycerols than glucose, as fructose metabolism bypasses the key rate limiting step in the liver that slows glucose metabolism.20
Thus, consumption of excess amounts of fructose, but not the same amount of glucose, have been found to significantly increase rates of lipogenesis. In addition, fructose consumption does not increase leptin or decrease ghrelin levels, in contrast to the hormonal response after glucose ingestion. (Leptin generally inhibits food intake and increases energy expenditure, while ghrelin appears to increase hunger and appetite.)

The chemical-reducing properties of free fructose allow it to form stable complexes with iron that promote both iron and zinc absorption. Fructose and sucrose both reduce the bioavailability of copper in animals at high intakes, but not in humans at intakes of 20% of total energy, which is higher than most people consume. Because HFCS contains free fructose, it is possible that HFCS could affect the balance of certain minerals in the body. HFCS and sucrose did not affect the balance of iron, magnesium, calcium, and zinc over 2 weeks in one study that examined this issue, although another study found HFCS-sweetened beverages to adversely affect magnesium, calcium, and phosphorous homeostasis over 6 weeks.

Fructose and Adverse Health Outcomes

Human and animal studies have found direct associations between high intakes of fructose and adverse health outcomes, including obesity and the metabolic syndrome. In most animal models, diets high in fructose increase total energy intake, insulin resistance, weight gain, dyslipidemia, and hypertension. In humans, fructose has been associated with increased total energy intake, body weight, hepatic and adipose tissue insulin resistance, and dyslipidemia. Individuals with diabetes and hyperinsulinemia may be particularly sensitive to these adverse effects of excessive fructose intake. However, fructose in both sucrose and HFCS appears equally detrimental, although the adverse effects appear limited to high intakes and not to the small amount of naturally occurring fructose in fruits and vegetables (approximately 15 g/d; for comparison, a 12 oz serving of a soft drink may contain 25 g of fructose, and average fructose intakes are about 97 g/d).

More immediate adverse consequences of excessive fructose intake include diarrhea, flatulence, borborygmus, abdominal distention, and abdominal pain. More than half of healthy individuals report symptoms of gastrointestinal distress after consuming 25 g or more of crystalline (pure) fructose. However, when fructose is consumed with glucose, as it is usually found in citrus juices, sucrose, and HFCS, absorption of fructose is improved and malabsorption and its associated symptoms are less likely to occur. In addition, frequent consumers of fructose may have greater tolerance or threshold for these potential side effects.

Calorically Sweetened Beverages and Adverse Health Outcomes

Calorically sweetened beverages are a significant source of HFCS in the American diet. They have been associated with overconsumption of calories and with weight gain in animals and humans, as well as with other adverse health outcomes. The body does not appear to compensate for extra calories from beverages as well as those from soups or solid foods. A recent review and meta-analysis found that soft drinks, whether sweetened with HFCS or sucrose, were strongly and consistently associated with higher total calorie consumption in cross-sectional, longitudinal, and long-term experimental studies, with the strongest associations seen in the experimental studies. Several studies have found higher energy intakes than could be explained by consumption of the soft drinks alone, suggesting that soft drinks may reduce feelings of satiety, increase hunger, or acclimate individuals to prefer sweeter and generally more calorie-dense foods. In addition, soft drink
consumption has been positively associated with body mass index (BMI), particularly in experimental studies. A much smaller body of literature reports soft drink consumption to be inversely associated with consumption of milk, calcium, fruit, and dietary fiber, and with overall dietary quality, and directly associated with dental caries, kidney stones, diabetes, and systolic and diastolic blood pressure. In general, industry-funded studies reported significantly smaller effect sizes, particularly those examining the relationship between soft drinks and energy intake.

HFCS and Obesity

At present, insufficient evidence exists that HFCS consumption has contributed to obesity more than sucrose, increased consumption of total calories (from any source), or decreased physical activity. Recent studies have not found statistically significant differences between HFCS and sucrose on total energy intake, macronutrient intake, taste, hunger, thirst, overall satiety, or concentrations of insulin, glucose, glucagon-like peptide 1 (GLP-1), uric acid, leptin, and/or ghrelin. Both beverages sweetened with HFCS and those sweetened with sucrose contribute to the overconsumption of calories at meals served 50 to 120 minutes later compared with a diet beverage or no beverage. In addition, men and women may respond to the sweeteners differently, as one study found that men experienced significantly less hunger after consuming HFCS than sucrose, while women experienced less hunger after consuming sucrose-sweetened beverages. However, another study found increased hunger in women the day after consuming 30% of calories from sucrose as compared with HFCS.

Unfortunately, these small experimental studies examined only the short-term effects of sucrose and HFCS and may have been underpowered. At least two of the studies (which provided details on their statistical power) were only powered to detect 120 to 150 kcal differences in response, even though smaller differences in energy intake may contribute long-term to obesity or other health outcomes. In one study, the authors expressed concern about their lack of statistical power to detect a difference between sucrose and HFCS and repeated the experiment comparing sucrose to solutions of free glucose and free fructose, but not to HFCS. However, this second experiment was only powered to detect a 120 kcal difference in response between 20% glucose:80% fructose and 80% glucose:20% fructose solutions, not to detect differences between the more similarly composed sucrose and HFCS beverages. In fact, intake was 192 kcal greater at the test meal after consumption of the 50:50 solution of free glucose/free fructose compared with the sucrose solution, but this difference was not statistically significant. Moreover, all four of these recent studies received financial support from the sweetener industry or involved investigators who have consulted with the sweetener industry.

It has been hypothesized that the extra 5% fructose in HFCS-55 compared to sucrose has acclimated individuals to a sweeter diet, although the sweetness intensity of HFCS-55 is similar to that of sucrose. Food use data show that between 1909 and 1997, there was an 86% increase in per capita use of added caloric sweeteners in the United States, with added caloric sweeteners now comprising about 16% of total calories, and HFCS comprising 7% to 10% of total calories. Among the 20% of Americans consuming the most HFCS (conservatively estimated at 11% of total calories), half of their carbohydrate intake comes from caloric sweeteners. The affordability and versatility of HFCS compared to sucrose may have contributed to the sweetening of the American diet. However, the replacement of some sucrose with HFCS has not altered the ratio of fructose to glucose in the food supply. In 1966, before the use of HFCS, the ratio of fructose to glucose was 0.78, compared with 0.79 in 2002.
Epidemiologic studies have yet to directly measure total HFCS intake in individuals, because food databases do not contain data on the HFCS content of foods. The increase in HFCS in the food supply has been highly correlated with the increased prevalence of obesity and type 2 diabetes, but because there are no individual-level data on HFCS consumption, only ecological associations are available for consideration. It is possible that other aspects of diet and physical activity that occurred simultaneously with increases in HFCS consumption may play a larger role in the rising rates of obesity and diabetes seen in recent years. For example, caloric intake increased by 523 kcal/d between 1970 and 2003. Additionally, obesity rates are rising even in those countries where trade barriers have limited the use of HFCS.

Guidelines on Caloric Sweeteners

Dietary guidelines generally recommend limiting intake of added caloric sweeteners of any type. In order to meet required nutrient needs and limit weight gain, sample diets in the Dietary Guidelines for Americans recommend limiting discretionary calories, including those from added sugar, to no more than 32 g (8 tsp or 128 kcal) per day on a 2,000 calorie diet, which is less than that found in most calorically sweetened soft drinks. While the sample diets are just suggestions, current average intakes, estimated at 318 kcal/d, far exceed these limits. Additionally, an Expert Consultation for the World Health Organization and the Food and Agriculture Organization of the United Nations recommended limiting intake of "free sugars" to < 10% of total calories to improve overall diet quality and prevent overweight and dental caries. In this recommendation, "free sugars" includes all monosaccharides and disaccharides added to foods by manufacturers, food preparers, and consumers, as well as sugars naturally found in honey, syrups, and fruit juices.

Potential Impact of Limiting Fructose-containing Sweeteners

Regarding the first resolve of Resolution 407 (A-07), a ban on the use of fructose-containing sweeteners would include not just pure fructose and high fructose syrups, but also naturally occurring sweeteners such as honey, cane and beet sugars, and fruit juices. Regulation to limit the use of HFS, including HFCS, will likely result in the replacement of HFS with sucrose and other caloric sweeteners in food products, not in a reduction in the use of added sugars by food manufacturers. This replacement would not change the caloric content of sweetened foods and beverages, and would likely not change the ratio of fructose to glucose in the food supply.

Regarding the second resolve of Resolution 407, HFCS is generally recognized as safe (GRAS) by the FDA; thus, in accordance with AMA policy (H-150.971), warning labels on products containing HFCS would be unwarranted. At the present time, there is insufficient evidence that HFCS is more likely to contribute to adverse health outcomes than sucrose or any other caloric sweetener. The GRAS status of HFCS is unlikely to be revoked unless such evidence is found.

Areas Requiring Further Research or Attention

More information is needed to clarify the impact of HFCS and other sweeteners on health. While a few studies have examined the metabolism of HFCS compared to sucrose, more research is needed on the long-term effects of high consumption of these sweeteners to confirm their similarities. In addition, research is needed on the possible effects of different sweeteners in various subpopulations, including overweight and obese individuals, or those at risk of obesity due to family history or other conditions. It is important that the research be free of potential bias, as most previous studies were
conducted by researchers who had received funds from the sweetener industry. While this does not necessarily bias the results, the bias found in the soft drink studies discussed above suggests the need for more independent research.

Information on HFCS should be added to the USDA food composition and nutrient databases to allow for epidemiological research on intakes of HFCS in individuals and its relationship with health outcomes. While the USDA has constructed a database containing the added sugar content of selected foods, it does not distinguish between types of added sweeteners. There is currently no analytical method for differentiating between naturally occurring sugars of any type and added sugars; thus, the values in the database were calculated by the USDA from the ingredients listed on product labels. Improved databases on the amount of added sweeteners in all foods are still needed.

Summary and Conclusion

HFCS is a common food ingredient in the United States. The most commonly used types of HFCS (HFCS-42 and HFCS-55) are similar in composition to sucrose, consisting of roughly equal amounts of fructose and glucose. The primary difference between HFCS and sucrose is that these monosaccharides exist free in solution in HFCS, but in disaccharide form in sucrose. The free monosaccharides in HFCS provide better flavor enhancement, stability, freshness, texture, color, pourability, and consistency to foods in comparison with sucrose. As use of HFCS increased over the last 30 years, so did rates of obesity and diabetes. Human and animal studies have found direct associations between fructose and adverse health outcomes, including obesity. However, the adverse health effects of HFCS, beyond those of other caloric sweeteners, most of which contain fructose, are not well established. Consumption of added caloric sweeteners in general increased over the same period, as did total calories. Likewise, rates of obesity have risen even in countries where little HFCS is consumed.

The literature on HFCS consists mostly of ecological or small, short-term experimental studies, many of which have been industry-supported. Because the composition of HFCS and sucrose are so similar, particularly on absorption by the body, it appears unlikely that HFCS contributes more to obesity or other conditions than sucrose. Nevertheless, it is difficult to thoroughly examine the potentially differential effect of various sweeteners, particularly as they relate to health conditions such as obesity, which develop over relatively long periods of time. Improved nutrient databases are needed to analyze food consumption in epidemiological studies, as are more strongly designed experimental studies. At the present time, there is insufficient evidence to restrict use of HFCS or other fructose-containing sweeteners in the food supply or to require the use of warning labels on products containing HFCS.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted in lieu of Resolution 407 (A-07) and the remainder of this report be filed:

1. That our American Medical Association (AMA) recognize that at the present time, insufficient evidence exists to specifically restrict use of high fructose corn syrup (HFCS) or other fructose-containing sweeteners in the food supply or to require the use of warning labels on products containing HFCS. (Directive to Take Action)
2. That our AMA encourage independent research (including epidemiological studies) on the health effects of HFCS and other sweeteners, and evaluation of the mechanism of action and relationship between fructose dose and response. (Directive to Take Action)

3. That our AMA, in concert with the Dietary Guidelines for Americans, recommend that consumers limit the amount of added caloric sweeteners in their diet. (Directive to Take Action)

Fiscal Note: $500
References


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APPENDIX.

Current AMA Policy on Food Labeling and Poor Nutritional Value of Added Sugars

**H-150.971 Food Labeling and Advertising**

Our AMA believes that there is a need for clear, concise and uniform labeling on food products and supports the following aspects of food labeling: (1) Required nutrition labeling for all food products that includes a declaration of carbohydrates, protein, total fat, total saturated and polyunsaturated fatty acids, cholesterol, sodium and potassium content, and number of calories per serving. (2) Use of and/or ingredient labeling to declare the source of fats and oils. Knowledge of the degree of saturation is more important than knowing the source of oils in food products. It is not uncommon for manufacturers to use blends of different oils or to hydrogenate oils to achieve specific functional effects in foods. For example, vegetable oils that are primarily unsaturated may be modified by hydrogenation to more saturated forms that bring about desired taste, texture, or baking characteristics. This recommendation is therefore contingent upon nutrition labeling with saturated fat content. (3) The FDA’s proposed rule on food labeling that requires quantitative information be provided on both fatty acid and cholesterol content if either one is declared on the label, as an interim step. (4) Warning statements on food labels are not appropriate for ingredients that have been established as safe for the general population. Moreover, the FDA has not defined descriptors for foods that are relatively higher in calories, sodium, fat, cholesterol, or sugar than other foods because there are no established scientific data indicating the level at which any of these substances or calories would become harmful in an individual food. (5) Our AMA commends the FTC for its past and current efforts and encourages the Commission to monitor misleading food advertising claims more closely, particularly those related to low sodium or cholesterol, and health claims. (6) Our AMA supports the timely approval of the Food and Drug Administration’s proposed amendment of its regulations on nutrition labeling to require that the amount of trans fatty acids present in a food be included in the amount and percent daily value, and that definitions for “trans fat free” and “reduced trans fat” be set. (BOT Rep. C, A-90; Reaffirmed: Sunset Report, I-00; Appended: Res. 501, A-02; Reaffirmation A-04; Reaffirmed: in lieu of Res. 407, A-04)

**Policy H-150.945 Nutrition Labeling and Nutritionally Improved Menu Offerings in Fast-Food and Other Chain Restaurants**

Our AMA: (1) supports federal, state, and local policies to require fast-food and other chain restaurants with 10 or more units (smaller, neighborhood restaurants could be exempt) to provide consumers with nutrition information on menus and menu boards; (2) recommends that nutrition information in fast-food and other chain restaurants include calorie, fat, saturated fat and trans fat, and sodium labeling on printed menus, and, at a minimum, calories on menu boards, since they have limited space, and that all nutrition information be conspicuous and easily legible; (3) urges federal, state, and local health agencies, health organizations, and physicians and other health professionals to educate people how to use the nutrition information provided in restaurants to make healthier food choices for themselves and their families; and (4) urges restaurants to improve the nutritional quality of their menu offerings—for example, by reducing caloric content; offering smaller portions; offering more fruits, vegetables, and whole-grain items; using less sodium; using cooking fats lower in saturated and trans fats; and using less added sugars/sweeteners. (Res. 419, A-07)

**Policy H-150.960 Improving Nutritional Value of Snack Foods Available in Primary and Secondary Schools**

The AMA supports the position that primary and secondary schools should replace foods in vending machines and snack bars, which are of low nutritional value and are high in fat, salt and/or sugar, with healthier food choices which contribute to the nutritional needs of the students. (Res. 405, A-94; Reaffirmation A-04; Reaffirmed: in lieu of Res. 407, A-04; Reaffirmed: CSA Rep. 6, A-04)
D-150.987 Addition of Alternatives to Soft Drinks in Schools
Our AMA will seek to promote the consumption and availability of nutritious beverages as a healthy alternative to high-calorie, low nutritional-content beverages (such as carbonated sodas and sugar-added juices) in schools. (Rcs. 413, A-05)
Whereas, The issue of reforming our health care system is a central theme of President Obama’s administration and among leaders in the Congress of the United States; and

Whereas, Significant reforms have been enacted at a rapid pace; and

Whereas, Physicians provide medical care which is a professional service based on the physician-patient relationship; and

Whereas, The right of the physician and the patient to enter into a private contractual relationship for medical services is the sine qua non of the private practice of medicine, and

Whereas, Our AMA has formulated well-founded policy of pluralism, freedom of enterprise and the professional values that underpin the private practice of medicine as a profession; and

Whereas, There is great uncertainty as to the scope of reform that will be enacted and the degree to which these reforms will impact the private practice of medicine making it imperative that AMA immediately focus on fundamental free-market tenets that will ensure the continuation of the private practice of medicine including the right to privately contract with patients, the right to balance bill, or not, pursuant to a private contract with the patient and the ability of physicians to negotiate equitable contracts with health plans and insurers; and

Whereas, The physicians of America face a crucial moment in the history of medicine: a time which requires clarity of purpose and a highly focused agenda; therefore be it,

RESOLVED, That our AMA Board of Trustees immediately make as its highest priority:

1. The enactment of federal legislation that ensures and protects the fundamental right of physicians to privately contract with patients, without penalties for doing so and regardless of payer within the framework of free market principles with the goal of accomplishing this by 2010; and

2. The restoration of fairness to the current health care marketplace through changes in statutes and regulations so that physicians are able to negotiate (individually and as defined groups) fair contracts with private sector and public sector health plans. (Directive to take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $4,580.

Received: 05/06/09
Private Contracting Policy

H-385.961 Medicare Private Contracting

Our AMA will: (1) continue to pursue legal and administrative efforts to permit patients to contract privately with their physicians in appropriate circumstances; and (2) support repeal of the restrictions placed on private contracts between physicians and Medicare beneficiaries to ensure that there is no interference with Medicare beneficiaries’ freedom to choose a physician to provide covered services and give priority to this goal as a legislative objective. (BOT Rep. OO, A-93; Reaffirmed: Sub. Res. 132, A-94; Appended: Res. 203, I-98; Reaffirmation A-99; Reaffirmation I-99; Reaffirmation I-00; Reaffirmation A-01; Reaffirmation A-02; Reaffirmation A-04; Reaffirmation A-08)

D-380.997 Private Contracting by Medicare Patients

(1) Our AMA reaffirm Policy H-380.989 which states that 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 reaffirm Policy H-165.913(2) which states that the AMA advance 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)

H-380.989 Patient and Physician Right to Privately Contract for Health Care

It is the policy of the AMA: (1) 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; (2) to pursue appropriate legislative and legal means to permanently preserve the patient's basic right to privately contract with physicians for wanted or needed health care services; (3) 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 (4) 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. (Sub. Res. 20, A-90; Reaffirmed: Sub. Res. 132, A-94; Reaffirmed A-97; Reaffirmed: CMS Rep. 7, A-99; Reaffirmation I-99; Reaffirmation I-00; Reaffirmation A-01; Reaffirmation A-02; Reaffirmation A-05)

H-330.932 Cuts in Medicare and Medicaid Reimbursement

Our AMA: (1) continues to oppose payment cuts in the Medicare and Medicaid budgets that may reduce patient access to care and undermine the quality of care provided to patients; (2) supports the concept that the Medicare and Medicaid budgets need to expand adequately to adjust for factors such as cost of living, the growing size of the Medicare population, and the cost of new technology; (3) aggressively encourages CMS to affirm the patient's and the physician's constitutional right to privately contract for medical services; (4) if the reimbursement is not improved, the AMA declares the Medicare reimbursement unworkable and intolerable, and seek immediate legislation to allow the physician to balance bill the patient according to their usual and customary fee; and (5) supports a mandatory annual “cost-of-living” or COLA increase in Medicaid, Medicare, and other appropriate health care reimbursement programs, in addition to other needed payment increases. (Sub. Res. 101, A-97; Reaffirmation A-99 and Reaffirmed: Res. 127, A-99; Reaffirmation A-00; Reaffirmation I-00; Reaffirmed: BOT Action in response to referred for decision Res. 215, I-00; Reaffirmation A-01; Reaffirmation and Appended: Res. 113, A-02; Reaffirmation A-05)
H-330.969 Medicare Program
Our AMA: (1) urges the taking of all actions possible to repeal Public Law 101-239 and the restoration of the rights of physicians to privately contract with Medicare beneficiaries for the provision of health care services outside of the Medicare program, and (2) supports making its position known to the U.S. Congress. (Res. 30, A-91; Reaffirmation A-97; Reaffirmation I-00; Reaffirmation A-01; Reaffirmation A-02)

Antitrust/Collective Bargaining Policy
H-285.995 Managed Care - Policy and Initiatives
(2) Our AMA will continue to advocate strongly to Congress, the Department of Justice, and the Federal Trade Commission the need for changes in relevant antitrust laws to allow physicians and physician organizations to form bargaining groups to engage in group negotiations with managed care plans. (BOT Rep. MM, I-92; Reaffirmed: BOT Rep. I-93-25; Reaffirmed by Res. 725, A-95; Reaffirmed by BOT Rep. 12, I-95; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmation I-96; Reaffirmation A-97; Reaffirmation I-98; Reaffirmation A-99; Reaffirmation A-00; Reaffirmation I-04; Reaffirmation A-05; Reaffirmed: BOT Rep. 10, I-05; Reaffirmation A-06)

H-383.993 Negotiations Issue
(6) will continue to pursue enhanced roles for physicians in private sector health plans, including lobbying for appropriate modification of the antitrust laws to facilitate physician negotiation with managed care plans and for legislation requiring managed care plans to allow participating physicians to organize for the purpose of commenting on medical review criteria, and including the development of an AMA team to develop the information and networks of consultants necessary to assist physicians in their interactions with managed care plans. (BOT Rep. QQ, I-92; BOT Rep. HHH, A-93; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: BOT Reps. 25 and 40, I-93; Reaffirmed: Sub. Res. 110, A-94; Reaffirmation I-98; Reaffirmation A-00; Reaffirmation I-00; Reaffirmation A-04; Reaffirmation A-05; Reaffirmed: BOT Rep. 10, I-05; Consolidated and Renumbered: CMS Rep. 7, I-05; Reaffirmation A-06)
EXECUTIVE SUMMARY

I. INTRODUCTION

Over the last thirty years, antitrust enforcement in health care has been a major priority of federal antitrust authorities. Both antitrust Agencies – the Federal Trade Commission (FTC) and the Department of Justice (DOJ) – have devoted considerable resources to actions involving health care services. Within health care, no group has received greater attention from the Agencies than physicians.

We believe that changes in health care markets warrant a shift in focus. When the Agencies charted their current course, payers did relatively little to manage the cost or volume of services provided. Today the landscape is far different. Governmental and private payers take a much more active role in regulating the price and volume of physician services. Further, consolidation among private payers has resulted in more powerful health payors and a substantial reduction in physician autonomy. These forces reduce both the practical and the economic risks of joint activity among physicians.

Equally important, professional, market and regulatory developments are encouraging physicians to collaborate in new ways. In particular, the federal government is encouraging physicians and other providers to invest in health information technology ("HIT") to facilitate the collection and sharing of clinical data. HIT “has the potential to significantly increase the efficiency of the health sector” and to “improve the quality of care.”¹ However, the adoption of HIT requires a level of physician investment and network integration that pose significant barriers to implementation. At the same time, the emergence of new reimbursement mechanisms such as “pay for performance” -- i.e., paying physicians in part based on their ability to meet or exceed quality or other performance benchmarks -- place a premium on physicians’ ability to collect data and utilize HIT. For physicians, who still practice predominantly in small groups, network arrangements provide one way of achieving the economies of scale necessary to participate in these initiatives.

Despite these developments, enforcement policy – embodied today in the Statements of Enforcement Policy in Health Care developed jointly by the FTC and the DOJ during the 1990s – still casts a suspicious eye on physician collaboration through network arrangements. The AMA submits that the Statements of Enforcement Policy go too far in deterring the formation and operation of legitimate physician networks. Joint contracting arrangements that are ancillary to the implementation of HIT or to the
participation in innovative payment arrangements among other physician collaborations on quality improvement, ordinarily create plausible efficiencies and should not face summary condemnation. Accordingly, the AMA proposes a modification of the existing standards to reflect changes in the health care market and to provide greater flexibility for physicians to engage in procompetitive joint arrangements.

The AMA proposes the following specific modifications of the Statements:

1. Physician networks supported by plausible efficiencies should not face summary condemnation under the *per se* rule or the “inherently suspect” standard. The Agencies should explicitly recognize that joint contracting is ordinarily reasonably necessary to the attainment of the plausible efficiencies associated with implementing HIT or participating in P4P, among other physician collaborations on quality improvement.

2. Non-exclusive physician networks – those in which the physicians are genuinely available to contract with payers separately from the network – should almost always be found lawful under the rule of reason.

3. Exclusive physician networks should be evaluated under the rule of reason. Absent proof of market power or actual anticompetitive effects, such networks should be found lawful. If an exclusive network is shown to have market power or to result in anticompetitive effects, the network should be viewed under a full rule of reason analysis that balances the anticompetitive effects against efficiencies created by the exclusive network. Among the expected benefits of exclusivity that the Agencies should explicitly recognize are the elimination of free riding and the removal of obstacles to the acquisition and implementation of HIT.

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This paper begins by describing changes in the health care market since the Agencies adopted their current enforcement policy relating to physician networks. It then describes the Statements and considers whether antitrust law leaves room for a change in policy. Finally, the paper describes a more flexible approach based on the rule of reason.
II.  CHANGES IN THE HEALTH CARE MARKETPLACE

Since the *Statements of Enforcement Policy* were last revised in 1996, health care market conditions have changed in significant ways. The principal changes include (a) increasing health insurer consolidation and market power; (b) a retreat from financial risk-sharing between health insurers and physicians; and (c) the emergence of HIT and new payment methodologies.

A.  Health Insurer Monopsony Power

The Agencies adopted the *Statements of Enforcement Policy* shortly before a tidal wave of mergers swept through the health insurance industry. In the last decade, dozens of major health insurer mergers have resulted in an increasingly consolidated payer market. Premiums have steadily increased, even as patient co-pays and deductibles have expanded, effectively shrinking the scope of coverage. As a result of these mergers, health insurance markets throughout the country are at levels of concentration associated with monopsony power.

The AMA’s most recent study of the health insurance industry shows that 96% (or 299 of 313) of the metropolitan statistical areas ("MSAs") analyzed by the AMA, are controlled by a single insurer with a combined HMO/PPO market share of 30% or more. The report further shows that 64% (or 200 of 313) of the MSAs were controlled by a single insurer with a combined HMO/PPO market share of 50% or greater. In addition, 96% of the MSAs studied by the AMA are considered highly concentrated (with a Herfindahl-Hirschman Index above 1,800) under the Agencies’ Horizontal Merger Guidelines. The AMA’s “study shows unequivocally that physicians across the country have virtually no bargaining power with dominant health insurers and that those health insurers are in a position to exert monopsony power.” Put another way, if physicians were to refuse the terms of the dominant health insurer, they would likely suffer an irrecoverable loss of revenue. Consequently, physicians can be forced
to accept inadequate reimbursement rates likely to lead to a reduction in the supply of physician services – despite the demand for such services by patients. Indeed, recent projections by the Health Resources and Services Administration suggest a looming shortage of physicians in the United States.\(^6\)

It is a mistake to assume that, when insurers push down the cost of physician services, their interests are perfectly aligned with those of consumers.\(^7\) Health insurers who exercise monopsony power by driving physician fees below the competitive level may cause patients to receive an inadequate level of service and quality.\(^8\) Also, because health insurer monopsonists typically are also monopolists, lower input prices (for physician services) do not lead to lower consumer output prices (for health care premiums).\(^9\) Indeed, the evidence from mergers throughout the U.S. strongly suggests that the creation of buyer power from health insurance consolidation has not benefited competition or consumers.\(^10\) Although compensation to physicians has been reduced, health insurance premiums have continued to increase rapidly.

In this environment, one of the key concerns historically animating antitrust enforcement policy in health care – preventing physicians’ collective resistance to the entry of managed care – has only marginal relevance. Between the statutorily-fixed prices of Medicare and Medicaid in the governmental sector, and the negotiating leverage of private health plans that dominate commercial markets, there is only a narrow slice of the market left that is even theoretically vulnerable to a physician-orchestrated conspiracy.

B. Retreat from Risk-Sharing

In 1996, when the *Statements of Antitrust Enforcement Policy* were adopted, managed care was in its ascendancy. Many in health care expected to see continued growth in HMOs and other forms of risk sharing. Today, by contrast, employers and other purchasers of health care coverage have largely rejected payer-
provider risk-sharing arrangements. Many IPAs that previously attempted to share financial risk experienced significant financial losses and ceased offering the model. Consumers also resisted arrangements that placed physicians at financial risk. Contrary to early predictions, in most areas of the country physician capitation proved to be an unpopular and highly controversial payment methodology. Employers wanted broad networks that allowed patients a significant choice among physicians, but without any perceived incentives to ration care.

C. The Emergence of HIT and New Payment Methodologies

One of the more significant and promising developments in the health care market since the promulgation of the Statements in the mid-90s is the emergence of HIT. HIT has the potential, if adopted widely and used effectively, to save the health care sector about $80 billion annually (in 2005 dollars). At the same time, by making it possible for physicians to collect and analyze vast numbers of patient encounters, HIT promises to drive advancements in medical science and clinical practice.

Notwithstanding the tremendous promise of HIT, its adoption has lagged. To date, only 14% of physicians have minimally functional EMR systems. Solo or single partner practices, accounting for about half of all doctors, had the lowest level of comprehensive EMR use – 7.1% of solo practitioners, 9.7% of those with a partner. The Congressional Budget Office (CBO) attributes this disappointing response to challenges in implementing HIT systems and to physician inability to achieve financial returns from HIT sufficient to offset its daunting implementation costs. Most of the benefits of HIT – such as less duplication of diagnostic tests or increased availability of patient data – accrue to health insurance companies or patients rather than to the physicians who incur the costs of implementation. This lack of symmetry leads the CBO to conclude that “[h]ow well HIT lives up to its potential
depends in part on how effectively financial incentives can be realigned to encourage the optimal use of the technology’s capabilities.” Network arrangements provide one way for physicians in small practices both to spread the costs of HIT implementation and to internalize the potential gains from enhanced efficiency.

Closely linked to the adoption of HIT is the emergence of a new payment methodology known as “pay for performance” (“P4P”). The core purpose of P4P is to provide financial incentives for physicians to meet pre-established performance benchmarks. While P4P is in its infancy and has raised a host of methodological concerns – including errors in data used, over-reliance on cost measures, and lack of transparency and physician input in performance metrics – it is “now routinely used by both private and public payers in the U.S. health care system.” A majority of commercial HMOs use P4P, and the Center for Medicare and Medicaid Services has been directed by Congress to adopt value-based purchasing. P4P depends upon accurate and medically appropriate performance measurement, which in turn depends upon HIT. If the adoption of P4P spreads and its use expands, physicians in small practices will face yet another force driving them into “integrated care networks that [will] allow the physicians to more seamlessly coordinate care.”

III. CURRENT ENFORCEMENT POLICY

A. The Statements of Enforcement Policy in Health Care

The initial version of the Statements was released in September, 1993. Issued in response to calls from the American Medical Association, the American Hospital Association, and other leading health care organizations, the Statements reflected a significant effort to provide heightened clarity to medical professionals and companies. The Statements articulated in a clear, accessible format policies that had emerged previously only in advisory letters, speeches, and consent decrees.
1. Financial Integration

As originally issued, the Statements contained eight separate policy statements. Statement 8, entitled “Physician Network Joint Ventures,” identified two features of particular importance to the antitrust analysis of physician networks: (1) the size of the network, in terms of participating physicians, as a measure of potential market power; and (2) whether the physicians had integrated their practices by sharing “substantial financial risk.” The AMA’s focus is on the latter requirement.

As set forth in the initial version of the Statements, physicians in a contracting network could share “substantial financial risk” in either of two ways: (1) by accepting “capitated” or “per-member per-month” payments; or (2) by incentivizing physicians to contain costs through the use of a substantial withhold from payments. With capitation or substantial withholds in place, the network would be deemed to have sufficient financial incentive to enhance efficiencies. Otherwise, without such financial integration, a physician network that engaged in joint price negotiations with health insurers would be summarily condemned as a per se illegal price-fixing agreement.

The concept of integration as an antitrust guidepost did not originate in the Statements. Rather, antitrust law has long sought to distinguish between mere cartels and legitimate joint ventures. “Integration” is used as shorthand to describe attributes that make a joint arrangement sufficiently likely to generate efficiency that application of the rule of reason is appropriate. What was distinctive in the Agencies’ approach was the suggestion that, in the specific context of physician contracting networks, only the sharing of “substantial financial risk” would suffice to allow the network to escape application of the per se rule. Other forms of integration – structural, functional, or transactional – would not carry the day.

With the rapid decline of risk sharing arrangements since the Statements’
inception, the requirement of financial risk-sharing as the defining feature of a legitimate physician network proved unduly restrictive.

2. Clinical Integration

In the 1996 version of the Statements, the Agencies recognized a second type of integration that could qualify a physician network for rule of reason treatment. “Clinical integration,” as defined in the Statements, is evidenced “by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and to create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.” Clinical integration as so defined represented a sort of “as if” standard: A physician network that acted “as if” its members shared financial risk – by instituting the types of cost containment techniques that would necessarily be in place for a capitated group – might qualify for rule of reason treatment despite the absence of “substantial financial risk.”

For several years following the publication of the 1996 Statements, the Agencies gave no further guidance on the meaning of clinical integration. In 2002, however, the Commission issued a staff advisory letter to MedSouth, Inc., an IPA based in Denver, Colorado with over 400 physicians. And in 2007, the Commission issued a staff advisory letter to the Greater Rochester Independent Practice Association, Inc. (GRIPA), a network based in Rochester, New York with over 600 physician members. The MedSouth and GRIPA letters demonstrate how high the bar has been set for physician networks seeking to qualify for rule of reason treatment through clinical integration.

While the MedSouth and GRIPA arrangements are not identical, they bear significant similarities. Notably, both networks were originally built for capitation, but needed to be retooled in the face of market resistance. Thus, both MedSouth and
GRIPA were constructed “as if” the physicians would be sharing substantial financial risk. Only when risk contracting proved to be commercially infeasible did the networks seek Commission approval for their programs of clinical integration.

In addition, both MedSouth and GRIPA made significant investments in capital and resources, using a cadre of consultants and technology experts to assist in the effort. Both networks invested in electronic medical records and tracking technology to share information on their patients and to monitor data relating to utilization and medical outcomes. And both networks developed clinical practice guidelines and procedures for monitoring compliance with them. In both instances, the Commission advisory letters noted no apparent anticompetitive motivation for the physicians’ efforts.

Despite these features, neither MedSouth nor GRIPA achieved agency approval easily or without significant caveats. Both letters reflected intensive Commission investigation of the networks’ histories, purposes, contracting mechanisms, disciplinary methods for non-compliant physicians, and strategies for producing efficiencies. Each involved a searching examination of the so-called “ancillarity” of the networks’ pricing mechanisms to their efficiency-enhancing potential. Each left the Commission plenty of room to bring a later enforcement action if the networks’ operations could not later be shown to produce significant efficiencies.

Interestingly, however, both MedSouth and GRIPA included a structural feature which might have persuaded the Commission to forego such probing examination. Both networks were “non-exclusive” in the sense that members were permitted to, and did, participate in other contracting networks. The Statements make clear that whether a network is judged to be “non-exclusive” depends on the “physician participants’ activities, and not simply by the terms of the contractual relationship.”25 In both MedSouth and GRIPA, the Commission was persuaded that the network was
designed to be truly non-exclusive. In practical terms, this meant that any payer that did not wish to support the physicians’ experiment in clinical integration could simply walk away, without losing access to any desirable physicians who belonged to the network.

Without the ability to force any payer to accept its terms, it is difficult to see how either network could have an anticompetitive effect – even if it were not particularly adept at generating efficiency. Indeed, the Commission appeared to recognize as much when it stated in \textit{GRIPA}:

[I]t appears that, if GRIPA in fact operates as it has proposed, Rochester-area payers unwilling for whatever reason to negotiate and contract jointly with physicians through GRIPA nevertheless should be able to deal individually or through other networks in order to obtain the services of GRIPA’s member physicians. Under these conditions, it appears unlikely that GRIPA’s program would permit it or its physician members to exercise market power or have anticompetitive effects in the market for physician services in the Rochester area.\textsuperscript{26}

If a non-exclusive network has no discernible mechanism by which to restrain trade, why require it to adopt all the bells and whistles of clinical integration in order to escape summary condemnation? Why not let it sink or swim in the market? One answer may be that the law simply does not leave room for such ventures. The AMA addresses that issue below.

\textbf{B. Does Antitrust Law Leave Room For Greater Flexibility In The Concept Of Integration?}

As their name attests, the Statements of Antitrust Enforcement Policy in Health Care represent enforcement policy rather than law. As such, the Statements do not necessarily stand at the outer boundaries of what antitrust law permits. Indeed, the AMA submits that the Statements impose restrictions tighter than required by either the law itself or by sound enforcement policy in the current market environment.
Outside the health care context, courts and the Agencies themselves apply a more flexible analysis than is found in the *Statements*. For example, in the Agencies’ guidelines on competitor collaboration, the Agencies make no mention of financial or clinical integration. Instead, the *Competitor Collaboration Guidelines* ask more generally whether a joint venture involves “an efficiency-enhancing integration of economic activity” and whether any restraints are “reasonably related to the integration and reasonably necessary to achieve its procompetitive benefits.”27 The Supreme Court, too, in its joint venture cases has eschewed any fixed formulation of what may constitute integration sufficient to warrant rule of reason treatment.

The Agencies’ approach to integration has its origins in the Supreme Court’s decision in *Arizona v. Maricopa County Medical Society*.28 *Maricopa* involved physician foundations in Phoenix and Tucson, Arizona. Both foundations included a large number of the physicians in the community; the Maricopa County foundation included over 70% of the county’s physicians. And both foundations established maximum fee schedules that were voted on and approved by their memberships. In a 4-3 decision, the Supreme Court held that these maximum fee schedules represented *per se* unlawful price-fixing agreements.

In so holding, the Court distinguished the foundations from “partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share the risks of loss as well as the opportunities for profit.”29 The physicians in the foundations did not put up capital; they did not accept capitation, but instead billed on a fee-for-service basis. Nor did the Court observe any other indicia of integration among the physician practices that comprised the foundations. By contrast, Justice Powell and the two justices who joined his dissent reasoned that the foundations were comparable to the joint licensing arrangements held subject to the rule of reason rather than the *per se* rule in *Broadcast Music Inc. v. CBS*.30
Since *Maricopa* was decided, the Agencies have struggled to determine its proper scope. Read for all its worth, *Maricopa* might be said to prohibit any fee-for-service contracting by a physician-sponsored network. But the Agencies have not read the decision this broadly, and for good reasons. *Maricopa* was decided by a closely divided Court and is in significant tension with other Supreme Court cases holding joint arrangements to be subject to the rule of reason. Indeed, the strictest reading of *Maricopa* might prohibit even the robust programs of clinical integration considered in *MedSouth* and *GRIPA*.

Further, the principal issue before the Court in *Maricopa* was whether maximum price-fixing should be treated differently under Section 1 of the Sherman Act from minimum price-fixing. In upholding the application of the *per se* rule to both forms, the Court had no need to – and did not – consider the potential efficiencies of joint contracting. Nor did the Court consider whether the foundations’ fee schedules had any actual harmful effect on competition.

In addition, *Maricopa* was decided in 1982, at the dawn of health care antitrust enforcement – only a few years after the Supreme Court held in *Goldfarb v. Virginia State Bar* that professions were subject to the antitrust laws. Nothing in the decision suggests that it was intended to provide the final word on whether and under what conditions physician networks might qualify for rule of reason treatment. If anything, the decision can be criticized as a rush to judgment on a relatively new business form with which the judiciary lacked the experience usually considered necessary before a practice is deemed *per se* unlawful.

Finally, the Supreme Court has long recognized that “the boundaries of the doctrine of *per se* illegality should not be immovable.” This principle applies to the antitrust Agencies as well as courts. Indeed, it is the Agencies that have often led the
way toward judicial abrogation of *per se* rules when “the economic realities underlying earlier decisions have changed.” For all these reasons, *Maricopa* should not be viewed as posing an obstacle to a more accommodating enforcement policy for physician networks.

**IV. A RECONSIDERATION OF EXISTING POLICY**

This section describes a more flexible approach to analyzing the activities of physician networks engaged in joint contracting. It begins by describing the potential efficiencies of joint contracting by a physician network. It then considers whether joint pricing is “reasonably necessary” to the attainment of these efficiencies. Finally, it applies the rule of reason to the network’s activities.

**A. Efficiencies in Physician Network Contracting**

The Agencies have long been skeptical of the potential for efficiencies in joint contracting by a physician network. In *GRIPA*, the Commission compared the transactional efficiencies of network contracting to those offered by a mere cartel. The AMA believes the Agencies have been too dismissive. While the efficiencies offered by joint contracting in a physician network may not always be sufficient to warrant a favorable outcome under the rule of reason, these efficiencies should almost invariably be enough to avoid application of the *per se* rule. In the current environment, this is particularly true of networks formed to facilitate joint investment in and use of HIT.

Joint contracting by physicians in a network can result in significant cost savings both for payers and for physicians. On the payer side, joint contracting can make it possible for a payer to obtain ready access to a panel of physicians offering broad geographic and specialty coverage. Because physicians still practice predominantly in solo practice or in small groups, creating a physician panel can be a
very time-consuming and expensive task for a payer seeking to enter or expand its place in a market. In its complaint in *United States v. Aetna*, the Justice Department noted that “effective new entry for an HMO or HMO/POS plan in Houston or Dallas typically takes two to three years and costs approximately $50,000,000.”\(^{39}\) When the initial task of network formation is undertaken by the physicians themselves, the costs of entry and expansion for payers may be substantially reduced. Joint contracting thus has the potential both to reduce costs for payers and to increase competition in payer markets. These are cognizable efficiencies, with real potential to lower premiums and expand coverage for purchasers. Any doubt concerning the intrinsic efficiency of physician networks is eliminated by the thriving rental network business that has emerged to service the needs of self-insured employers and even national insurers with inadequate directly contracted networks.

Joint contracting can also make physician contracting more efficient and lead to better informed contract decisions. Most physician practices are simply too small to afford to hire businesspersons and lawyers to review their contracts with payers. Such practices do not have the resources to analyze complex contracts. Whereas payers have sophisticated actuarial and financial resources that enable them to structure and evaluate complex contract proposals, physicians are often in the dark when they consider a contract. By pooling their resources, physicians can spread the costs associated with the analysis of payer contracts, and develop appropriate counter-offers that can benefit physicians, payers, and patients. The effect is to enhance the efficiency of the physicians’ practices and make them more responsive to the demands of competition.

Likewise, joint contracting makes it much more practical for physicians to create a network that will facilitate collaboration on information technology, data collection, and other programs designed to monitor patient care and improve quality.
Indeed, joint contracting is essential for those physicians in small or solo practices who wish to participate in performance-based payment initiatives. P4P initiatives are often specifically targeted at medical groups or networks rather than small practices. As a Commonwealth Fund study on P4P recently noted:

"Smaller groups generally have few incentives for care coordination, as they usually do not receive payment beyond the evaluation and management fees they are able to bill for acute visits. However, by banding together under the umbrella of organizations, and becoming eligible for performance payments through [the Medicare P4P Demonstration Project] or similar incentive programs, they have more motivation and support for care coordination."

Under existing enforcement policy, however, physicians in small practices must either lose out on such programs or take the risk that their venture will fall short of the Agencies’ notions of clinical or financial integration.

B. Is Joint Contracting “Reasonably Necessary” to the Attainment of Efficiencies?

For a joint venture to qualify for rule of reason treatment under the antitrust laws, it is not enough that the venture generate efficiencies. In addition, to the extent that the venture involves agreements on price, such agreements must be “reasonably related to the integration and reasonably necessary to achieve its procompetitive benefits.” This requirement that price restraints be “ancillary” to the procompetitive features of a joint venture is well established in the Statements and in case law. We think that, in the context of a physician network engaged in the acquisition and deployment of HIT, this requirement is readily met.

The Commission gave the issue of so-called “ancillarity” extensive consideration in its advisory letters to MedSouth and GRIPA. In the end, the Commission found that joint negotiation of network contracts was ancillary to the networks’ procompetitive purposes. For example, in GRIPA, the network asserted that
it could establish an effective program of care coordination among its members only if all physicians were contractually bound at the same time. Achieving this goal required that the physicians be represented jointly rather than individually in contract negotiations with payers. As the Commission stated:

Identifying up front a set network of physicians, all of whom will participate in all aspects of the program of integration regarding all patients covered under all GRIPA contracts, on its face appears calculated to assure that those efforts will have maximum application and efficacy. And this can only be achieved if GRIPA jointly negotiates the contracts with payers on behalf of all of its physician members.43

In reaching this conclusion, the Commission considered the proposition that, because some programs promoting clinical coordination and quality improvement are initiated and administered by payers, a physician-sponsored program cannot “ever be ‘reasonably necessary’ to achieving the efficiencies of clinically integrated programs.”44 The Commission properly rejected this conclusion. The standard for “ancillarity,” after all, is one of reasonable necessity, not absolute necessity. It does not mandate a “one-size-fits-all” solution. As the Commission recognized, “[d]ifferent types of programs may have different strengths and weaknesses, and the market should determine which programs are most desirable.” Moreover, “the competitive restraints that may accompany integrated physician-initiated network programs must be evaluated for their reasonable necessity in the context in which they occur.”45

The same reasoning should apply generally to physician networks that acquire and use HIT to collect medical data regarding the physicians' collective performance and use it to enhance quality. Joint contracting is reasonably necessary to the efficiencies created by an HIT-driven network for several reasons. First, as in GRIPA, the network may need an up-front commitment from its physicians to participate in all contracts negotiated by the network in order to ensure the integrity of the network’s
program of data collection and analysis. Without such a commitment, the network cannot know in advance how many physicians will participate, and therefore cannot effectively determine the degree to which the efficiencies of its quality improvement program will be realized.

Second, joint contracting makes it much more practical for physicians to make investments in HIT to monitor patient care and improve quality. HIT systems require considerable investments in time and money. As noted in a recent Congressional Budget Office report, acquiring an office-based HIT system costs between $25,000 and $45,000 per physician, with an additional recurring cost of 12 to 20 percent of that amount in annual operating and maintenance expenses. In addition to these out-of-pocket costs, physicians must also “devote considerable time to training, to personalizing the system, and to adapting their work processes to achieve the maximum benefits.”

Physicians cannot be expected to bear such costs without a reasonable prospect of making a return on investment. Yet, as the CBO report notes, from the perspective of a small physician practice, most of the benefits of HIT accrue to payers and other third parties. For example, information technology systems may reduce the frequency of primary and specialty physicians ordering the same test. Although physicians are committed to increasing the quality of care and reducing unnecessary care, neither primary care physicians nor specialists reap an economic advantage by eliminating this duplication. Network formation provides a method for physicians to deal with this “externality” – i.e., to internalize the gains of HIT while spreading its costs, which in turn makes it more likely that physicians will invest in HIT. If in this process the network were to charge higher unit prices than individual members, there remains the potential for overall savings to consumers. As the Commission recognized in GRIPA:
Higher unit prices may be of little concern to a customer if they occur within integrated programs that result in lower total costs (e.g., through elimination of unnecessary and inappropriate utilization of services) and higher quality (e.g., better medical outcomes).

GRIPA, at 27.

Third, joint contracting addresses a potential “hold out” problem faced by networks that develop HIT. As documented in the CBO report, HIT is characterized by network effects: Some of its benefits increase in value as more providers purchase and use interoperable systems. Accordingly, physicians may wish to postpone the commitment decision until more of their colleagues have purchased systems, allowing them to benefit from others’ experience. More importantly, many physicians may decide it is better to wait and see if the organization succeeds than to join it up front. To solve this hold out problem, the HIT network needs the up-front commitment of its physicians to participate in network contracts. This commitment makes it more likely that the HIT network will achieve the necessary critical mass to achieve efficiencies. Potential hold outs who are not willing to make that commitment risk exclusion from the network’s contracts.

Because network joint contracting is reasonably necessary to achieving the efficiencies associated with the adoption and implementation of HIT, networks involved in the use of HIT should generally be accorded rule of reason treatment. The required nexus between joint pricing and the potential for efficiency is even more evident when the adoption of HIT is linked to alternative payment mechanisms. For example, in the context of P4P initiatives, most solo or small physician practices lack the scale to participate. By teaming up with other practices in a network, small practices may gain the scale necessary both for care coordination and for the aggregation of data necessary to implementation of performance-based incentives. Accordingly, negotiation by a network of performance-based incentives tied to the achievement of specified
quality goals by the network’s members should be treated as “ancillary” to the network’s procompetitive purposes.

3. Application of the Rule of Reason

Once the efficiencies of joint contracting are recognized both as non-trivial and as “ancillary” to a network’s procompetitive purposes, the rule of reason provides the appropriate analytical approach for balancing those efficiencies against the potential for harm to competition. In the case of a non-exclusive network – one that does not prohibit its members, in law or in fact, from contracting with payers apart from the network – the potential harm to competition is minimal. As explained above, without the ability to force a payer to do business with the network, the physicians have no mechanism for forcing up fees. Non-exclusive networks therefore should generally be found lawful under the rule of reason, without the need for extensive analysis.

Exclusive physician networks may require a more searching examination under the rule of reason. A critical consideration at the outset is the percentage of physicians in the geographic market who participate in the venture. If a large percentage of the available physicians participate in an exclusive network, the network may have the potential to exercise market power. In that event, it then becomes appropriate to look at the competitive effects. Among the potential procompetitive effects, exclusivity may reflect the physicians’ enhanced commitment to working together in the network to achieve efficiencies. Without exclusivity, physicians might not invest in a joint venture by coordinating their work, purchase expensive technologies like HIT, pool knowledge by educating each other on best practices, or engage in forms of practice supervision to advance patient care. Concerns about externalities – that are acute in the context of HIT – may make it impossible for the network to have initial success. In addition, exclusivity may help address physician concerns that some
members will “free ride” on the network’s efforts by using the jointly-developed HIT to strike their own separate deals with payers. It is well-recognized that exclusive dealing arrangements are a common method of preventing free riding.51

In the analysis of an exclusive physician network possessing high market shares and engaged in the acquisition and use of HIT, additional considerations under the rule of reason may include:

- How much capital and time have the physicians invested in the acquisition, operation, and maintenance of HIT?
- How effectively is the network using HIT to collect and analyze medical data?
- To what extent is the network able to document cost savings and improvements in quality resulting from the use of HIT?
- To what extent has the use of HIT enabled the network to participate in performance-based payment or other alternative forms of reimbursement?

As is always the case under the rule of reason, these considerations should be carefully examined to determine whether the network’s procompetitive benefits outweigh its anticompetitive effects. The fundamental point, however, is that competitive harm should not merely be presumed, but should be determined based upon a full consideration of the record.

V. CONCLUSION

Price-fixing is, and of course should continue to be, treated as the most serious form of antitrust offense. However, the Statements overestimate the anticompetitive potential that networks lacking market power have on the ability to restrain trade. Arrangements that create plausible efficiencies while posing little risk of anticompetitive injury should not face summary condemnation.

Also, antitrust enforcement policy must adjust to market developments. Presently, however, the Statements impede the ability of physician networks to achieve
plausible efficiencies through joint contracting on a basis that would allow for the implementation of HIT and the participation in P4P and other quality initiatives.

Accordingly, the AMA proposes the following modifications of the existing Statements to reflect changes in the health care market and antitrust law and to provide greater flexibility for physicians to engage in procompetitive joint arrangements.

1. Physician networks supported by plausible efficiencies should not face summary condemnation under the *per se* rule or the “inherently suspect” standard. The Agencies should explicitly recognize that joint contracting is ordinarily reasonably necessary to the attainment of the plausible efficiencies associated with implementing HIT or participating in P4P, among other physician collaborations on quality improvement.

2. Non-exclusive physician networks – those in which the physicians are genuinely available to contract with payers separately from the network – should almost always be found lawful under the rule of reason.

3. Exclusive physician networks should be evaluated under the rule of reason. Absent proof of market power or actual anticompetitive effects, such networks should be found lawful. If an exclusive network is shown to have market power or to result in anticompetitive effects, the network should be viewed under a full rule of reason analysis that balances the anticompetitive effects against efficiencies created by the exclusive network. Among the expected benefits of exclusivity that the Agencies should explicitly recognize are the elimination of free riding and the removal of obstacles to the acquisition and implementation of HIT.

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3 *Id.*
4 *Id.*
5 *Id.* at 2.
6 See Health Resources and Services Administration, *Physician Supply and Demand: Projections to 2020* (Oct 2006) (projecting a shortfall of approximately 55,000 physicians in 2020); see also Merritt, Hawkins, et al., *Will the Last Physician in America Please Turn Off The Lights? A Look at America’s Looming Doctor Shortage* (2004) (predicting a shortage of 90,000 to 200,000 physicians and that average wait
times for medical specialties is likely to increase dramatically beyond the current range of two to five week).

7 Affidavit of Professor David Dranove at 6-7 (May 13, 2008) submitted in United States v. UnitedHealth Group Inc. and Sierra Health Service Civil No:1:08-CV-00322.


11 In the Matter of North Texas Specialty Physicians, FTC Docket No. 9312, slip op. at 46.

12 See FTC Staff Advisory Opinion to MedSouth, Inc. (Feb. 19, 2002), at http://www.ftc.gov/bc/adops/medsourth.htm [hereinafter “MedSouth”] [acknowledging that many financially integrated IPAs have “experience significant financial difficulties under [capitated] contracts, and a number of the organizations [have] declared bankruptcy. In the wake of this experience, payers and most physician groups,…terminated their capitated contracts”).

13 CBO Report, at 18.

14 Id. at 19.

15 Office of National Coordinator for Health Informational Technology (July 2007).

16 Id.


18 Id. at 7.


21 Pham & Ginsburg, supra, at 1596; see id. at 1590 (“One obstacle to performance measurement and incentive programs’ have an impact remains the fragmented nature of U.S. care delivery systems.”).


23 Letter from Jeffrey W. Brennan, Asst. Director, Bureau of Competition, to John J. Miles (Feb. 19, 2002) (“MedSouth”). When the FTC took a second look at MedSouth five years later, the network had decreased in size to 280 physicians. See Letter from Markus H. Meier to John J. Miles (June 18, 2007).

24 Letter from Markus H. Meier to Christi J. Braun & John J. Miles (Sept. 17, 2007) (“GRIPA”.

25 Health Care Statements, at 66.

26 GRIPA, at 26.


29 Id. at 356.


See 457 U.S. at 367 (Powell, J., dissenting).


The Fifth Circuit's recent decision in North Texas Specialty Physicians is not to the contrary. ___ F.3d ___ (5th Cir. 2008). Indeed, rather than finding a per se violation by the physician network in that case, the court viewed the network's activities under the rule of reason.

GRIPA, at 23 ("Any joint marketing arrangement, and indeed any cartel, provides transaction costs efficiencies when compared to engaging in individual sales transactions in markets with numerous participants.")


Competitor Collaboration Guidelines at § 3.2.


GRIPA, at 19.

Id. at 17.

Id.

CBO Report, at 17 (and studies cited therein).

Id. at 19.

Id. (noting that "many providers cannot generate the additional income necessary to justify the significant investment in time and money that the adoption of such a system would require").

See H. Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice § 5.6 (1994) (a non-exclusive physician network is "absolutely inconsistent with the economics of cartelizeation: no cartel could restrict its output and raise price if it permitted its members freely to come and go, or to make unlimited 'non-cartel' sales.").


REPORT OF THE BOARD OF TRUSTEES

Subject: Update on Resolutions 209 and 232, A-07
Antitrust/Collective Bargaining Strategy

Presented by: Edward L. Langston, MD, Chair

PURPOSE

The purpose of this informational report is to update the House of Delegates on our AMA’s antitrust/collective bargaining strategy.

BACKGROUND

At the 2007 Annual Meeting, two resolutions regarding antitrust and collective bargaining were introduced. Resolution 209, introduced by the California Delegation, asks that our AMA advocate for changes in the law to allow joint negotiations by groups of physicians for payment of services by third party carriers without the threat of violating antitrust laws and actively campaign for passage by the U.S. Congress of legislation that accomplishes such changes. Resolution 232, introduced by the Organized Medical Staff Section, asks that our AMA immediately reinstitute its efforts to seek legislative relief from the antitrust constraints to which independent physicians are subjected with the goal being to allow those independent physicians to collectively bargain to obtain reasonable and equitable payment for their medical services and to be strong advocates for their patients’ welfare. At the 2007 Annual Meeting, our House of Delegates voted to refer Resolutions 209 and 232 for decision with a report back at the 2007 Interim meeting. The Board considered these resolutions at its September 2007 meeting. The Board’s decision is discussed below.

Since the 104th Congress (1995/1996), our AMA has pursued numerous attempts to enact federal legislation that would reform antitrust laws to allow physicians to negotiate jointly with health plans. Congress has failed to enact federal antitrust legislation despite passage of an AMA-supported antitrust reform bill that passed in the House of Representatives in 2000. Our efforts, however, inspired the U.S. Department of Justice (DOJ) and Federal Trade Commission (FTC) to make changes to the “Statements of Antitrust Enforcement Policy in Health Care” Guidelines (“Guidelines”), which provide direction on the criteria used by federal antitrust agencies in analyzing certain recurring issues in health care antitrust enforcement. While the Guidelines have been modified, they still do not allow solo practitioners who are not part of a physician network to jointly negotiate with a health plan. Moreover, they do not address enforcement issues relating to health insurers, HMOs, or other third party payers.

DISCUSSION

Our AMA has been working with a number of specialty medical associations that have lobbyists with expertise in antitrust reform issues to comprehensively review and consider federal legislation and an antitrust reform advocacy strategy. This coalition (the Antitrust Steering Committee) includes staff from the American Society of Anesthesiologists, American Academy of Family Physicians, American Association of Neurological Surgeons, American Academy of...
Otolaryngology - Head and Neck Surgery, and the American Academy of Neurology. The Coalition has held several meetings with, and has received suggestions from, key Senate staff regarding the most effective approach to garner support for the introduction of federal antitrust legislation. Senate staff urged the Coalition to pursue a strategy to modify the existing DOJ/FTC Guidelines prior to seeking the introduction of a federal antitrust reform bill.

Thus, our AMA has been working with outside counsel to develop proposed changes to the current DOJ/FTC Guidelines. The key proposed changes include: expanding the definition of financial integration so that it goes beyond risk-sharing arrangements and includes joint capital investment and sharing of staff, space, equipment, and administrative services; expanding the definition of clinical integration so that it includes substantial investment in shared health information technology; modifying the existing “safety zones” for exclusive and non-exclusive physician networks; adding new Guidelines addressing health plan mergers, collusion among health plans, and abuse of market power by dominant health plans; and adding cautionary language to accompany the description of the “messenger model.”

Approaching the DOJ and FTC and attempting to modify the Guidelines are consistent with AMA Policy H-385.976, “Physician Collective Bargaining” (AMA Policy Database), which recommends that our AMA enhance physician’s collective bargaining abilities within existing antitrust laws and continue “meeting with the Justice Department and FTC to enhance their understanding of the unique nature of medical practice and to seek interpretations of the antitrust laws which reflect that unique nature,” and AMA Policy D-383-985, which suggests that our AMA “reopen a dialogue with the Department of Justice and the Federal Trade Commission concerning more flexible approaches to physician network joint ventures.” Members of the Antitrust Steering Committee support this approach. In addition, our AMA’s Council on Legislation recommended to the Board at its September 2007 meeting that our AMA continue to pursue an antitrust advocacy strategy, in collaboration with the medical specialty stakeholders in the Antitrust Steering Committee, to urge the DOJ and FTC to amend the “Statements of Antitrust Enforcement Policy in Health Care” and adopt new policy statements regarding market concentration that are consistent with AMA policy; and, that our AMA execute a federal legislative strategy. The Board adopted the Council’s recommendation in lieu of Resolutions 209 and 232.

In June 2007, as a result of continued discussions with Senate Judiciary Committee staff, our AMA met with the American Hospital Association (AHA) to discuss pursuing a new revised interpretation of the Guidelines on clinical integration. As a result of the meeting, our AMA is drafting documents to provide guidance for physicians on clinical and financial integration in order to help physicians take advantage of existing options for collective negotiation and to influence the DOJ and FTC to either signal acceptance and support for our interpretation of the Guidelines or revise them as necessary to clearly authorize pro-competitive innovation. Our AMA will also use the suggested changes to the Guidelines as a basis for pursuing a legislative strategy. In addition, our AMA is planning to work with the AHA on crafting a legislative strategy to combat health plan mergers. Further, our AMA testified at the hearings on the United/Sierra merger in Nevada in July 2007, and is working to encourage both the Nevada State Attorney General and the DOJ to block the merger.

It should be noted that Representative Tom Price, MD (R-GA) introduced a comprehensive health care reform bill this year (H.R. 2626) that includes a provision that would provide health care professionals negotiating with health insurance plans the same bargaining powers as are accorded groups covered under the National Labor Relations Act (NLRA). The antitrust provision in the
Price bill is similar to legislation from a previous Congress. In addition, former Representative Tom Campbell has recently urged introduction of a modified version of his prior legislation, the “Health Care Antitrust Improvements Act of 2007.” This legislation, which to date has not been introduced, would create a general antitrust exemption for physicians to act jointly to negotiate and enter contracts with health plans when the share of the relevant market served by the health professionals is smaller than the share of the relevant market of purchasers of such services comprised by the health plans. It does not appear likely that either of these specific legislative proposals will continue to advance through the legislative process during the current session of Congress. Thus, as discussed above and suggested by Senate staff, our AMA, along with the Antitrust Steering Committee, is pursuing an administrative approach while continuing to build support to execute an effective federal legislative strategy.

CONCLUSION

Based upon the current political climate, our AMA is continuing to aggressively pursue changes to the FTC/DOJ Guidelines and use our suggested changes to the Guidelines as a basis for pursuing a legislative strategy.
October 21, 2008

The Honorable Sam Johnson  
U.S. House of Representatives  
1211 Longworth House Office Building  
Washington, DC 20515

Dear Representative Johnson:

On behalf of the members of the American Medical Association (AMA), I am writing to express our support for H.R. 7148, the “Medicare Beneficiary Freedom to Choose Act of 2008.” We applaud your leadership in introducing this important legislation. It is a critical step in providing Medicare beneficiaries with flexibility and freedom of choice in contracting with physicians for medical services.

Within six months of enactment, your bill would allow Medicare beneficiaries to contract privately with a physician or health care practitioner for Medicare-covered services. Your bill would eliminate the current requirement that physicians “opt-out” of the Medicare program for two years if they enter into a private contract with a Medicare beneficiary. This requirement is a strong disincentive for physicians to enter into a Medicare private contract as well as a significant barrier to beneficiaries who wish to have the flexibility and freedom of choice to contract with physicians on a private basis.

The AMA thanks you for your efforts to provide Medicare beneficiaries with increased freedom and flexibility in choosing their physician, and we look forward to working with you to enact H.R. 7148.

Sincerely,

Michael D. Maves, MD, MBA
Statement

of the

American Medical Association

to the

Committee on Small Business
United States House of Representatives

RE: Small Business Competition Policy: Are Markets Open for Entrepreneurs?

Presented by William A. Hazel, Jr., MD

September 25, 2008
The American Medical Association (AMA) appreciates the opportunity to present testimony to the Committee on Small Business regarding Small Business Competition Policy. We commend Chairwoman Velazquez, Ranking Member Chabot, and Members of the Committee for your leadership in recognizing that important changes in the health care market warrant new approaches to health care antitrust policy.

Current health care antitrust enforcement policy unduly restricts physician collaboration, especially among small physician practices. As such, it has chilled physician attempts at joint contracting, hindered physicians’ ability to participate in the full spectrum of health care initiatives, and perpetuated a severe imbalance in the market whereby dominant health insurers that have enjoyed unfettered consolidation force physicians to adhere to contracts that create obstacles to providing optimal patient care and unduly restrict their autonomy. We believe that the Federal Trade Commission (FTC) should provide for more flexibility on physician joint contracting in order to allow small practices to collaborate on Health Information Technology (HIT) and health care quality improvement initiatives. In addition, the Department of Justice (DOJ) must more aggressively challenge health insurer mergers. These steps would restore balance to the health care market and help to ensure an innovative and efficient health care system.

1 Since April 2002, the FTC has brought at least 25 cases against physician groups based upon contracting arrangements with health insurers. All but one of the groups chose to settle with the FTC rather than engage in a protracted, financially devastating legal battle.
Current Antitrust Policy

Despite recent developments and changes in the health care market, enforcement policy—embodied today in the Statements of Enforcement Policy in Health Care (the Statements) developed jointly by the FTC and the DOJ during the 1990s—casts an overly suspicious eye on physician collaboration through network arrangements. Specifically, the Statements give too little credence to the benefits of physician collaboration that do not fit within the agencies’ rigid models of allowable “integration”—attributes that make a joint arrangement sufficiently likely to generate efficiency such that application of a reasonableness standard in evaluating the joint arrangement is appropriate—and overestimate the anticompetitive potential of physician collaborations that lack market power and therefore lack the ability to restrain trade. Arrangements that have benefits to the health care system while posing little risk of anticompetitive injury should be embraced so that physicians may engage in pro-competitive joint arrangements that result in efficiencies and improved patient care and coordination.

The initial version of the Statements was released in September 1993. They reflected efforts to provide clarity to medical professionals and companies by articulating policies that had emerged previously only in advisory letters, speeches, and consent decrees. As originally issued, the Statements contained eight separate policy statements, including one on “Physician Network Joint Ventures.” Statement 8 identified two features of particular importance: (1) the network’s percentage or “share” of the physicians in each physician specialty practicing in the relevant geographic market; and (2) whether the physicians had integrated their practices by sharing “substantial financial risk.”

According to the Statements, sharing “substantial financial risk” could be accomplished in one of two ways: (1) by accepting “capitated” or “per-member per-month” payments, or (2) by incentivizing physicians to contain costs through the use of a substantial withhold from payments. The existence of either of these examples of substantial financial risk meant that the physician collaboration, if challenged, would be evaluated under the rule of reason standard. The absence of any evidence of substantial financial risk would result in summary condemnation as per se illegal price fixing.

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2 The FTC declared in Statement 9, that networks that are not substantially integrated can instead use a "messenger model" arrangement to facilitate their individual contract negotiations with health plans and avoid price fixing. Essentially, proper implementation of the messenger model is achieved when the messenger shuttles between health care professionals and payers, carrying offers on reimbursement rates in a back-and-forth process that eventually will yield a rate acceptable to both the professional and the plan.

3 In the specific context of physician contracting networks, only the sharing of “substantial financial risk” was embraced as sufficient to allow a network to be evaluated under a reasonableness standard. Other forms of integration—structural, functional, or transactional—were not considered adequate.

4 The so-called “rule of reason” has been the hallmark of judicial construction of the antitrust laws. Under its aegis, the anticompetitive consequences of a challenged practice are weighed against the business justifications upon which it is predicated and its putative pro-competitive impact, and a judgment with respect to its reasonableness is made.

5 Per se illegality conclusively presumes the challenged practices to be unreasonable. In other words, when a per se offense (such as price fixing among competitors) is charged, all the government must establish is that the defendant
With the rapid expansion of managed care in the 1990’s, the requirement of financial risk-sharing as the defining feature of a legitimate physician network proved to be unduly restrictive. Contrary to early predictions, in most areas of the country physician capitation proved to be an unpopular and highly controversial payment methodology. Employers wanted broad networks that allowed patients a significant choice among physicians, without perceived incentives to ration care. Yet the definition of “substantial financial risk” adopted by the agencies raised a substantial barrier to the participation of physician-led contracting networks.

In the 1996 version of the Statements, the agencies recognized a second type of integration that could qualify a physician network for rule of reason treatment—“Clinical Integration.” Clinical integration, as defined in the Statements, is evidenced “by the network implementing an active and ongoing program to evaluate and modify practice patterns by the network’s physician participants and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.” 6 Clinical integration as so defined represented a sort of “as if” standard: A physician network that acted “as if” its members shared financial risk—by instituting the types of efficiencies associated with financial risk sharing—might qualify for rule of reason treatment despite the absence of “substantial financial risk.” For several years following the publication of the 1996 Statements, the agencies gave no further guidance on the meaning of clinical integration.

In 2002, however, the FTC issued a staff advisory letter to MedSouth, Inc., an Independent Practice Association (IPA) based in Denver, Colorado with over 400 physicians. 7 And in 2007, the FTC issued a staff advisory letter to the Greater Rochester Independent Practice Association, Inc. (GRIPA), a network based in Rochester, New York with over 600 physician members. 8 The MedSouth and GRIPA letters demonstrate how high the bar has been set for physician networks seeking to clinically integrate. While the MedSouth and GRIPA proposals are not identical, they bear significant similarities. 9 Both MedSouth and GRIPA made significant investments in capital and resources, using myriad consultants, lawyers, and technology experts to assist in the effort. Both networks invested in electronic medical records and tracking technology to share information on their patients and to monitor data relating to utilization and medical outcomes. Both networks developed clinical practice guidelines and procedures for monitoring their compliance, and both networks were “non-exclusive,” meaning that payers choosing not to support the clinically integrated program would not lose access to any desirable physicians who were participating in the network.

has, in fact, engaged in the proscribed practice; illegality follows as a matter of law, no matter how slight the anticompetitive effect, how small the market share of the defendants, or how proper their motives.


9 Notably, both networks were originally built for capitation, but needed to adapt in the face of market resistance. Thus, both MedSouth and GRIPA were constructed “as if” the physicians were sharing substantial financial risk. Only when risk contracting proved to be commercially infeasible did the networks see FTC approval for their clinical integration programs.
Importantly, in both instances, the FTC advisory letters noted no apparent anticompetitive motivation for the physicians’ efforts. Despite this lack of anticompetitive motivation and the significant time and resources employed, however, neither MedSouth nor GRIPA achieved agency approval easily or without significant caveats. Both advisory letters reflected intensive agency investigation of the networks’ history, purposes, contracting mechanisms, disciplinary methods for non-compliant physicians, and strategies for producing efficiencies. Each involved a searching examination of the so-called “ancillarity”\(^\text{10}\) of the networks’ pricing mechanisms to its efficiency-enhancing potential. And each left the agency plenty of room to bring a later enforcement action if the networks’ operations could not later be shown to produce significant efficiencies.

The MedSouth and GRIPA advisory letters reflect the extremely high level of clinical integration required by the FTC. Absent vast resources, such as those available to MedSouth and GRIPA, most physicians are effectively barred from forming physician networks. Without such networks, physicians cannot work collaboratively on costly and involved health care quality initiatives or participate in balanced negotiations with health insurers. We believe that where such collaborative efforts have no ability to restrain trade, there should be more flexibility for physicians to jointly contract.

**Current Antitrust Law**

As their name attests, the Statements of Antitrust Enforcement Policy in Health Care represent enforcement policy rather than law. As such, the Statements do not necessarily stand at the outer boundaries of what antitrust law permits. Indeed, the Statements impose restrictions tighter than required either by the law itself or by sound enforcement policy in the current market environment.

Outside the health care context, courts and the Agencies themselves apply a more flexible analysis than is found in the Statements. For example, in the Agencies’ Guidelines on Competitor Collaboration, there is no mention of financial or clinical integration. Instead, the Competitor Collaboration Guidelines ask more generally whether a joint venture involves “an efficiency-enhancing integration of economic activity” and whether any restraints are “reasonably related to the integration and reasonably necessary to achieve its pro-competitive benefits.”\(^\text{11}\) The Supreme Court, too, in its joint venture cases has eschewed any fixed formulation of what may constitute integration sufficient to warrant rule of reason treatment.\(^\text{12}\)

**RECENT CHANGES IN THE HEALTH CARE MARKET**

Over the past several years, health care market conditions have changed in significant ways that suggest a need to revisit the antitrust landscape. Health plan consolidation has severely limited

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\(^{10}\) Ancillarity refers to whether a price mechanism is “reasonably related to the integration and reasonably necessary to achieve its pro-competitive benefits.” See, e.g., NCAA v. Board of Regents of the Univ. of Oklahoma, 468 U.S. 85 (1984).

\(^{11}\) Antitrust Guidelines for Collaborations Among Competitors (April 2000) (“Competitor Collaboration Guidelines”) at § 3.2.

\(^{12}\) See generally Arizona v. Maricopa County Medical Society, 457 U.S. 332 (1982)
physicians’ ability to advocate on behalf of themselves and their patients. Also, market and regulatory developments are encouraging physician integration for the purposes of purchasing and using HIT and measuring and improving medical care. Rather than protect potential physician clinical integration efforts, current enforcement agency policy discourages them. They have only recognized as lawful, efforts that are out of reach for small and solo physician practices.

Uncontrolled Health Insurer Market Power and Consolidation

The health insurer market has also changed significantly due to a wave of mergers among large HMOs and health insurers over the past decade, steadily eroding the competitive payer market.\(^\text{13}\) In the last decade, over 400 health insurer mergers, only three of which have been challenged by the DOJ, have resulted in an increasingly consolidated payer market.\(^\text{14}\) This consolidation has resulted in the steady increase of premiums, even as patient co-pays and deductibles have expanded, effectively shrinking the scope of coverage, and an extreme imbalance in insurer-physician contracting that threatens all aspects of patient care.

The power garnered by health insurers through rapid, large-scale consolidation has not been used to the advantage of patients or physicians. Patient premiums have soared in this increasingly consolidated market and physician reimbursement has decreased. As premiums have risen, many employers have stopped providing coverage, reduced the scope of benefits provided, and/or asked employees to pay a higher share of the overall premium. As of 2006, premiums for employer-based health insurance rose more than twice as fast as overall inflation and wages for the seventh straight year.\(^\text{15}\) Since 2000, the amount that workers pay toward family health care coverage has skyrocketed 84 percent\(^\text{16}\) and five million fewer workers were receiving job-based coverage in 2006 than in 2000.\(^\text{17}\) During the same period, average wages have increased only 20 percent.\(^\text{18}\) These skyrocketing costs have directly contributed to an increase in the number of uninsured. Research shows that a one percent increase in premiums results in a net increase in the uninsured of 164,000 individuals.\(^\text{19}\)

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\(^{13}\) In 2000, the two largest health insurers, Aetna and UnitedHealth Group (United), had a total combined membership of 32 million people. Due to aggressive merger activity since 2000, including United’s acquisition of California-based PacifiCare Health Systems, Inc., and John Deere Health Plan in 2005, United’s membership alone has grown to 33 million. Similarly, WellPoint, Inc. (Wellpoint), the company born of the merger of Anthem, Inc. (originally Blue Cross Blue Shield of Indiana), and WellPoint Health Networks, Inc. (originally Blue Cross of California), now owns Blue Cross plans in 14 states. In 2005, WellPoint acquired the last remaining Blue Cross Blue Shield plan, the New York-based WellChoice. Consequently, in 2005, WellPoint covered approximately 34 million Americans. Most recently, United acquired Sierra Health Systems in Nevada, allowing United to acquire over 50 percent of the Nevada market, including a 90 percent share of the health maintenance organization (HMO) market. Irving Levin Associates, supra.

\(^{14}\) American Medical Association, [Competition in Health Insurance: A Comprehensive Study of US Markets / 2007 Update], 1

\(^{15}\) The Kaiser Family foundation and Health Research Educational Trust; [Employer Health Benefits 2006 Summary of Findings].

\(^{16}\) Id.

\(^{17}\) Id.

\(^{18}\) Id.

Like America’s patients, physicians have not been the beneficiaries of these increases either. Powerful insurers have depressed physician revenues. The median real income of all U.S. physicians remained flat during the 1990s and has since decreased. Health plan executives and shareholders, on the other hand, are reaping enormous monopoly profits. Recent reports on health insurer profits show that the profit margins of the major national firms have experienced double-digit growth since 2001. United and WellPoint, specifically, have had seven years of consecutive double-digit growth that has ranged from 20 to 70 percent year after year (through 2003).

In addition to effecting costs, payments, and profits, consolidation has given way to an environment in which health plans are able to dictate important aspects of patient care and material contract terms to physicians. Physicians have little to no ability to influence insurer contracts that touch on virtually every aspect of the patient-physician relationship. This means that physicians must agree to contracts that often include provisions that make it difficult, if not impossible, for them to promote what they deem to be the highest quality patient care. For example, many contracts define “medically necessary care” in a manner that allows the health plan to overrule the physician’s medical judgment and require the lowest cost, but not necessarily optimal, care for the patient. Others require compliance with undefined “utilization management” or “quality assurance” programs that often are nothing more than thinly disguised cost-cutting programs that penalize physicians for providing care they deem necessary.

These contracts also often dictate material terms. They may refer to “fee schedules” that are never provided and can be revised unilaterally by the health insurer. Many contracts, in fact, define “medically necessary care” in a manner that allows the health plan to overrule the physician’s medical judgment and require the lowest cost, but not necessarily optimal, care for the patient. Others require compliance with undefined “utilization management” or “quality assurance” programs that often are nothing more than thinly disguised cost-cutting programs that penalize physicians for providing care they deem necessary.

20 Depressed physician reimbursements contribute to higher costs to patients. That lower physician fees paid by insurers may result in higher prices to patients was emphasized by R. Hewitt Pate, a former Assistant Attorney General of the Antitrust Division, in a statement before the Senate Judiciary Committee:

A casual observer might believe that if a merger lowers the price the merged firm pays for its inputs, consumers will necessarily benefit. The logic seems to be that because the input purchaser is paying less, the input purchaser’s customers should expect to pay less also. But that is not necessarily the case. Input prices can fall for two entirely different reasons, one of which arises from true economic efficiency that will tend to result in lower prices for final consumers. The other, in contrast, represents an efficiency-reducing exercise of market power that will reduce economic welfare, lower prices for suppliers, and may well result in higher prices charged to final consumers.


23 See id. at 19-20

24 See id.


26 Many contracts, in fact, are essentially “contracts of adhesion”—standardized contracts that are submitted to a weaker party on a take-it or leave-it basis and do not provide for negotiation.
allow the health insurer to change any term of the contract unilaterally. These contracts also frequently contain such unreasonable provisions as “most favored payer” clauses—clauses requiring physicians to bill the dominant health insurer at a level equal to the lowest amount the physician charges any other health insurer in the region—and “all products” clauses—clauses requiring physicians to participate in all products offered by a health insurer as a condition of participation in any one product.

Despite the improper restrictions and potential dangers of these contracts, current imbalance in the market dictates that physicians typically have no choice but to accept them. Any alleged “choice” is illusory given that choosing to leave the network often means terminating patient relationships and drastically reducing or losing one’s practice. Because medical services cannot be stored or exported, physicians have limited options for selling their services. If physicians were to refuse the terms of the dominant health plan, they would likely suffer an unrecoverable loss. Consequently, a physician’s ability to terminate a relationship with a health plan depends on that physician’s ability to make up for the loss by switching to an alternative insurance coverage plan. Where alternatives are lacking, physicians are forced to accept unfair contracts. Furthermore, even where there are alternatives, physicians are limited in their ability to encourage patients to switch plans, as patients can only switch employer-sponsored plans once a year during open enrollment, and even then, they have limited options and could incur considerable out-of-pocket costs.

In this environment, the antitrust enforcement agencies need to do more to protect competition in health insurer markets. They should also acknowledge that their present antitrust policies on physician networks incur the considerable cost of discouraging important forms of physician clinical integration. Therefore, these policies require revision.

**Insufficiency of Integration models**

Integration, as currently envisioned by the FTC, does not provide a viable option for the vast majority of physicians hoping to contract jointly. Financial risk sharing, as described in the Statements, has largely fallen out of favor. Employers and other purchasers of health care coverage have largely rejected payer-provider risk sharing arrangements. While clinical integration provides a nominal alternative, as noted above, the MedSouth and GRIPA letters suggest a level of investment that for small physician practices is at best an enormous obstacle.

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27 This permits the dominant health insurer to guarantee that it will have the lowest input costs in the market, making it that much more difficult for new payers to enter the market.

28 This often includes the health insurer reserving the right to introduce new plans and designate a physician’s participation in those plans. Given the rapid development of new products and plans, the inability of physicians to select which products and plans they want to participate in makes it difficult for physicians to manage their practices effectively.


30 See id.
and at worst a complete bar to physician collaboration. Likewise, the messenger model, the alternative to integration, is not adequate. It is confusing and complex and has proven to be a minefield for many physicians who have attempted to make use of it.

**Recent Health Care Initiatives**

Another significant change in the health care market is the desire to implement HIT and the rise of quality and consumer directed health care initiatives. There are increasingly focused efforts on developing methods of promoting and measuring quality. At the same time, the federal government is seeking to encourage physicians and other providers to invest in HIT to facilitate the collection and sharing of clinical data. On the payer side, employers are favoring plans that put increasing responsibility on patients to participate actively in choosing (and paying for) care. For physicians, who still practice predominantly in small groups, network arrangements provide one way of achieving the economies of scale necessary to participate in these initiatives.31

The shift towards performance-based reimbursement provides a good example of the strong incentives for physicians to collaborate with one another to collect and analyze quality data. “Pay-for-performance” (P4P) reimbursement is “now routinely used by both private and public payers in the U.S. health care system.”32 A majority of commercial HMOs use P4P, and recent legislation requires Medicare to adopt performance-based incentives.33 As the adoption of P4P spreads and its use expands, physicians in small practices will be increasingly motivated to align in networks in order to have the capability to participate in these programs. Such arrangements will have a strong potential to enhance efficiency, but will not necessarily rise to the level of clinical integration recognized by the agencies.

**PHYSICIAN COLLABORATION WILL IMPROVE HEALTH CARE**

Joint contracting by physicians in a network can result in significant cost savings for both payers and physicians. On the payer side, joint contracting can make it possible for a payer to obtain ready access to a panel of physicians offering broad geographic and specialty coverage.34 Because physicians still practice predominantly in solo practices or in small groups35, creating a physician panel can be a very time-consuming and expensive task and can be a barrier to entry or

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31 *See* H. Pham and P. Ginsburg, “Unhealthy Trends: The Future of Physician Services,” 26 Health Aff. 1586, 1590 (2007) (“widespread adoption [of HIT] will occur only when … [most physicians] practice in large networks that have adequate capital and can both make unified decisions regarding the investment in and optimal use of the integrative potential of the technology.”).


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expansion for new or less significant insurers. In its complaint in United States v. Aetna, the Justice Department noted that, “effective new entry for an HMO or HMO/POS plan in Houston or Dallas typically takes two to three years and costs approximately $50,000,000.” When the physicians themselves undertake the initial task of network formation, payers may substantially reduce the costs of entry and expansion. Joint contracting thus has the potential both to reduce costs for payers and to increase competition in payer markets. These are cognizable benefits, with real potential to lower premiums and expand coverage for America’s patients.

Joint contracting can also make physician contracting more efficient and lead to better-informed contract decisions. Most physician practices are simply too small to afford to hire businesspeople and lawyers to review their contracts with payers. Such practices do not have the resources to analyze complex contracts. Whereas payers have sophisticated actuarial and financial resources that enable them to structure and evaluate complex contract proposals, physicians are often in the dark when they consider a contract. By pooling their resources, physicians can spread the costs associated with the analysis of payer contracts, and develop appropriate counter-offers that can benefit patient, physicians, and payers. The effect is to enhance the efficiency of the physicians’ practices and make them more responsive to the demands of competition.

Likewise, joint contracting can provide the resources physicians need for creating networks that will facilitate collaboration on HIT. Currently, however, physicians are unable to capture the financial returns or significant benefits from HIT that are necessary to offset the daunting implementation costs. Instead, those benefits and financial returns accrue mainly to health plans or patients, rather than physicians. The benefits of HIT fall into two basic categories. First, the system may reduce the costs of running a medical practice. It is unlikely, however, as noted by the Congressional Budget Office, that a solo practitioner or a small group practice will realize any real, internal cost savings from information technology systems. Second, these systems can create cost savings by increased availability of patient data and reducing things such as duplication in services provided to patients. For instance, HIT may reduce the frequency of primary and specialty physicians ordering the same test.

This is a common problem recognized in economics—the problem of externalities. An externality arises when an individual cannot recover the costs of investing in an asset because most of the benefits fall to an individual whom the investor has no way of charging for the benefit. In the health care context, the benefits of costly HIT systems do not produce the

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37 Any doubt concerning the intrinsic efficiency of physician networks should be eliminated by the thriving rental network business that has emerged to supplement inadequate networks.
39 Building roads is a good example, as is putting air filtration systems on factories. When the externality is large and the upfront costs for the investment are significant in relation of the expected recoverable benefit, a market failure occurs. This market failure means the investment is not made and consumers are made worse off.
40 Acquiring and implementing an Electronic Health Record (EHR) system, for example, entails a significant financial investment. One study examining such acquisition costs for solo or small group practices estimated that “[i]ntial EHR costs were approximately $44,000 per full-time equivalent (FTE) provider per year, and ongoing costs were about $8,500 per FTE provider per year.” R.H. Miller, et al., “The Value of Electronic Health Records in
necessary incentives for physicians to invest in them. For this reason, only 14 percent of physicians have minimally functional Electronic Health Record (EHR) systems.\textsuperscript{41} Solo or single partner practices, accounting for about half of all doctors, had the lowest level of comprehensive EHR use—7.1 percent of solo practitioners and 9.7 percent of those with a partner.\textsuperscript{42}

While joint negotiation may have an impact on costs for physician services, it will reduce overall system costs. HIT systems will create efficiencies that will improve care and likely reduce costs. According to the CBO report, HIT has the potential, if adopted widely and used effectively, to save the health care sector about $80 billion annually (in 2005 dollars).\textsuperscript{43} Thus, gains in the form of market efficiencies, reduced utilization, and increased availability of patient data will offset higher costs for networks to implement HIT. The FTC recognized this in its GRIPA advisory letter:

Higher unit prices may be of little concern to a customer if they occur within integrated programs that result in lower total costs (e.g., through elimination of unnecessary and inappropriate utilization of services) and higher quality (e.g., better medical outcomes).\textsuperscript{44}

How well HIT lives up to its potential, however, depends in part on how effectively financial incentives are realigned to encourage the optimal use of the technology’s capabilities.\textsuperscript{45} In the current environment, health insurers, the entities most likely to benefit from cost savings, have demonstrated little interest in implementing these systems and are unlikely to make substantial investments in HIT in the future. Given the expense of HIT implementation and the inability of physicians, the group to which the burden of implementation has fallen, to capture the majority of benefits and returns, physicians should be permitted to negotiate jointly with payers to properly allocate cost savings. Without the ability to recoup some of the expense of these systems by joining a network and achieving increased contracting efficiencies, it will be difficult, if not impossible for many physicians across the country to make the significant investments in time and money that the adoption of such a system would require.

Joint contracting is also essential for those physicians in small or solo practices who wish to participate in performance-based payment initiatives. The data and coordination required for these programs is out of reach for the majority of physicians. The FTC in its GRIPA advisory letter recognized this when it noted that implementing a program in which different subsets of physicians are participating in different payer contracts “could interfere with the network’s ability to effectively gather data and monitor and evaluate physician performance under the program.” Currently, most performance-based payment initiatives are specifically targeted at medical groups or networks rather than small practices. As a Commonwealth Fund study on P4P recently noted:

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Solo or Small Group Practices,” 24 Health Aff 1127, 1130 (2005).
\textsuperscript{41} Office of National Coordinator for Health Informational Technology (July 2007).
\textsuperscript{42} Id.
\textsuperscript{43} CBO Report, at 18
\textsuperscript{44} GRIPA at 27
\textsuperscript{45} CBO Report at 7.
Smaller groups generally have few incentives for care coordination, as they usually do not receive payment beyond the evaluation and management fees they are able to bill for acute visits. However, by banding together under the umbrella of organizations, and becoming eligible for performance payments through [the Medicare P4P Demonstration Project] or similar incentive programs, they have more motivation and support for care coordination.46

Physicians, who still practice predominately in small groups, lack the scale to participate in quality and HIT programs. By teaming up in a network, small practices may gain the magnitude for the care coordination, aggregation of data, and purchasing power required for the implementation of these initiatives.

CONCLUSION

The health care antitrust landscape has changed. FTC and DOJ policies that have led to aggressive antitrust enforcement actions against physicians, unfettered consolidation of health insurers, and limited opportunities for physicians to collaborate on important initiatives should be re-examined. Physician joint contracting provides ready access to physician panels, fair, efficient, and informed contract negotiations, and economies of scale to participate in HIT and quality programs. In addition, most physician networks pose no threat to competition. Rather than restraining trade, a more flexible approach to joint contracting will have a pro-competitive result—promoting and rewarding efficiency and innovation in the health care system. Thus, we encourage the FTC to revisit the Statements to accommodate the needs of the changing health care market.

Whereas, In some countries PLI issues are treated as criminal concerns; and
Whereas, Most PLI issues are unrelated to intent to commit a crime; therefore be it
RESOLVED, That our American Medical Association oppose the criminalization of professional liability concerns and lawsuits. (New HOD Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09
H-160.954 Criminalization of Medical Judgment
(1) Our AMA continues to take all reasonable and necessary steps to insure that medical decision-making, exercised in good faith, does not become a violation of criminal law. (2) Henceforth our AMA opposes any future legislation which gives the federal government the responsibility to define appropriate medical practice and regulate such practice through the use of criminal penalties. (Sub. Res. 223, I-93; Reaffirmed: Res. 227, I-98; Reaffirmed: Res. 237, A-99; Reaffirmed and Appended: Sub. Res. 215, I-99)

H-160.946 The Criminalization of Health Care Decisionmaking
The AMA opposes the attempted criminalization of health care decisionmaking especially as represented by the current trend toward criminalization of malpractice; it interferes with appropriate decision making and is a disservice to the American public; and will develop model state legislation properly defining criminal conduct and prohibiting the criminalization of health care decisionmaking, including cases involving allegations of medical malpractice, and implement an appropriate action plan for all components of the Federation to educate opinion leaders, elected officials and the media regarding the detrimental effects on health care resulting from the criminalization of health care decisionmaking. (Sub. Res. 202, A-95; Reaffirmed: Res. 227, I-98; Reaffirmed: BOT Rep. 2, A-07)
IN THE GENERAL ASSEMBLY
STATE OF ____________

An Act*

To Prohibit the Criminalization of Health Care Decision-Making

Be it enacted by the People of the State of ____________, represented in the General Assembly:

Section 1. Title. This Act shall be known and may be cited as the "Act to Prohibit the Criminalization of Health Care Decision-Making."

Section 2. Purpose. The Legislature hereby finds and declares that:

(a) There is a current trend among prosecutors and courts to subject physicians to criminal prosecution in cases of medical liability;

(b) A physician’s exercise of clinical judgment is already subject to peer review processes, regulation by the state licensing board, including license revocation, and civil liability for cases of medical liability.

(c) The state also has the authority under the state penal code to prosecute physicians whose acts or omissions reflect sufficient criminal intent and cause sufficient injury.

(d) Subjecting physicians to criminal prosecution for clinical decisions made based on their professional judgment would have a serious detrimental impact

*This model bill may be used by states in several ways: (1) as a separate enactment or (2) as an amendment to the state penal code.
on their ability to exercise that judgment, which is contrary to the interests of
the public.

Section 3. Definitions.

(a) “Criminal intent” means the intent to commit a crime.
(b) “Health care services” means acts of diagnosis, treatment, medical evaluation
or advice or such other acts as may be permissible under the health care
licensing statutes of this state.
(c) “Physician” is an individual who has received a “Doctor of Medicine” or
“Doctor of Osteopathy” degree following successful completion of a
prescribed course of study from a school of medicine or osteopathy.

Section 4. Requirements. Any physician licensed to provide health care
services in the state who, in the absence of criminal intent, renders or fails to render
health care services, shall not be subject to criminal liability resulting from any act or
omission related to such rendering of or failure to render health care services.

Section 5. Effective Date. This Act shall become effective immediately upon
being enacted into law.

Section 6. Severability. If any provision of this Act is held by a court to be
invalid, such invalidity shall not affect the remaining provisions of this Act, and to this
end the provisions of this Act are hereby declared severable.

Revised 11-2007
Whereas, Electronic prescribing (E-prescribing) is becoming more common in physician practices; and

Whereas, The prevalence of E-prescribing will become even more commonplace as government and insurers incentivize physicians to use this technology and later penalize them for not using it; and

Whereas, E-prescribing improves patient safety and quality of care by eliminating illegibility and oral miscommunication, providing warning and alert systems and contemporaneous access to patient medications; and

Whereas, E-prescribing makes more efficient use of physicians’ time by reducing time spent on the phone and faxing prescriptions, automating the prescription and renewal process, and increasing patient convenience and compliance; and

Whereas, Current federal regulations do not allow for the E-prescribing of Class 3 controlled substances such as Hydrocodone and benzodiazepines; and

Whereas, This prohibition negates all of the advantages noted above, increasing time spent by physicians and their staffs in all specialties, but especially those in primary care, oncology and pain management; and

Whereas, Currently physicians are allowed to transmit Class 3 drugs via facsimile, which is a form of “electronic transmission”; therefore be it

RESOLVED, That our American Medical Association work through appropriate channels to permit secure electronic prescriptions of controlled substances. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $9,294.

Received: 05/05/09
Whereas, The Centers for Medicare & Medicaid Services has mandated electronic prescription as part of the electronic medical record for 2011; and

Whereas, The Drug Enforcement Agency does not recognize either computer to computer or computer to facsimile transmissions of controlled substance prescriptions to be valid prescriptions; and

Whereas, Any controlled substance prescription received other than by oral transmission must bear a manual signature (not a computer-generated one) when received from the patient directly or via the facsimile machine; and

Whereas, American Medical News in an opinion piece on April 27, 2009 talked about E-prescribing; and

Whereas, Prescriptions for Schedules II through V may also be transmitted orally by either the prescriber or his or her agent to the pharmacist; therefore be it

RESOLVED, That our American Medical Association work with the US Drug Enforcement Agency to allow the electronic submission of prescriptions for Schedule II thru V medications. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $867.

Received: 05/06/09
D-120.958 Federal Roadblocks to E-Prescribing

1. Our AMA will initiate discussions with the Centers for Medicare and Medicaid Services and state Medicaid directors to remove barriers to electronic prescribing including removal of the Medicaid requirement that physicians write, in their own hand, “brand medically necessary” on a paper prescription form.
2. Our AMA will initiate discussions with the Drug Enforcement Administration to allow electronic prescribing of Schedule II prescription drugs.
3. It is AMA policy that physician Medicare or Medicaid payments not be reduced for non-adoption of E-prescribing
4. Our AMA will work with federal and private entities to ensure universal acceptance by pharmacies of electronically transmitted prescriptions.
5. Our AMA will advocate for appropriate financial and other incentives to physicians to facilitate electronic prescribing adoption. (Res. 230, A-08; Reaffirmed in lieu of Res. 215, I-08)

D-120.972 Electronic Prescribing

digital certificate standards for direct electronic transmission of controlled substance prescriptions to support the patient safety goals and other governmental initiatives; and (2) urge Congress to

Our AMA will (1) ask the Drug Enforcement Administration to accelerate the promulgation of work towards unifying state prescription standards and standard vocabularies to facilitate adoption of electronic prescribing. (Res. 525, A-05; Reaffirmed in lieu of Res. 215, I-08)

H-120.957 Prescription of Schedule II Medications by Fax and Electronic Data Transmission

Our AMA: (1) encourages the Drug Enforcement Administration to rewrite Section 1306 of Title 21 of the Code of Federal Regulations to accommodate encrypted electronic prescriptions for Schedule II controlled substances, as long as sufficient security measures are in place to ensure the confidentiality and integrity of the information. (2) Our AMA supports the concept that public key infrastructure (PKI) systems or other signature technologies designed to accommodate electronic prescriptions should be readily adaptable to current computer systems, and should satisfy the criteria of privacy and confidentiality, authentication, incorruptibility, and nonrepudiation. (3) Because sufficient concerns exist about privacy and confidentiality, authenticity, and other security measures, the AMA does not support the use of "hard copy" facsimile transmissions as the original written prescription for Schedule II controlled substances, except as currently allowed in Section 1306 of Title 21 of the Code of Federal Regulations (BOT Rep. 8, A-99; Reaffirmed in lieu of Res. 215, I-08)
September 25, 2008

Michele M. Leonhart
Acting Administrator
Drug Enforcement Administration
DEA Federal Register Representative/ODL
8701 Morrissette Drive
Springfield, Virginia 22152


Dear Acting Administrator Leonhart:

The American Medical Association (AMA) along with the undersigned organizations appreciate the opportunity to provide comments on the Drug Enforcement Administration’s (DEA) proposed rule on electronic prescriptions for controlled substances. Under the rule, the DEA proposes a process for electronic prescribing (e-prescribing) of controlled substances that supplements, but does not replace, existing prescribing and dispensing requirements established by the Controlled Substances Act (CSA) and DEA regulations.

Currently, prescribers are prohibited from e-prescribing controlled substances. When properly implemented, an e-prescribing process and system for controlled substances will assist physicians with improving patients’ quality of life in a safer, more secure, and efficient manner. Automating our current paper-based process is expected to create a safer prescribing environment by eliminating errors due to illegible handwritten prescriptions, providing physicians with drug interaction information at the point of care, and creating electronic audit trails of prescriptions for tracking purposes. In order to be successful, the e-prescribing process and system should be practical, functional, secure, as well as affordable for physicians.

Although we recognize the challenges associated with establishing a secure process and system for e-prescribing, we believe that the NPRM falls short of the goal of establishing a secure process for e-prescribing of controlled substances that is also effective and practical, and so we urge the DEA to revise language accordingly. Our initial concern is that the proposed rule would instead impose multiple stringent
security, authentication, and risk management requirements for users of e-prescribing. These additional requirements will force physicians to implement two different electronic workflows for e-prescribing: one for controlled substances and one for noncontrolled substances. Furthermore, the proposed standards go above and beyond many of the current requirements physicians must meet when prescribing non-electronic controlled substances. Given the complexity, costs, and liability concerns associated with the proposed rule, physicians may be reluctant to adopt e-prescribing for controlled substances. **We, therefore, strongly recommend that the DEA establish an advisory panel comprised of key stakeholders, including physicians, to develop a process for e-prescribing that properly balances efforts to minimize drug diversion and the nonmedical use of prescription drugs while maintaining a clinical practice environment conducive to safer, efficient, and high quality care.**

**In-Person Identity Proofing**

Under the DEA’s proposed rule, a non-federal health care facility would be required to undergo in-person identity proofing and submit documentation to authenticate their identity. The identity proofing would be conducted by a DEA registered hospital, a State licensing board, or a State or local law enforcement agency. Although some states currently require physicians to register with their state board of pharmacy, prescribers are not required to undergo in-person identity proofing. We fail to see the rationale for requiring in-person identity proofing only for e-prescribing of controlled substances given that there are no assurances that this burdensome requirement will actually reduce prescription forgery, fraud, theft, and other-related crimes to drug diversion. Even the proposed rule acknowledges that, “most identity theft occurs not from people hacking into systems, but rather from insiders who know how to manipulate the system.” Furthermore, if this stringent standard is adopted, physicians practicing in rural and remote areas, who would be required to travel significant distances for identity proofing, would likely be reluctant to engage in this process.

The imposition of additional fees for identity proofing is an additional barrier to e-prescribing adoption and use. The proposed fees associated with identity proofing—costs estimated by the DEA at $62 per physician—would add to an already costly DEA registration process that includes a $551 license fee for renewals; which is disproportionately high as compared to other registrants’ fees. The DEA’s costly registration / renewal process is made further unaffordable by the fact that the fees apply to all the states in which the prescriber needs to be registered. **We urge the DEA to remove in the final rule any fees on prescribers for identity proofing or increases in DEA prescriber registration fees.**

We also believe that the DEA should reconsider the current requirement that physicians, who prescribe in multiple states, as well as locum tenens physicians, obtain a separate DEA number per state. If the DEA were to make DEA numbers less accessible to non-DEA registrants and the public, such stringent controls would not be necessary, including the proposed in-person identity proofing. **We, therefore, strongly urge the DEA not to require in-person identity proofing and**
recommend the issuance of one federal DEA number that would be physician-specific and not site-specific in order to reduce the unnecessary burdens and costs on physicians for maintaining multiple DEA numbers.

**Digitally Signed Records**

The DEA explored, but chose not to require, practitioners to digitally sign electronic controlled substances. Digital signatures are created as part of a public key infrastructure (PKI) — a method for ensuring the integrity of an electronic message. This system uses asymmetric cryptography where an algorithmic function is used to create two mathematically related or complimentary public and private keys. Under an e-prescribing scenario, a prescriber would send an encrypted prescription to a pharmacy. With PKI, a trusted party conducts identity proofing and provides a subscriber (prescriber) with a pair of keys; a private key just for the subscriber and a separate public key which can be made available to anyone. The advantage of PKI is that it allows the confidential transmission of information in open networks when parties do not know one another in advance and eliminates the need to share secret key information.

We support the use of PKI systems or other signature technologies designed to accommodate electronic prescriptions for sending Schedule II prescriptions. We believe these technologies should be adaptable to current computer systems, and satisfy the criteria of privacy and confidentiality, authentication, incorruptibility, and nonrepudiation. The DEA however, proposes not to use the PKI because the “intermediaries” in the existing e-prescribing system frequently reformat prescriptions during transmission, and in essence, alter what was originally sent by the prescriber making it impossible to validate a physician’s digital signature. Physicians must be assured that the prescriptions they issue will be transmitted to the pharmacy as intended.

While we believe that the standards should accommodate the use of PKI for those prescribers who would like to use PKI, we do not support instituting separate prescribing requirements for the electronic transmission of Schedule II prescriptions vs. Schedules III-V, as this would impose an unnecessary level of complexity for prescribers and would result in a burdensome process that is likely to impede the e-prescribing adoption and use rates for controlled substances. **We urge the DEA to reconsider the use of PKI or other signature technologies, should a physician elect to use them.**

**Authentication**

Authentication is information (e.g., PINs, passwords, biometrics) that is used to verify a person’s identity for security purposes. The authentication methods could be one-factor, two-factor, or multi-factor, and can be described as something you know, something you have, or something you are. The DEA has proposed a two-factor authentication requirement that calls for something you know and something you
have. The DEA further proposes the use of two factors with one of them to be stored on a “hard token” or the use of a multi-factor one time password token (e.g., hardware device like a PDA that generates one time passwords for use in authentication). The known item could be a password, while a hard token could be a PDA, cell phone, thumb drive, smart card, etc. According to the DEA’s proposed rule, hard tokens would need to meet certain standards and the password could not be used without the hard token.

We are very concerned about the DEA’s authentication proposal and believe that the requirement to use a hard token is unworkable in most practice settings. A recent AMA e-prescribing survey indicated that primary care physicians wrote up to 100 prescriptions per day. Specialists usually write an average of 10 to 25 prescriptions per day. Given the sheer volume of prescription activity, requiring a physician, especially a high volume prescriber, to comply with two-factor authentication with a hard token combined with a separate authentication process is onerous and will significantly affect practice workflows. This proposed requirement is even more challenging for physicians who prescribe controlled substances for patients in multiple states as they would need multiple tokens. For example, a small group practice that serves patients from a tri-state area would be required to manage multiple tokens for each physician, a situation that would be confusing and ultimately unmanageable. Adding just a few minutes a day for each controlled substance prescription would substantially affect physician practice workflows and take time away from patient care. The efficiencies intended under an electronic system would be lost if the hard token approach is adopted. In order for hard tokens to work, the computer to which it is authenticating must be properly configured. The technological complexities and costs associated with these adjustments, especially for smaller practices, have not been thoroughly assessed by the DEA.

Moreover, hospitals and other settings outside the physicians’ practice must also be configured to accept hard tokens and most of these settings prohibit the connection of foreign devices to their systems due to security concerns. We believe the DEA’s proposed authentication requirement will detract significantly from the workability of an e-prescribing system for controlled substances and would deter physicians from using the system. The Certification Commission for Healthcare Information Technology (CCHIT), an electronic health records (EHRs) certification body funded by the Department of Health and Human Services (HHS), does not recommend the requirement of a hard token. **A two-factor authentication is not unreasonable however, the requirement that one factor be a hard token is. Should the DEA adopt a two-factor authentication standard, we strongly urge the DEA to remove the requirement that one factor be a hard token.**

**Access Limitations and Signing**

The proposed rule requires that the prescriber authenticate to the system using the two-factor authentication immediately prior to signing and transmitting the electronic prescription. This is not practical given that there may be a significant time lapse
between writing and transmitting a prescription. Physician practices often prepare information ahead of time (i.e., during patient visit) but must submit the prescription within a specified time period (i.e., time periods identified in the patient’s certificate of coverage). In addition, under the current system, physicians are able to write prescriptions with future fill dates and thus the DEA’s proposed rule would not allow for the transmission of predated prescriptions.

The DEA also proposes that after authenticating to the system but prior to the transmission of the electronic prescription, the system must present the following statement that the prescriber is required to positively attest to and “sign” (electronic signature):

“

I, the prescribing practitioner whose name and DEA registration number appear on the controlled substance prescription(s) being transmitted, have reviewed all of the prescription information listed above and have confirmed that the information for each prescription is accurate. I further declare that by transmitting the prescription(s) information, I am indicating my intent to sign and legally authorize the prescription(s).”

Today, under paper-based systems, prescribers are not required to positively attest to the above-mentioned statement. The DEA indicates that the purpose of agreeing to this statement would be to “help positively bind the practitioner to the prescription” and provide nonrepudiation. We do not agree. Physicians will already be required to authenticate to the system in order to gain access. Requiring a physician to electronically sign or attest to such a statement provides no further assurance of the identity of the prescriber. Therefore, we believe that this attestation is unwarranted and should not be required. Furthermore, prescribers must currently adhere to CSA and DEA requirements and e-prescribing controlled substances does not alter this responsibility. The sheer volume of information proposed by the DEA, which the prescriber needs to review prior to the transmission of the prescription, is not workable in existing practice settings. **We urge the DEA to remove the attestation requirement.**

However, we do agree that after authenticating to the system but prior to transmitting the controlled substance prescription, a limited summary of the controlled substance prescription being transmitted should be displayed (i.e., full name and address of the prescribing practitioner, the DEA registration number of the prescribing practitioner, full patient’s name and address, the name of the drug prescribed, the dosage strength and form, quantity prescribed, and directions for use); a process that could further help avert medication errors. The medication list should also be available prior to the authentication and transmission of a single prescription.

As the DEA notes, electronic signatures are considerably different from digital signatures. Signing an electronic prescription is merely an attestation by the prescriber to the validity of the prescription which would legally bind them to that prescription. Because it does not provide any further assurance against
nonrepudiation, we oppose such a requirement. Digital signatures on the other hand, as discussed earlier, are used to maintain the integrity of the prescription and are thus preferable. The advantage of using digital signatures is that “they provide, in a single step, what other systems do not: a straightforward means of determining record integrity. If the first recipient of an electronic prescription signs it digitally, (the) DEA will be able to prove what the practitioners signed.”

**Automatic “Timeout”**

The DEA proposes a two-minute “timeout,” which would lock a prescriber out of an electronic system if the system is not used within the two-minute time frame. The two-minute timeout rule is just not practical and does not take into account the realities of a fast-paced prescribing environment where physicians are constantly multi-tasking. For example, if a physician began to enter a prescription into the system and had to take an urgent call, the physician would be logged out of the system within 2 minutes. **We, therefore, recommend that the physician be provided with the flexibility to set an automatic timeout according to his/her practice workflow.**

**Prescribing Logs**

The DEA’s proposal requires service providers to generate a monthly log of prescriptions for controlled substances to prescribers. Requiring physicians to review a monthly log of all of their electronic controlled substance prescriptions, affirmatively indicate having done so, and retain such records for at least 5 years, is overly burdensome. Given the sheer volume of prescribing activity, it is too onerous and time-consuming for physicians, especially high volume prescribers, to review a log of their prescriptions on a monthly basis and attest to this review. It is entirely unclear why this is being required when paper-based prescriptions could be altered and yet there is no requirement for reviewing lists of non-electronic controlled substances prescriptions. However, we agree that logs should be made available for review but requiring physicians to review every single electronic prescription and attest to the log’s accuracy is excessive. **We, therefore, recommend that the DEA remove the requirement for physicians to confirm monthly reviews of prescription logs generated by service providers.**

**Third-Party Audits**

The proposed rule also calls for prescribers to only use systems that meet DEA’s security and prescribing requirements. The DEA proposes that vendors and pharmacies pursue third-party audits performed by qualified certified public accounting firms in order to confirm that their systems meet DEA standards. In turn, prescribers would be required to initially and annually thereafter review the third-party audit report provided by their service vendor and affirm that their system complies with DEA requirements. If the system is non-compliant the prescriber
would be required to immediately cease use. Physicians do not have the technical or law enforcement expertise to make such determinations.

Furthermore, the CCHIT does not certify stand alone e-prescribing systems so physicians would be unable to determine whether their e-prescribing systems are compliant with widely-recognized technical and security standards. Moreover, the requirement that a physician immediately cease using a system that is determined not to meet DEA’s requirements could significantly affect patient access to needed prescriptions. **We urge the DEA to remove the requirement for physicians to attest that their EHRs or e-prescribing systems are compliant with the DEA requirements.**

**Service Provider and Intermediary Accountability**

The term, service provider, which is not defined in the proposed rule, refers to a software vendor that a prescriber uses to create a prescription and to parties involved with transmission of the prescription. We recommend that terms and definitions for both of these described parties be clearly defined because their functions differ.

We also are concerned that in order for prescribers and pharmacies to comply with DEA requirements they must rely upon the services of other parties, the “service providers” and “intermediaries,” which are not required to comply with the CSA or DEA regulations. The lack of accountability of non-regulated parties could adversely effect requirements intended to ensure the integrity and security of controlled substance prescriptions. This lack of accountability is already being experienced with the enforcement of the Health Insurance Portability and Accountability Act (HIPAA). Under HIPAA, health care providers, payers, and clearinghouses are considered “covered entities” and are required to comply with privacy and security standards when using or disclosing protected health information. Although third party billers, employers, personal health record vendors, marketing firms, as well as other non-HIPAA covered entities may handle protected health information, they are not held directly accountable under HIPAA. This creates a gap in federal privacy protection coverage that leaves large volumes of identifiable health information vulnerable to improper access and disclosure without meaningful enforcement mechanisms or remedies. The DEA’s lack of jurisdiction over service providers and intermediaries also creates a gap in ensuring the integrity and security of e-prescribing of controlled prescriptions. **We, therefore, urge the DEA to pursue legislation that extends legal responsibilities to non-DEA covered parties involved with the electronic transmission and processing of prescriptions for controlled substances.**

**Cost Impact of Security Measures and Requirements**

One of the most significant and widely-recognized barriers for physician adoption of e-prescribing and health information technology (HIT) is cost. The proposed rule indicates that the average cost of an EHR ranges from approximately $20,000 to $50,000 per physician, not including an annual maintenance charge of
$6,000 per doctor. Additionally, the extensive technical, security, and other standards requirements (i.e., costs for registration, hard token hardware, software, indirect costs, reprogramming, and audit requirements) for e-prescribing controlled substances will undoubtedly be significant and ultimately be passed on to physicians and others. For example, the proposed rule indicates that the initial programming costs in order to comply with the DEA requirements will be $36,700 for an EHR. Moreover, the DEA projects a 4 percent per year adoption rate and 15 years for implementation which clearly indicates that the DEA requirements are too costly and burdensome. **Given that the costs of acquiring and maintaining EHRs and the additional costs associated with adoption of the DEA proposed standards, we strongly recommend that the DEA work with an advisory panel comprised of key stakeholders, including physicians, in order to come up with an affordable, functional, practical, and secure mechanism for e-prescribing controlled substances.**

**Other Standards**

Converting Electronic Prescriptions to Fax or Paper

Under the proposed DEA rule, once a controlled substances prescription has been sent electronically, it can not be printed or faxed, otherwise the prescription would be rendered invalid. In the case of the use of "hard copy" facsimile transmissions, as with the original written prescription for Schedule II controlled substances, we agree that faxes should not be permitted, except as currently authorized in accordance with Section 1306 of Title 21 of the Code of Federal Regulations.

We are concerned however about precluding prescribers from printing documentation of copies of their controlled substance prescriptions. There may be situations which call for the printing of a controlled substance prescription after it has been electronically transmitted to a pharmacy. For example, a physician may be audited by a health care payer and contractually required to furnish medical records, including prescriptions for controlled substances. Moreover, HIPAA requires physicians to furnish patients with a copy of their medical record, including prescription information, upon request. It is also unclear what protocol a physician would have to follow for network transmission failures. The resubmission of a prescription due to a network transmission failure could be erroneously deemed as a duplicate. **We, therefore, urge the DEA to permit physicians to print documentation of controlled substance prescriptions so long as the print out clearly delineates the copy as a “duplicate” or a “copy.”** We also urge the DEA to define the term “transmission” and explain how transmission errors would be identified and handled.

Reporting Lost or Stolen Tokens

We are concerned with a provision in the proposed rule that would hold physicians responsible for any controlled substance prescriptions written using the hard token if
the hard token is lost, missing, or compromised, and not reported within 12 hours of discovery. We strongly believe that this additional legal burden imposed on physicians will act as a disincentive for physicians to e-prescribe controlled substances given that they can be held liable for unforeseeable actions resulting from a lost or stolen smart card, cell-phone, or PDA. We also believe that the 12 hour time frame for reporting purposes is not practical. For instance, if a prescriber’s cell phone is lost or stolen on a Friday evening, and the service provider is not available until Monday morning, the 12 hour time limit would not be met. We also recommend defining the vague term “compromised” or removing it altogether. **We strongly recommend that the time frame for reporting a lost or stolen token be extended to 48 hours and that physicians not be held responsible for actions resulting from a lost or stolen hard token.**

The “Medicare Improvements for Patients and Providers Act of 2008” (MIPPA)

Shortly after the DEA published the proposed regulation for electronic prescriptions of controlled substances, the President signed the “Medicare Improvements for Patients and Providers Act of 2008” (MIPPA) (P.L. 110-275) into law on July 15, 2008. In order to encourage the adoption and use of e-prescribing, this new law includes both incentives and the imposition of penalties for e-prescribing, and among many other things, creates incentives for physicians to electronically prescribe prescriptions written for Medicare patients under Part D of the Medicare program. Based upon allowed Medicare charges, physicians who e-prescribe in 2009 and 2010 will be eligible for a 2 percent Medicare payment bonus, which will be phased down to 1 percent in 2011 and 2012 and 0.5 percent in 2013. Physicians, who do not e-prescribe, will be penalized by 1 percent in 2012, by 1.5 percent in 2013, and by 2 percent in 2014 and beyond.

At this time, the Secretary has not published conforming regulations stipulating how the e-prescribing program in MIPPA will operate. For example, it is unclear whether controlled substances will be excluded from determining whether a physician will be exempt from receiving incentives and/or facing penalties. Given the complexity, costs, and liability concerns associated with the DEA's proposed rule, physicians may be reluctant to adopt e-prescribing for controlled substances. **We, therefore, urge the DEA to recommend that CMS use discretionary authority as provided under MIPPA to exempt the e-prescribing of controlled substances from any assessment of penalties against physicians who choose not to e-prescribe controlled substances. In order to enhance e-prescribing adoption and use rates, the DEA should also recommend to CMS that physicians be entitled to receive incentive payments, regardless of whether they choose to e-prescribe controlled substances in accordance with the DEA's final rule and requirements.**

**Conclusion**

We appreciate the opportunity to comment on this proposed rule and look forward to providing ongoing input to the DEA to ensure the development of an e-prescribing
process and system for controlled substances that is practical, functional, affordable, and secure for physicians. Should you have questions about these comments, they can be directed to Mari Savickis at mari.savickis@ama-assn.org or 202-789-7414.

Sincerely,

American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Home Care Physicians
American Academy of Hospice and Palliative Medicine
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Pain Medicine
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Physicians
American College of Radiology
American College of Surgeons
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Psychiatric Association
American Society of Addiction Medicine
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society of Hematology
American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
Congress of Neurological Surgeons
Infectious Diseases Society of America
Medical Group Management Association
Society of Hospital Medicine
Society of Interventional Radiology
Whereas, Physicians are now required to provide interpretive services to their non-English speaking patients; and

Whereas, It is nearly impossible to find licensed medical interpreters for some languages; and

Whereas, Reimbursements continue to decrease in relation to the cost of maintaining an office practice; and

Whereas, Physicians are now being found legally liable if they do not provide these services; therefore be it

RESOLVED, That our American Medical Association initiate legislation or regulation that physicians be reimbursed for the cost of providing interpretive services. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $9,294.
H-160.924 Use of Language Interpreters in the Context of the Patient-Physician Relationship
AMA policy is that: (1) further research is necessary on how the use of interpreters--both those who are
trained and those who are not--impacts patient care; (2) treating physicians shall respect and assist the
patients’ choices whether to involve capable family members or friends to provide language assistance
that is culturally sensitive and competent, with or without an interpreter who is competent and culturally
sensitive; (3) physicians continue to be resourceful in their use of other appropriate means that can help
facilitate communication--including print materials, digital and other electronic or telecommunication
services with the understanding, however, of these tools’ limitations--to aid LEP patients’ involvement in
meaningful decisions about their care; and (4) physicians cannot be expected to provide and fund these
translation services for their patients, as the Department of Health and Human Services’ policy guidance
currently requires; when trained medical interpreters are needed, the costs of their services shall be paid
directly to the interpreters by patients and/or third party payers and physicians shall not be required to
participate in payment arrangements. (BOT Rep. 8, I-02; Reaffirmation I-03; Reaffirmed in lieu of Res.
722, A-07)

H-385.928 Patient Interpreters
Our AMA supports sufficient federal appropriations for patient interpreter services and will take other
necessary steps to assure physicians are not directly or indirectly required to pay for interpreter services
mandated by the federal government. (Res. 219, I-01; Reaffirmed: BOT Rep 8, I-02; Reaffirmation I-03;
Reaffirmed in lieu of Res. 722, A-07)

D-385.978 Language Interpreters
Our AMA will: (1) continue to work to obtain federal funding for medical interpretive services; (2)
redouble its efforts to remove the financial burden of medical interpretive services from physicians; (3)
urge the Administration to reconsider its interpretation of Title VI of the Civil Rights Act of 1964 as
requiring medical interpretive services without reimbursement; (4) consider the feasibility of a legal
solution to the problem of funding medical interpretive services; and (5) work with governmental
officials and other organizations to make language interpretive services a covered benefit for all health
plans inasmuch as health plans are in a superior position to pass on the cost of these federally mandated
services as a business expense. (Res. 907, I-03; Reaffirmed in lieu of Res. 722, A-07)

D-160.992 Appropriate Reimbursement for Language Interpretive Services
Our AMA will seek legislation to eliminate the financial burden to physicians, hospitals and health care
providers for the cost of interpretive services for patients who are hearing impaired or do not speak
English. (Res. 209, A-03)

H-385.929 Availability and Payment for Medical Interpreters Services in Medical Practices
It is the policy of our AMA to: (1) the fullest extent appropriate, to actively oppose the inappropriate
extension of the OCR LEP guidelines to physicians in private practice; and (2) continue our proactive,
ongoing efforts to correct the problems imposed on physicians in private practice by the OCR language
interpretation requirements. (BOT Rep. 25, I-01; Reaffirmation I-03; Reaffirmed: Res. 907, I-03)

D-270.998 Oppose Scope of Limited English Proficiency Guidance
Our AMA BOT, to the fullest extent appropriate, will authorize further efforts necessary to actively
oppose the inappropriate extension of the Limited English Proficiency Guidance issued by the US
Department of Health and Human Services’ Office of Civil Rights’ to physicians in private practice. (Res.
216, I-00)
To require appropriate reimbursement for federally-mandated interpreter services furnished to individuals with limited English proficiency, as well as to those who are hearing impaired.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress Assembled,

SEC. 101. The following shall be inserted in the appropriate section(s) of the Public Health Service Act (Title 42 of the United States Code), Employee Retirement Income Security Act of 1974 (ERISA) (Title 29 of the United States Code), and Internal Revenue Code of 1986 (Title 26 of the United States Code):

“No physician’s office covered by the Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency or any other similar regulatory requirement issued by the Office for Civil Rights of the Department of Health and Human Services, shall be required to pay any costs associated with implementation of the guidance or regulatory requirement, and any such costs shall be paid directly by the beneficiary’s or enrollee’s primary health insurance plan or group health plan to the provider of the oral or written interpretive services; provided further, that in the case of individuals without health insurance coverage, the Secretary of the Department of Health and Human Services shall directly pay the provider of the written or oral interpretive services for any costs associated with such services.”.

SEC. 102. The following shall be inserted in the appropriate section of the Americans with Disabilities Act (Title 42 of the United States Code)

The provisions under section [insert appropriate section number] of the Public Health Service Act shall also apply to interpreter services provided by physicians to patients who are hearing impaired under this Act.”.
October 25, 2002

The Honorable C.W. Bill Young
Chairman
Committee on Appropriations
U.S. House of Representatives
H-118 Capitol Building
Washington, DC  20515

Dear Chairman Young:

On behalf of the physician members of the American Medical Association (AMA), I am seeking your assistance in addressing an important matter that adversely impacts access to health care for Medicaid patients.

In August 2000, pursuant to Executive Order 13166, the Department of Health and Human Services’ (HHS) Office of Civil Rights (OCR) published a notice that sets forth a comprehensive list of requirements with which health care organizations must comply when treating patients with limited English proficiency (LEP). These OCR requirements force all physicians who receive any Medicaid dollars (or any other funds that constitute “federal financial assistance”) to provide, at their own expense, a trained clinical interpreter for all of their LEP patients, regardless of whether the patient is insured by Medicaid, Medicare or a private payer. The OCR notice also requires physicians to meet numerous other unreimbursed requirements that are outside of their clinical expertise, including (i) ensuring that interpreters are trained and demonstrate competency as interpreters, and (ii) providing the interpreter with orientation and training that includes skills and ethics of interpreting.

The AMA strongly believes that clear, direct communication and understanding is the bedrock of the patient-physician relationship, and thus is a very important concern in providing quality medical care to all patients. The OCR requirements, however, do more harm than good, and do not support the delivery of such quality care.

Indeed, these requirements impose yet another unfunded federal mandate on the medical community, which seriously threatens access to patient care for LEP persons, particularly since it forces all physicians treating Medicaid patients to incur, at their own expense, the cost of hiring trained clinical interpreters to assist their LEP patients. In some states, for example, a physician may have to hire an interpreter for an LEP patient at a cost exceeding $200 per visit. This cost would significantly exceed the Medicaid payment for the patient’s office visit, which, on average, may be no more than $40. If forced to absorb this
cost for all LEP patients, many physicians will not be able to treat Medicaid patients, who often are most in need of care.

The extreme burden of this unfunded mandate has been acknowledged by the federal government. Earlier this year, the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) released its Report to Congress: Assessment of the Total Benefits and Costs of Implementing Executive Order No. 13166, Improving Access to Services for Persons with Limited English Proficiency. This report suggested that one way in which the federal government might mitigate the costs of implementing the LEP requirements would be to “facilitate the availability of, and increased access to, telephonic interpretation and other interpretation and translation services.” The report also stated that “[a]gencies should endeavor to find creative ways, including through technology, to reduce the costs . . . of obtaining necessary oral or written translation services.”

The AMA agrees with the sentiment expressed in this report, and believes the federal government should take the necessary steps to lift the unfunded mandate imposed by the OCR requirements.

Sincerely,

Michael D. Maves, MD, MBA
March 5, 2002

Ms. Christy Schmidt
Executive Coordinator
Regulatory Reform Initiative
Office of the Assistant Secretary
for Planning and Evaluation
200 Independence Avenue, SW
Washington, DC  20201

Dear Ms. Schmidt:

On behalf of the American Medical Association (AMA), I thank you for the opportunity to provide input to the Secretary’s Advisory Committee on Regulatory Reform (the Committee) regarding burdensome regulatory matters in need of reform or modification, pursuant to 67 Fed. Reg. 599 (Jan. 4, 2002).

We greatly appreciate the Secretary’s commitment to addressing the complexity of the Medicare program and reducing the regulatory burden for physicians and their Medicare patients. In preparing the list of regulatory issues discussed below, we solicited feedback from our physician members, the state medical societies and national medical specialty organizations.

We received broad feedback from these individuals and organizations, which agree with the AMA that our number one priority issue is halting the 5.4 percent Medicare physician payment cut effective in 2002 and replacing the payment update formula. Although this requires a legislative remedy, we bring it to the Committee’s attention as the most important problem facing physicians and beneficiaries.

With respect to regulatory matters, many of these individuals and organizations agreed that each of the issues set forth below need reform or resolution. Many identified the evaluation and management (E&M) documentation guidelines (which are requirements that physicians must meet when recording in their medical records the items and services they provide to a patient) as the single, largest paperwork burden imposed by the Medicare program. The AMA’s Current Procedural Terminology (CPT) Editorial Panel recently established a taskforce in consultation with the Centers for Medicare and Medicaid Services (CMS) to begin to alleviate this paperwork burden. Currently, the taskforce is in the process of reviewing the adequacy
of current CPT E&M codes, descriptors and coding guidelines, with the intention of making any needed modifications and thus mitigating the need for extensive documentation guidelines.

Other critical issues include the language interpreter requirements for patients with limited English proficiency, regulatory compliance costs, advanced beneficiary notices, carrier oversight and seclusion and restraint.

Several years ago, the CMS created the Physician Regulatory Initiative Team (PRIT), which was designed to reduce the regulatory burden on physicians. Although a number of the issues outlined below are already under review by PRIT, we have included them on our list to underscore their importance.

Finally, we refer the Committee to the Medicare Payment Advisory Commission’s (MedPAC) December 2001 Report to Congress: Reducing Medicare Complexity and Regulatory Burden. We urge consideration of the recommendations made in this report with respect to proposed and final rules that will be published in the future.

**MEDICARE PHYSICIAN PAYMENT UPDATE**

42 U.S.C. §1395w-4(d) and (f); see also 66 Fed. Reg. 55,246 (Nov. 1, 2001)

The Administration cannot meaningfully address physicians’ regulatory burden until there is an immediate halt in the 5.4 percent Medicare payment cut to physicians and other health care practitioners in effect for 2002. Further, the flawed payment update system, including the sustainable growth rate, must be replaced, as recommended by MedPAC.

This 5.4 percent cut is forcing physician practices, as small businesses, to make difficult choices, ranging from not seeing new Medicare patients, to opting out of the program, to discontinuing certain low-payment/high-cost services, laying off administrative staff or leaving the practice of medicine. Each of these choices has a grave impact on beneficiary access to medical care. **Thus, it is imperative that both the Administration and Congress work together to immediately halt the 2002 Medicare physician payment cut and replace the update formula.**

**LIMITED ENGLISH PROFICIENCY**


Under the policy guidance, OCR establishes comprehensive standards that require all physicians who receive any federal financial assistance, including payments under the Medicaid program to provide, at their own expense, a trained clinical interpreter for all their LEP patients, regardless of whether the patient is insured by Medicaid, Medicare or a private payer. Physicians also must meet numerous other requirements, including (i) ensuring that interpreters are trained and demonstrate competency as interpreters, and (ii) providing the interpreter with orientation and training that includes skills and ethics of interpreting.

The AMA is fully committed to the importance of achieving greater access for LEP patients. Indeed, we strongly believe that clear, direct communication and understanding is the bedrock of the patient-physician relationship, and thus is a very important concern in providing quality medical care to all patients. Nevertheless, it is extremely inequitable to require physicians to fund written and oral interpretation services. On this basis, we have strong policy opposing the OCR requirements. The cost of hiring an interpreter, which can greatly vary between $30 and $400, is significantly higher than the payment for a Medicaid office visit, which in many states ranges between $30 and $50.

The net result of the cost and feasibility issues associated with the OCR requirements is that some physicians may not be able to afford to treat LEP patients. This could create serious access problems for all Medicaid patients, which is already a very vulnerable patient population. The OCR requirements could reduce, not strengthen access to health care services for LEP patients.

Accordingly, we urge HHS to allow medical interpreters to bill for services they provide that may be ordered by the physician or requested by the patient. Further, we recommend that the LEP safe harbors be expanded. For instance, a safe harbor could allow patients to choose to have a family member or friend serve as their interpreter, or there could be a safe harbor for small practices. Finally, we urge the Administration to republish the August 2000 letter to state Medicaid directors indicating that federal matching dollars are available to pay for interpreter services.

REGULATORY COMPLIANCE COSTS

Nearly every final rule, program memorandum, operational policy letter and carrier bulletin issued by CMS imposes new burdens on physicians. These rules force physicians to invest an ever-increasing proportion of their resources on heavy paperwork and other requirements. These resources could be better utilized on investment in new medical technologies and expansion of patient care services.

We urge HHS to ensure that CMS and other relevant agencies implement greater efforts to conduct more accurate regulatory impact and cost-benefit analyses and to account for the regulatory costs imposed on all impacted parties, including
physicians, providers and patients. We further urge that CMS or other agency consult with all impacted parties concerning these regulatory costs in advance of the proposed rulemaking.

ADVANCE BENEFICIARY NOTICES


Advanced beneficiary notices (ABNs) have long been a problem and have created unnecessary burdens and conflicts for physicians and health care providers. We are extremely encouraged, however, that CMS/PRIT has designated ABNs as one of its top priorities for resolving problems about these forms. In addition, we are very pleased that CMS has proposed a new one-page ABN form.

Further, although we completely support the brevity and simplicity of the proposed one-page form, the most recent draft ABN instructions were 14 pages, plus an additional 5 pages of exhibits addressing the confusion and conflict between ABN and EMTALA policy. These lengthy instructions defeat the purpose of a one-page ABN form, and further impose an unreasonable and unnecessary paperwork burden on physicians. Thus, we recommend that before finalizing the one-page ABN form, that CMS consult with the physician and provider community to ensure that the instructions (i) are shortened and simplified, and (ii) contain “physician/provider friendly” language, in contrast to unfamiliar, needlessly complex regulatory language.

Finally, surveys have shown that physicians consistently list this requirement as imposing a barrier to the patient-physician relationship as well as an administrative burden on physicians. Whether Medicare covers a service is often confusing and ambiguous, especially with regard to different carrier policies regarding the same service. Thus, the Medicare program should focus on educational efforts to inform beneficiaries concerning their Medicare benefits, as occurs in the private sector, and should eliminate the ABN requirement. Although we understand that legislation may be needed to do so, we urge CMS’ support of the elimination of ABNs.

SECLUSION AND RESTRAINT

- Re-authorization of the Substance Abuse and Mental Health Services Administration
- 64 Fed. Reg. 36,070 (Jul. 2, 1999);
- Standards issued by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
- Standards issued by the Council on Accreditation for Children and Family Services (COA); and
- State laws and regulations.
In July 1999, CMS isolated certain seclusion and restraint provisions from a 1997 proposed rule on hospital conditions of participation for purposes of Medicare and Medicaid and published them in an interim final. This regulation included the so-called “one-hour” rule that requires physicians to conduct a face-to-face physician evaluation within one hour of the order to restrain or seclude a patient in the behavioral management setting even though CMS did not include this provision in the initial 1997 proposed rule. Thus, the physician community never had a chance to comment prior to implementation of this provision. Moreover, CMS never issued a final rule responding to the thousands of comments and strong clinical objections it received on the rule. Nor has the agency ever responded to findings from both the Small Business Administration’s Office of Advocacy and a Federal Court that CMS did not comply with the Regulatory Flexibility Act in promulgating this rule.

The “one-hour” rule is over-prescriptive, does not reflect the current or best practice of medicine, and places an undue and unfair burden on all hospitals, especially psychiatric, small and rural hospitals. Although a timely evaluation should occur when a patient is restrained or secluded, the one-hour rule amounts to the practice of medicine. A face-to-face evaluation within one hour by a physician is not clinically or medically necessary in every instance where a patient is restrained or secluded. Evaluations can routinely be made over the telephone by discussing the patient’s condition with the nurse or other caregiver attending to the restrained or secluded patient. The physician, based on this discussion, can then make a professional medical decision as to whether a face-to-face evaluation is required.

Accordingly, we recommend that CMS withdraw the one-hour rule and re-promulgate the regulation in consultation with the medical community.

Further, in January 2001, the Clinton Administration published an interim final rule governing the use of seclusion and restraint in psychiatric residential treatment centers (RTCs). With this latest rule, mental health providers must now comply with at least four different sets of requirements governing the use of restraint and seclusion. These myriad rules are confusing, often duplicative, extremely costly to implement (without any offsetting payment for compliance costs) and may result in less access to important medical care for patients.

We further recommend that CMS (ii) review the various rules that have been published governing the use of seclusion and restraint in various settings, and (ii) conduct meetings with affected physician and provider groups to design a reasonable and consistent policy for use of restraint and seclusion in all facilities.

We are pleased that CMS/PRIT adopted seclusion and restraint as a priority matter for resolution. It should remain on the priority list until timely reform is achieved.

**CARRIER BULLETINS**

Some monthly carrier bulletins contain up to fifty or more pages of new instructions directing physicians concerning proper submission of claims to the Medicare program. Although this substantial and continual infusion of new instructions may include
important information about services the physician frequently provides, this information often is buried among other details that are not at all relevant to the physician’s practice. Further, the language is often complicated and “user unfriendly,” e.g., includes many acronyms unfamiliar to the average physician or other provider and their staff.

We recommend that each carrier bulletin contain a brief executive summary of the materials that are contained in each bulletin. This would allow the physician to quickly determine what issues may be of greater interest to the physician's practice. Further, we recommend consultation with the physician and provider community concerning the use of more simple and “user-friendly” language.

Further, only a single bulletin is sent to each physician practice. This presents great difficulty for physicians who are part of a large group practice or a medical school. Thus, multiple copies should be sent upon request.

Finally, we recommend that CMS develop and make available to physicians free of charge a single source Medicare provider manual. Currently, physicians have to search multiple sources for complete up-to-date information regarding Medicare rules, regulations and administrative requirements, which is inefficient, costly and time consuming. A single source, with a physician-friendly index (or a user’s guide), that is available on CMS websites, CD-ROM and in an easy-to-update paper format would help physicians understand the complex and confusing Medicare regulations and requirements.

Overall, CMS should give top priority to educating physicians and other providers regarding physician knowledge about Medicare law and regulations.

CERTIFICATES OF MEDICAL NECESSITY

42 U.S.C. 1395m(j)(2)(A); 42 CFR 402.1

In an AMA survey, 39 percent of physician respondents identified certificates of medical necessity (CMNs) as posing one of the largest burdens under Medicare, and this is especially true for physicians practicing in rural areas. Thus, we are pleased that CMS/PRIT has designated this issue as a priority.

During the last year, 45 percent of physicians have had more than 10 percent of the CMN forms returned with a request for more information, while 20 percent of physicians have had more than 25 percent of the forms returned for more information. Given the difficulties physicians are experiencing with CMNs, we urge that the form be eliminated. Alternatively, these forms need to be simplified and the different forms used by various Medicare carriers need to be streamlined. For example, the paperwork burden would be reduced if home health professionals (not affiliated with the durable medical equipment provider) who administer care to a patient were permitted to complete the CMN.
CLAIMS RESUBMISSION

CMS currently requires physicians to resubmit previous claims when the carrier or CMS has improperly applied a carrier edit or other payment decision. This inappropriately shifts the resubmission burden to the physician who submitted the claim and forces the physician to sift through previously submitted claims and patient accounts to determine which claims need to be resubmitted. The labor costs required to reconstruct these claims may result in some physicians opting not to incur these additional record-keeping costs and to simply “write off” the cost of the service provided.

We recommend that CMS adopt a new Medicare policy that would require carriers to make any necessary corrections to a claim if it is properly submitted by a physician but inappropriately denied by the carrier.

COVERAGE OF FOLLOW-UP VISITS FOR CANCER PATIENTS

Carriers often deny coverage of services for follow up visits for cancer patients (as well as for other types of services) on the alleged basis that the visit is a routine screening service not covered by Medicare. Practicing physicians frequently complain about such carrier denials of coverage since these services are necessary for diagnosis and treatment. For example, in Missouri, a carrier denied follow-up visits to ENT specialists for the five-year period following treatment for head and neck cancer. Although the carrier medical director stated his agreement that the follow-up visits to detect the possible recurrence of disease are medically necessary, he also stated that Medicare will not cover the visits unless residual cancer is actually detected because “the screening examination is not a medical benefit.”

Practicing physicians do not view an examination or test performed on a patient with a known history of the particular disease being evaluated as a routine screening service. The standard of care for patients that have had head and neck cancer is to have follow up visits at regular intervals for at least five years, particularly since these patients do not revert to a normal risk of cancer for about 15 years after cancer treatment.

Accordingly, we recommend that CMS determine that these types of follow-up visits are medically necessary diagnostic services, not routine screening services.

DIABETICS' GLUCOSE MONITORING SUPPLIES


The Balanced Budget Act of 1997 (BBA) expanded Medicare coverage for blood testing strips used by patients with diabetes to monitor their glucose levels, effective July 1, 1998, and thus the strips are covered whether or not a patient requires insulin. This expansion in coverage was part of a broader expansion of coverage for diabetes self-management services.
CMS became aware that some suppliers were continuing to send patients boxes of test strips regardless of whether the patient needed these additional strips. CMS, therefore, issued instructions to its durable medical equipment carriers stating that Medicare would cover the test strips only if a physician prescribed them. CMS further indicated that a physician's prescription must (i) be renewed every six months and (ii) state the frequency of testing.

Although the physician community clearly recognizes a need for some regulation of the provision of test strips, the requirement that prescriptions be renewed every 6 months has created a significant new paperwork burden. It is estimated that 25 percent or more of Medicare beneficiaries have diabetes, but the number of beneficiaries that need to visit their physician more often than once a year for management of their diabetes is considerably smaller. For this reason, the AMA House of Delegates adopted a policy that the AMA seek to change the “six month renewal” requirement to twelve months for purposes of Medicare coverage. **We recommend that CMS adopt this “twelve month renewal” requirement.** We recognize that CMS/PRIT is in the process of revising this policy, and we look forward to its implementation.

An additional paperwork problem was created by the wide variation among carriers, secondary insurers, and suppliers in their interpretations of what is meant by a “physician's prescription.” Instead of merely requiring a prescription, Medicare and insurance carriers and suppliers require a variety of written forms to be used. **We urge CMS to develop a standardized form that would be accepted by Medicare, third parties, and suppliers.**

**ELIGIBILITY DETERMINATIONS**

Medicare’s failure to create a mechanism by which physicians can track their patients’ enrollment status is a long-standing problem. Ironically, hospitals have access to enrollment data that enables them to determine whether patients are enrolled in traditional Medicare or a particular Medicare+Choice plan. Physicians, however, do not.

It is our understanding that access to enrollment data is governed by Social Security Administration privacy rules that generally prohibit the release of such information. An exception is made for hospitals, however, since they sign participation agreements with the government.

The AMA believes that when a physician agrees to participate with Medicare, this is an express agreement with the program, similar to hospitals. Thus, physicians, like hospitals, should have access to enrollment data. Physicians need to know if a patient is in Medicare+Choice, and, if so, which plan the patient has selected. Each plan has different rules and drug formularies, and physicians cannot be expected to comply with those rules unless they know in which plan a patient is enrolled.
We recommend that CMS reassess its conclusion that Social Security privacy laws preclude CMS from giving physicians access to Medicare enrollment data for purposes of appropriately furnishing and billing for care provided to Medicare patients.

**HOME HEALTH ISSUES**

42 U.S.C. 1395x(m); 42 C.F.R. Part 484

In an AMA survey, physician respondents identified home health certifications as a major problem. Indeed, 28 percent of respondents indicated that home health certification is another Medicare paperwork burden for their practice. For example, 46 percent of respondents have more than 10 percent of their home health certification forms returned with a request for more information, while 16 percent have more than 25 percent of these forms returned for the more information.

We recommend, therefore, that the entire home health certification process be reviewed for purposes of simplification, as recently recommended by a recent Office of Inspector General (OIG) Report on the physician’s role in home health (OEI-02-00-00620; Dec. 2001). Matters to be reviewed might include the option of on-line availability, the definition of “homebound,” the need for home health medical directors, reduced paperwork burden, clearer coverage policies and better education about Medicare home health policies for physicians, patients and carrier personnel.

**MEDICARE SUMMARY NOTICES**

The AMA has long been strongly opposed to use of the phrase "not medically necessary" by the Medicare program. Several years ago, CMS finally removed this language from the Explanations of Medicare Benefits (EOMB) form that routinely is sent to patients describing the items and services for which Medicare provides or denies payment. This decision to remove the “not medically necessary” language from the patient EOMB was enthusiastically received by the physician community. CMS, however, continues to include this language on the "Summary Remittance Notice" that is sent to the physician and mirrors the patient's EOMB.

We recommend that CMS remove the “not medically necessary” language from correspondence with the physician community.

**EMERGENCY MEDICAL TREATMENT AND LABOR ACT**

42 U.S.C. §1395dd

The Emergency Medical Treatment and Labor Act (EMTALA) is the federal “anti-dumping law” enacted by Congress in 1986, as part of the Consolidated Omnibus Budget
Reconciliation Act of 1985. EMTALA amended Title XVIII of the Social Security Act, the Medicare statute, to assure that patients who come to hospitals for treatment for potential emergency conditions are not turned away or transferred to another facility without being stabilized.

Physicians strongly support the original intent of EMTALA — emergency care provided in emergency departments. However, EMTALA rules and enforcement have gone far beyond the original intent to create an unnecessarily complex and burdensome system. Regulations that exceed statutory intent coupled with interpretations of the rules by the Office of the Inspector General, subsequent judicial interpretations, and protective conservative advice from retained counsels, have increased hospital and physician liability for caring for EMTALA patients. Recent regulations have even expanded EMTALA to outpatient settings.

Overcrowding in hospital emergency departments and hospital diversions is brought about by a number of factors: increasing numbers of the uninsured, the reduced availability of inpatient beds, a national shortage of nurses, uncompensated care provided to emergency patients, physicians’ reluctance to serve in an on-call capacity to emergency departments, and the expansion of EMTALA to other care settings in the hospital. There are no easy or quick fixes for these problems but the Administration and the Congress must make a commitment to resolve them.

Last year the Office of the Inspector General and the General Accounting Office in separate reports on EMTALA recommended that the Administration form a public-private sector task force to address the problems of EMTALA. It is essential that the Administration understand the problems of the physician/provider community before attempting to regulate further in this area. Creating such a task force would be a good initial step to addressing the problems of EMTALA and overcrowded emergency departments.

CLINICAL LABORATORY IMPROVEMENT ACT

Section 353 of the Public Health Service Act; 42 C.F.R. Part 493

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory, including physician office laboratories, that performs diagnostic laboratory tests to meet comprehensive requirements established by the Department of Health and Human Services (HHS). Application of these requirements varies with the complexity of laboratory tests performed. The requirements are waived for certain simple tests (designated by HHS) for which a laboratory has obtained a certificate of waiver.

As a result of the burden and cost of compliance with current CLIA regulations, tens of thousands of physicians have opted to either curtail the menu of laboratory testing they perform for their patients or stop performing laboratory testing altogether. The ability to obtain immediately the results of these basic tests enable physicians to make decisions
and perform higher quality medicine. If a physician is forced, because of CLIA, to order tests from an outside laboratory, there is often a significant wait, sometimes days, before the physician can determine the best course of treatment. CLIA rules hamper patient access and quality of care.

For example, synovial fluid crystal identification, CPT 89060, is appropriate for inclusion in a simpler category of test, such as the waived category or the Physician Performed Microscopy (PPM) category. This test is much more accurate when the sample is analyzed within a short time of collection in the rheumatologist’s office. It is easy to perform and relatively inexpensive, yet some physicians do not perform the test due to the cost and administrative burden of meeting CLIA certification requirements.

We recommend that that HHS review the list of laboratory tests to determine, in consultation with physicians and other impacted providers, if any tests may be moved to a more appropriate and administratively simpler test category.

CARRIER OVERSIGHT

CMS should exercise greater oversight over its contractors. A number of reports issued by the General Accounting Office (GAO) in 1999 and 2000 highlight the fact that CMS has not set oversight priorities and that responsibility for contractor oversight is divided between the regional offices and CMS headquarters. Without assigning overall accountability to one office, it is difficult for CMS to determine which contractors are performing effectively.

CMS’ lack of oversight effectively vests too much authority in local carriers. Although, local carriers need some authority to make coverage and payment decisions, they should not do so in a vacuum. All too often, carriers are left on their own to make decisions that are not grounded in valid, scientific evidence nor are they made with respect to quality of care concerns. Further, many carrier decisions are vastly different from region to region, and CMS often is unaware of these inconsistent carrier policies, as well as when and how they differ from national policy. CMS, must have the knowledge of and ability to initiate change in local carrier coverage policy, if necessary. We recommend that CMS establish a system to periodically review local carrier policies for inconsistencies and to initiate a remedy, when necessary.

Further, it is imperative that physicians and national and state medical societies have the opportunity to provide input into local carrier coverage policy decisions and to initiate or make CMS aware of the need for a possible change in local policy. Physicians are in the best position to provide the information needed to establish appropriate coverage policy for a particular procedure. Their input must be sought and utilized. Indeed, physician input is sought through Carrier Advisory Committees (CACs). We recommend that CMS maintain existing CACs and allow physicians to provide input to CACs at the local level so that physicians continue to have the opportunity for input into the carrier coverage decision process.
In addition, if CMS replaces a single existing carrier with multiple carriers, each of which handles a different aspect of the traditional carrier functions, CMS should designate one point-of-contact carrier responsible for handling physician-carrier administrative issues or inquiries.

Finally, physicians continue to have persistent problems with repeated carrier denials of claims for covered Medicare services, despite the fact that they are properly documented and coded. For example, when physicians perform an in-office procedure at the same time that they provide an E&M service to a patient, often carriers will deny the claim for the procedure, even with the use of the proper modifier. The hassle factor involved in ultimately getting paid by the carrier for the service is so high, that physicians are forced to request that patients return on a separate day for the procedure. In addition, physicians' requests to secure durable medical equipment and other necessary treatment for patients must regularly be appealed, and it frequently takes two or three letters before medically necessary treatment or therapy is approved. Physicians should not have to incur these time-consuming and costly hassles while attempting to be paid for covered services. **We recommend that CMS enforce its coverage rules with respect to carriers that regularly deny claims for covered services.**

**CMS MEDICARE ENROLLMENT PROCESS**

**CMS Enrollment Form 855**

**Shorten Lengthy Enrollment Process**

The AMA has repeatedly expressed its concern regarding the length of time it currently takes for physicians to enroll in the Medicare program under Form 855. Often, physicians must wait months to receive enrollment approval. During this time, physician practices cannot submit claims to receive Medicare payment for services provided to beneficiaries, and thus are effectively precluded from treating Medicare patients. This is an extremely difficult situation for physicians who are just beginning to establish themselves in a community, and especially in rural communities that may have difficulty recruiting new physicians. This lengthy waiting period is also challenging for the practice that the new physician is joining.

The AMA recommends that CMS shorten the processing times for provider enrollment forms by moving expeditiously to allow physicians to enroll via an online version of Form 855 and to mail relevant attachments to CMS. Physicians currently cannot submit Form 855 or any changes to the Form electronically. Further, carriers are required to process enrollment applications within 60 days and there is a large number of categories for which carriers must return blank enrollment forms back to physicians for completion. **We recommend that carriers contact physicians by telephone or facsimile to complete missing information to avoid having to toll the deadline while an incomplete application is sent back to the physician.** Finally, we recommend that CMS provide temporary provider numbers to help facilitate a smooth transition for patients, physicians, and practices during the enrollment process.
Halt Expansion of Enrollment Program

Physicians incur substantial time and costs to complete Medicare enrollment forms. Yet, CMS is attempting to expand the scope of its enrollment efforts by requiring all physicians to enroll in the program. Previously only physicians who have enrolled in the Medicare program after 1996 have had to complete the Form 855. The agency is also seeking to require physicians to revalidate this application information every three years. Expansion of the enrollment program would place an enormous additional burden on physicians across the country with respect to costs and time needed to complete the forms. Further, it is not clear that carriers are ready to assume this responsibility, or that it would not disrupt the delivery of care to Medicare patients. Accordingly, we urge that CMS halt any plans to expand the enrollment process.

MEDICARE CONDITIONS OF PARTICIPATION FOR HOSPITALS

42 C.F.R. §482.22; 42 C.F.R. §481.125

In the December 19, 1997, proposed rule on Medicare and Medicaid conditions of participation (COP) for hospitals, CMS proposed to delete the medical staff COP under 42 C.F.R. 482.22. The rule has not yet been finalized.

Under current section 482.22, hospitals must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital. CMS is proposing, however, that medical staff operate under 42 C.F.R. 481.125 (“Human Resources”), which would simply require that all hospital areas be staffed with qualified personnel, who are present in sufficient numbers to meet the needs of the hospital’s patients. The AMA strongly opposes this proposal.

It is essential to maintain the function of an organized, self-governing medical staff, which plays a critical role in ensuring high quality care for patients. Practicing physicians must be involved in patient assessment, care planning, service delivery, and quality assessment and performance improvement. The medical staff provides an organizational structure for members of the medical staff to develop, communicate, and implement changes that will improve patient outcomes. Incorporating the medical staff into the new § 482.125 suggests that independent physicians are equated with employed staff and that the medical staff is similar to hospital departments. The increasing commercialization of health care requires more emphasis on an independent, self-governing medical staff and concomitant strengthening of the medical staff-related COPs. Indeed, we believe that existing COP § 482.22 should be strengthened to require an organized and self-governing medical staff as a counterweight to the market pressures for cost containment and inappropriate hospital interference.

We urge CMS to maintain and strengthen the organized medical staff requirement under 42 C.F.R. 482.22 in any final rule concerning Medicare and Medicaid COPs for hospitals.
The AMA has long advocated for strong patient privacy protections, a notion that is fundamental to the patient-physician relationship. We believe that with further improvement, the final privacy rule published by HHS can serve as a starting point for basic patient privacy protections until Congress acts to extend privacy requirements to all entities that maintain patient information.

The AMA is extremely concerned, however, with the administrative burden and associated costs that the rule will place on physician offices. Following is an outline of several major problems and suggested modifications to the rule that will ease the administrative burden and make certain aspects of the rule workable before compliance is required:

- **The business associate provisions are unfair as a matter of principle and should be eliminated from the rule.**

  The AMA strenuously objects to the requirement that physicians rewrite and renegotiate contracts to add terms that mandate compliance with the rule by “business associates” that are not covered by the rule. The business associate requirement will create additional burdens, costs, liabilities and hassles for physicians without adding any significant patient protections. Regardless of these contract terms, physicians will not be able to control the actions of third parties. However, the rule unreasonably holds physicians responsible for actions of their business associates and imposes an affirmative obligation on physicians to mitigate any damaging effects of unauthorized uses or disclosures of patient information by business associates. Out of basic fairness, any extension of privacy requirements to entities not covered by the rule must be through legislation, not by contract, so that the entities themselves can be held responsible for their own misuse of confidential patient information and can be subject to sanctions for their own noncompliance.

- **Many administrative provisions of the rule should be reexamined with respect to their application to physician offices.**

  The AMA believes that HHS has woefully under-estimated the impact of the rule on small physician offices. Much of the administrative burden and associated costs of compliance that are imposed on physicians do not improve privacy protections for patients. As a matter of fact, many requirements create undue paperwork, unnecessary processes and a high level of administrative complexity without adding any new privacy protections because the protections intended by the rule are already in place in most physician offices. Physicians are not in the same category as other entities covered under the privacy rule. Physicians are unique in that they have existing legal and ethical obligations to protect patient confidentiality. Therefore, we recommend the following:

  1. The privacy officer requirement should be eliminated for small physician practices.
2. Small physician practices should not be required to document all of the policies and procedures mandated in the final rule.

3. Physicians should not be required to create new bureaucratic procedures as set forth in the final rule. For example, physicians already provide patients access to their medical records. Therefore a federal requirement to provide for such access without any micro-management of how to do it would be enough for physician offices.

4. The right for patients to amend their medical record will require far too many burdensome steps that must be handled within specific time-frames and must be documented. We recommend instead, that individuals have the right to submit a limited statement to the covered entity that created the record to add to the record as a dated addendum.

5. Covered entities should be allowed to charge for reasonable costs associated with retrieval of information and preparation of a report associated with any accounting of disclosures requested by patients.

6. The right for patients to request restrictions should include a good-faith provision for compliance and enforcement purposes. Because it is a violation of the rule if physicians violate a restriction they agree to, many physicians that currently agree to such requests may no longer do so. Health care providers will be more likely to agree to such requests and patient expectations will be more realistic.

7. The final rule should qualify many other provisions with a good faith compliance standard.

8. Compliance reviews of physician offices should be explicitly limited or even eliminated in the absence of specific complaints or allegations of wrongdoing

**The compliance date for the privacy rule, and all HIPAA Administrative Simplification rules, should be two years after the last of these final rules is published (with the exception of the individual identifier rule, which may be significantly delayed).** Each of these rules will require significant administrative and technological changes to physician practices, some of which will overlap, while others will be incompatible if these rules cannot be considered as a whole. It is imperative that physicians have a complete and workable picture before they can adequately assess how and where to modify their practices in order to comply with these rules. Adjusting to moving targets with rolling compliance dates is not practicable for small physician offices.
ANESTHESIA ISSUES

Post-Anesthesia Reports

42 C.F.R. §482.52(b)(3)

Hospital conditions of participation currently require “a post-anesthesia follow-up report by the individual who administers the anesthesia that is written within 48 hours after surgery.” It is frequently difficult for the anesthesiologist who administered the anesthesia to perform and document the follow-up evaluation. Most anesthesiologists are part of a group, and the typical practice is for another member of the group to see inpatients post-operatively. If other anesthesiologists are on duty, the anesthesiologist who originally administered anesthesia to the patient may not be back in the hospital during the 48 hours following surgery.

In a December 19, 1997, proposed rule on Medicare and Medicaid conditions of participation for hospitals, CMS proposed that “a post-anesthesia evaluation for proper recovery be done by an individual qualified to administer anesthesia.” This policy would be consistent with the common practice of efficient anesthesia groups. Documentation would be entered in the anesthesia record promptly following surgery. This proposed rule has never been finalized.

**We urge that the proposed provision allowing another “individual qualified to administer anesthesia” to complete the post-anesthesia report be finalized and implemented as soon as possible.**

Medical Direction Requirements

42 C.F.R. § 415.110(b)

With regard to medical direction of anesthesia services, Medicare regulations provide that: “The physician alone inclusively documents in the patient’s medical record that the conditions set forth in [the medical direction rule] have been satisfied, specifically documenting that he or she performed the pre-anesthetic evaluation, provided the indicated post-anesthesia care, and was present during the most demanding procedures, including induction and emergence where applicable.”

Many anesthesiologists interpret this provision as requiring them to write in longhand the full text of the regulatory provision, as set forth above, beginning with the word “conditions.” Others have interpreted the provision to require their signature or initials or a check placed beside each medical direction element.

**We urge that CMS clarify that a signature or set of initials beside each medical direction element preprinted on the anesthesia record will satisfy the “personally documents” requirement.**
TEACHING PHYSICIAN SUPERVISION

42 C.F.R. §415.170-208

Medicare requires teaching physicians to be physically present during the key part of a CPT-coded service provided by a resident, and for the entire service if it is CPT psychotherapy codes. A major exception to this requirement permits primary care specialties to establish outpatient clinics where a teaching physician may bill Medicare Part B for low level E&M services for up to four residents at a time who are seeing patients. This primary care exception is unfair to other specialty programs, and particularly to psychiatry, and restricts access to medically necessary specialty services. The Practicing Physicians Advisory Council (PPAC) heard testimony on this matter at its December 10, 2001 hearing and recommended that the "primary care exception" be extended to all specialties for low level E&M (up to level 3) or equivalent codes.

We recommend that the HHS Secretary Advisory Committee on Regulatory Reform adopt the PPAC recommendation to open up the primary care exception to all specialties for low level E/M (up to level 3) or equivalent codes, and implement this change immediately.

PHYSICIAN PATHOLOGY SERVICES

42 C.F.R. §415.130(d)
64 Fed. Reg. 59,408-409 (Nov. 2, 1999)

Since the inception of the Medicare program, certain independent laboratories could bill Medicare directly for the technical component (TC), i.e., slide preparation, of physician pathology services provided to hospitals. In the November 2, 1999, Medicare physician fee schedule final rule, CMS determined that the inpatient technical component is payable only to the hospital under the DRG. Further, upon implementation of the hospital outpatient prospective payment system, outpatient technical components are payable only to the hospital under the APCs.

It is important that the Committee act during 2002 to make permanent the relief for TC pathology services, since the statutory relief expires at the end of this year. The proposed change in Medicare regulations regarding this issue was first published in the physician fee schedule proposed rule of July 22, 1999 and finalized in the November 2 final rule that year. The physician fee schedule rule for 2003 should include a provision to make permanent the regulatory relief for independent laboratories that provided pathology TCs to hospital inpatients and outpatients and were being paid under the physician fee schedule as of July 22, 1999. After comment, it could be finalized in November this year for implementation on January 1, 2003, immediately following expiration of the statutory relief.

Since this regulation change was initiated without a statutory mandate, it is within the authority of CMS to revise the same regulation to provide appropriate relief.
COVERAGE OF PRE-OP EVALUATIONS

Medicare Carriers Manual, 15047 (CMS transmittal 1707, May 31, 2001)

The issue of coverage for preoperative evaluations is similar to the issue of coverage for follow-up visits for patients with a recent history of cancer, as discussed above. Surgeons and anesthesiologists frequently recommend that patients be evaluated by a primary care physician and/or obtain certain diagnostic tests prior to being scheduled for surgery. The purpose of these evaluations is to inform the surgeon and anesthesiologist regarding any medical conditions that the patient may have that would impact the decision to perform the operation, the specific surgical procedure to be performed, the anesthesia to be utilized, and the recovery process. We are pleased that CMS recently instructed its carriers to treat these services as “medically necessary” and not simply as “routine screening” services.

We recommend that CMS monitor its carriers to ensure that this new policy is being properly implemented, and respond adequately if inappropriate denials are continuing.

PRIOR HOSPITALIZATION FOR SKILLED NURSING FACILITY PLACEMENT

We recommend that the Medicare requirement for a three-day period of hospitalization prior to Medicare coverage of skilled nursing facility (SNF) placement be eliminated. This requirement is often unnecessary and not reflective of current medical practice, and is costly and burdensome for patients requiring SNF care.

Although legislation may be needed to eliminate the prior hospitalization requirement, we urge the Administration to support efforts to repeal it.

MEDICARE COORDINATION OF BENEFITS

We urge CMS to adopt a clear regulation requiring third-party payers to pay up to the full Medicare fee schedule when Medicare is the primary payer and a third-party payer is the secondary payer. This is a major payment problem that results in unnecessary hassles and jeopardizes patient access to needed care.

Managed care organizations that pay secondary to Medicare are failing to pay Medicare’s approved amount, i.e., the Medicare copayment and deductibles. This practice has resulted from the plans’ coordination of benefits provisions which typically purport to allow the managed care organization to pay physicians “only those amounts when added to the amounts received by other payors equals the (managed care organization’s) maximum allowable payment under the agreement.” As a result of this provision, managed care organizations have paid physicians less than they otherwise would have been entitled to under Medicare’s fee schedule.
The AMA strongly objects to the Office of Inspector General's Compliance Program Guidance for Individual and Small Group Physician Practices. The guidelines set forth under this compliance program are burdensome and costly to medical practices. The guidelines set forth in the physician compliance program are similar to those that the OIG applies to health care institutions. These same guidelines are inappropriate for application to physician offices and small practices. An institution has infrastructure, sufficient funding, staff resources, and in-house expertise to accommodate a wide-scale compliance initiative. The small group practice, akin to a small business or a sole proprietorship, has none of these resources. When institutional requirements are translated to the small group practice environment, the end product is a set of onerous obligations that offer little value to the physician in participating.

Further, implementation of the guidelines by a physicians’ office does not appear to mitigate against over-zealous enforcement of confusing and ambiguous Medicare laws and regulations imposed by the federal government. Thus, the OIG should focus on education for, rather than criminal punishment of, physician practices.

The foregoing is a comprehensive list of regulatory issues that create tremendous burden and unnecessary hassles for physicians and patients. We appreciate your leadership in addressing these issues, and look forward to working with the Committee, CMS and PRIT to resolve these matters.

Please feel free to contact Jack Emery of the AMA Washington Office at (202) 789-7414 should you have any questions about the issues listed above.

Respectfully,

Michael D. Maves, MD, MBA

cc: Douglas L. Wood, MD – Chair
    Nancy Nielsen, MD
    Thomas Grissom
    Bobby Jindal
    Barbara Paul, MD
    Michael Rapp, MD
    Thomas A. Scully
    Rubin King Shaw
April 2, 2002

Ms. Deeana Jang
Office for Civil Rights
Department of Health and Human Services
200 Independence Avenue, SW, Room 506F
Washington, DC 20101

Attention: LEP Comments

Dear Ms. Jang:

The American Medical Association (AMA) appreciates the opportunity to comment on the Policy Guidance on the Prohibition Against National Origin Discrimination as it Affects Persons with Limited English Proficiency (LEP), as published by the Office for Civil Rights (OCR) at 67 Fed. Reg. 4968 (Feb. 1, 2002).

Under the policy guidance, OCR establishes comprehensive standards that require all physicians who receive any federal financial assistance, including payments under the Medicaid program to provide, at their own expense, a trained clinical interpreter for all their LEP patients, regardless of whether the patient is insured by Medicaid, Medicare or a private payer. Physicians also must meet other comprehensive requirements, including (i) ensuring that interpreters are trained and demonstrate competency as interpreters, and (ii) providing the interpreter with orientation and training that includes skills and ethics of interpreting. **The OCR policy guidance places Medicaid patients in a particularly vulnerable position with regard to access, since it may be very difficult to find a physician who can absorb the costs associated with these LEP requirements.**

OCR has set forth a number of questions in the guidance about which it is seeking public comment. Below we discuss our views with respect to questions two through nine, and we have attached the results of a national state survey we conducted last year, which provides an assessment of (i) what, if any, written and oral interpreter services are available, and the cost thereof; (ii) the Medicaid payment amount for a physician office visit; (iii) whether Medicaid pays for interpreter services; and (iv) miscellaneous comments on availability of interpreters for LEP patients. The results of this survey document the extraordinary cost burden that the OCR requirements place on physicians.

**Question 2:**

*Have persons with limited English proficiency faced challenges or problems in accessing health care or social services following issuance of the guidance? If so, what have been the challenges or problems? Please be specific about your experiences.*
**Answer:** A recent Institute of Medicine Report confirms that there are barriers for LEP patients in accessing health care services. The report, which studied disparities in health care provided to minorities, suggested that to overcome language barriers that may affect the quality of care, more interpreters should be available in clinics and hospitals located in neighborhoods with many foreign-language-speaking residents.

The AMA believes strongly in eliminating these barriers for LEP patients. Clear, direct communication and understanding is the bedrock of the physician-patient relationship, and thus is a very important concern in providing quality medical care to all patients. We continue to maintain, however, that unless the cost of providing the interpreter services is properly and fully addressed by the federal and state governments, physicians will inappropriately and unfairly bear the financial brunt of this new federal mandate. If there is not relief from this burden, physicians will no longer be able to treat Medicaid patients, and thus those with limited English proficiency, as well as the poor and medically indigent, will suffer adversely.

The 5.4 percent Medicare payment cut to physicians and other health care professionals that became effective on January 1 of this year, as well as the nearly 20 percent Medicare payment cut that the Center for Medicare and Medicaid Services (CMS) is predicting for 2002 through 2005, is forcing the physician community to reassess which patients they will be able to serve. **The unfunded LEP mandate imposed on physicians, coupled with the inadequacy of the Medicare payment update, will likely result in serious access problems for both Medicare and Medicaid patients.**

**Question 3:**

*Have health care or social services providers faced challenges or problems in providing these services to persons with limited English proficiency as a result of the guidance? If so, what have been the challenges or problems? The Secretary is particularly interested in the experiences of small providers.*

**Answer:** This question suggests that OCR recognizes that providing uncompensated interpretation services to patients has a major adverse impact on physician practices. We certainly agree, and appreciate this acknowledgement.

As discussed above, according to the Administration’s interpretation of the law, the treatment of a single Medicaid patient obligates a physician practice to provide interpreter services for every LEP patient treated by the physician and the physician’s practice – regardless of the payer. Physicians must also meet numerous other comprehensive requirements relating to written and oral translation services under the OCR guidance. This presents a tremendous and inequitable cost burden for physician practices, which often are small businesses that cannot afford the costs associated with the OCR translation requirements. These costs are more specifically discussed under questions 7 and 8.
In addition to cost issues, many practices face serious problems with respect to availability of interpreters, which often is very limited or even non-existent, especially for more difficult languages. This is particularly problematic in rural areas. For example, in Alaska, there is very limited availability of interpreters; the Inuit speak 8 different dialects and some do not easily translate into English. We understand from the states that availability of oral and written interpreter services is also extremely limited in states, such as Arkansas, Georgia, Indiana, Iowa, rural Kentucky, Minnesota and South Carolina. In our attached state survey, specific comments from certain states discuss concerns about availability of interpreters.

The lack of availability of interpreters is compounded by the fact that so many different languages are prevalent in many states, in both urban and rural areas. For example, there are 61 languages in Hamilton County, Indiana; Des Moines, Iowa has 37 languages, while there are 24 languages spoken in a very small rural community in Northeast Iowa; and in the Chicago public school system, more than 100 languages are spoken. Thus, it is often an extreme hardship to simply find an interpreter, and even if an interpreter speaks a particular language, that interpreter may have limited availability, especially in rural areas. Moreover, it would be extremely difficult, if not impossible, for a physician or health care institution to identify and have available bilingual staff or interpreter services for each of these languages.

We heard from one small physician practice whose practice expenses are almost as much as practice revenues. This practice treats a number of LEP patients from Spanish speaking countries, as well as Haiti, Bosnia, Poland, Chechnya, Malta, Serbia, Albania, India, Pakistan, China, Korea, several African countries, and southeast Asia. Traditionally, many of the LEP patients treated by this physician practice have requested that a family member or friend act as their interpreter, and this has worked very well. Yet, under the OCR guidelines, use of friends or family members could expose physicians to liability. Indeed, the guidelines suggest that “even if an LEP person elects to use a family member or friend, the [physician] should suggest that a trained interpreter should sit in on the encounter to ensure accurate interpretation.” Further, for this particular practice, and for many others, the cost of providing written and oral translation services in each of these languages is prohibitive.

We have also heard from physicians that it is often impossible to know in advance of the patient visit whether translation services are necessary. Thus, in many cases, the patient arrives at the physician’s office and the physician has no idea that an interpreter is needed. Again, it would be cost prohibitive to pay interpreters of various languages to be on hand in the office in the event that an interpreter is needed. If the patient arrives with a friend or family member, it should be permissible to allow the friend or family member to act as an interpreter, if requested by the patient. Otherwise, the patient has to re-schedule. This presents serious difficulties because the patient may be in need of medical attention, and, often LEP patients have problems obtaining transportation, and may not show up for a second visit when an interpreter can be present.
Further, it is not practical for a small provider to be able to group similar LEP patients together to take advantage of an interpreter being available to the physician office. Patients seek the care of a professional when they need medical attention. They are not likely to be willing to re-schedule their appointment to wait for other similar LEP patients to schedule their appointment.

One physician, who was emphatic that small providers cannot afford these interpreter costs, stated that Medicaid patients will have no alternative but to be treated in a hospital. The hospitals in the area where this physician practices are in serious financial difficulty, and cannot afford to treat a huge influx of new Medicaid patients.

Finally, federal and state funding for interpretation services is virtually unavailable. Of the respondents to the AMA’s survey of state medical associations, only two indicated that their state Medicaid program (Oregon and Utah) provide interpreter fees for LEP patients. In these states, reimbursement is made on a limited basis and does not cover the full cost of the interpreter. We understand that Utah, however, offers a promising approach by which the state provides interpreter services through a competitive procurement, with the state bearing the cost of the interpreter, which is designated as a separate provider type. Further, although we understand that the Washington state Medicaid program has provided reimbursement for interpreter services, the program has indicated that it will eliminate such payment this summer as it faces another state budget crisis.

The AMA has repeatedly urged CMS to republish the letter to State Medicaid Directors that was initially sent in August of 2000 indicating that there are federal matching dollars available to help defray the costs of providing interpreter services. CMS has failed to do so, and, predictably, states are not requesting matching dollars or providing reimbursement for interpreter services.

In addition, the Medicare program makes no provision for payment of interpreter services to physicians. The resource-based relative value system — the payment system for physicians under Medicare — does not take into account the cost of interpreter services as a practice expense nor other type of expense. The AMA has repeatedly requested that Medicare pay for this federal mandate, but, to date, this has not occurred.

**Question 4:**

Are there areas of the guidance that you believe need to be clarified or modified? If so, please explain what areas, why the area(s) need clarification or modification, and provide any suggestions for clarification or modification.

**Answer:** Prior to OCR’s issuance of the LEP requirements, the physician community historically made ample use of the patient’s family and friends to provide the interpretation services needed to properly communicate with LEP patients. This
method served the patient and the physician community remarkably well. As discussed above, the current “safe-harbor” for the LEP guidelines discourages family members and friends as interpreters. **We urge the OCR to reconsider this particular “safe-harbor,” and modify it to allow family or friends of the patient to serve as an interpreter – if the patient so chooses. Physicians should not be exposed to liability under the OCR requirements if the patient requests that a friend or family member act as an interpreter.**

**We also strongly urge the Administration to adopt a small provider exception under the OCR requirements.** The federal government itself cannot and does not provide translation services to all those non-English speaking constituents who call with questions about how their government operates, where to get forms, or what the federal entitlement benefit package contains. It is therefore unreasonable to require small physician practices to provide those translation services that the federal government cannot provide.

Further, the OCR guidance stipulates that the provider of care should periodically (i) ensure that interpreters are trained and demonstrate competency as interpreters, and (ii) provide the interpreter with orientation and training that includes skills and ethics of interpreting.

Physicians are skilled in the practice of medicine, but they are not in a position to determine the quality and competency of the interpreter’s translation services or provide training for interpreters. It is difficult enough to know how and which of the hundred thousand pages of rules, regulations, and interpretations that govern Medicare apply to the physician community, let alone determine the quality of language services or provide training. This is not physicians’ area of expertise, and thus this responsibility should be left to the states or the federal government.

In addition, the OCR guidance seems to suggest that a language line should be used only as a last resort or as a supplemental system, and not as the primary method for providing interpreter services. Language lines, however, can be an effective option, especially in areas in rural or other areas where the availability of interpreters is limited or non-existent. **Accordingly, we request that OCR clarify that language lines may be used when they are adequate to meet the needs of LEP patients, and not simply as a last resort or as a supplemental tool.**

Finally, we understand there have been questions among some states about whether the OCR requirements apply to physicians who contract with state Medicaid managed care programs. Some have queried that in this instance the “federal financial assistance” is provided to the state managed care plan, and not the physician. Rather, the physician is paid by the plan. We request that OCR clarify application of the LEP requirements under this scenario.
**Question 5:**

*Has the guidance been effective in identifying reasonable ways of providing services to individuals with limited English proficiency? What are some of the cost-effective ways that are used successfully to provide services for persons with limited English proficiency that are not included in the guidance? Again, the Secretary is particularly interested in the experiences of small providers.*

**Answer:** The OCR guidance has not been effective in identifying reasonable ways of providing services to individuals with limited English proficiency. The federal and state governments have failed to provide a comprehensive list of interpreter services available on a county-by-county basis. Most physicians have little or no information available to them concerning where such services exist, what language interpreters are available, and, if so, at what cost. Some physicians may be aware of interpreter services that may be available at the local hospital, but referring patients to the hospital is likely to result in care being provided at a higher cost.

As discussed above, we understand that some providers have very successfully used language lines for interpretation services. The federal and state governments could effectively establish and fund such lines for use by health care providers and their patients across the country. Further, we understand that Gallaudet University has implemented a model program under which sign language interpreter services are provided via computer; the federal government could explore a similar capability for the purpose of providing government-funded language interpreter services to physicians and LEP patients.

**Question 6:**

*What technical assistance from the Office of Civil Rights (OCR) and other components of HHS would be most helpful to recipients/covered entities?*

**Answer:** First, OCR could establish language interpreters as a separate provider type whose services could be requested by either the patient or the physician. The interpreter should be permitted to bill the appropriate health care program, leaving the patient and the physician free of the financial liability associated with providing the interpreter services. Until such time as interpreter services are provided by both the federal and state governments, physician practices should be exempt from the LEP requirements.

Alternatively, as discussed above, OCR could set forth a number of “safe harbor” exceptions to the OCR requirements, including a safe harbor for family and friends (if requested by the patient) and for small providers. In addition, as discussed above, the federal and state governments could provide a “1-800” language line in every language, with sufficient lines for more common languages so that patients and physicians will not have to needlessly wait for an interpreter. Finally, OCR could provide an analysis of what languages are spoken in each community, as well as the community resources that are readily available to provide interpreter services for those languages.
Questions 7 and 8:

In providing services to persons with limited English proficiency, what costs have health care or social services providers incurred in providing translation, interpreter, or other language services? Please be specific about your experiences. The Secretary is particularly interested in the experiences of small providers. If health care or social services providers have not yet provided translation, interpreter or other language services for persons with limited English proficiency, what costs are anticipated? Please provide the basis for your estimate.

Some may assert that the guidance has materially assisted in achieving the goal of access to health or social services by limited English proficient individuals. Others may assert that the guidance has unintentionally had the opposite effect. Is their actual experience to support either view? Please describe.

Answer (for questions 7 and 8): The data we received in response to our state survey clearly indicate that interpreter services consistently cost more than the total amount paid by Medicaid to physicians for the medical visit.

Specifically, the survey shows that the cost of hiring an interpreter can greatly vary between $30 and $400, which is significantly higher than the payment for a Medicaid office visit, which in many states ranges between $30 and $50. Further, interpreters generally charge for travel costs, which become exorbitant in rural areas where interpreters could potentially travel up to 6 or 8 hours round-trip. Physicians would sustain severe economic losses if forced to cover the cost of interpretation services, and thus may no longer be able to provide services to LEP patients, which could create serious access problems for all Medicaid patients, which is already are a very vulnerable patient population.

Accordingly, the OCR requirements could reduce, not strengthen, access to health care services for LEP patients.

Question 9:

Based on your experience, does the guidance and/or OCR’s application of the guidance in practice, strike the right balance with respect to the factors enunciated in the Department of Justice’s October 26, 2001 memorandum: (1) The number or proportion of limited English proficient persons, (2) the frequency of contact with the program, (3) the nature and importance of the program, and (4) the resources available? In considering the resources available, does the guidance and/or OCR’s application of the guidance adequately factor in the costs of providing translation, interpreter or other language services to limited English proficient individuals, as well as the resources available to the recipient/covered entity?

Answer: We do not believe that the OCR guidance and its application in practice strikes the right balance with respect to the factors enunciated in the Department of Justice’s October 26, 2001 memorandum, especially with respect to factoring in the cost of translation services (as discussed under questions 7 and 8).
Physicians have always provided high quality health care services to their patients — regardless of the patient’s language ability. This capability existed before the LEP guidance was issued and continues today. If the federal government wishes to impose a new mandate and burden on the physician community, it must be willing to pay for the services required under the guidance.

Historically, payments for providing evaluation and management services (for physician office visits) to Medicare, Medicaid, or private pay LEP patients never incorporated the cost of providing interpreter services as a part of the physician’s total work. The federal government, through this LEP guidance, is now forcing physicians to incur an unfunded mandate by not paying for the physician’s cost of providing the interpreter. As a result, physicians will inevitably be unable to continue treating Medicaid patients since the costs of interpreter services well exceed payment to the physician for the office visit.

In summary, we believe that unless the cost of providing interpreter services is properly and fully addressed by the federal and state governments, physicians will inappropriately and unfairly bear the financial brunt of this new federal mandate. Further, the current OCR requirements, with their associated costs, will reduce – not improve – access to health care services for LEP patients.

We appreciate the opportunity to provide our views on this critical issue to both patients and the physician community. We look forward to working with the OCR and the Administration to achieve resolution of this matter.

Respectfully,

Michael D. Maves, MD, MBA

Attachment
STATEMENT

of the

American Medical Association

to the

Practicing Physicians Advisory Council

Re: Overview Prescription Drug Benefit
Revisions to the Average Wholesale Price Methodology Regulation
Physician Enrollment
Limited English Proficiency Guidance
HIPAA Rule

September 15, 2003

Presented by: Edward L. Langston, MD
AMA RECOMMENDATIONS FOR PPAC

The AMA urges the Practicing Physicians Advisory Council to recommend that CMS —

- Ensures more specificity with regard to PPAC meeting agenda items in future Federal Register notices by publishing not only the agenda topics, but also the two or three questions CMS will be asking PPAC to address on each topic;

OVERVIEW OF THE PRESCRIPTION DRUG BENEFIT

Medicare Payment Update

- Continue efforts to ensure continued access to medical care for senior citizens and disabled Americans by supporting the inclusion of physician payment update provisions in any final conference report for the pending Medicare prescription drug legislation that, at a minimum, mirror those contained in H.R. 1;

- Support inclusion of provisions in any final Medicare conference agreement that address documented geographic payment disparities;

Electronic Prescribing

- Support the following principles as part of any final Medicare conference agreement:

  1. Adopt the Senate framework - develop uniform standards without a requirement to transmit or receive prescriptions electronically;

  2. Allow for a deliberative development process for electronic prescription standards;

  3. Involve practicing physicians in the standards development process;

ICD-10 Coding

- Support, in any final Medicare conference agreement, a modification of the H.R. 1 provision addressing ICD-10 to clarify that the new code set would replace only the current uses of ICD-9-CM;
REVISIONS TO THE AVERAGE WHOLESALE PRICE METHODOLOGY REGULATION

- Adhere to the following principles concerning modifications to the average wholesale price methodology (AWP) in any final Medicare conference agreement:

  1. Medicare payments for drug products should fully cover the physician’s acquisition cost;

  2. Any reductions in Medicare payments for drugs must be accompanied by adequate increases in what the program pays physicians to administer the drug;

  3. Increases in drug administration payments should not be limited to specific specialties, specific classes of drugs or specific remedies;

  4. Improvements in drug administration payments should not trigger pay cuts for other services;

  5. Medicare officials should explore the use of alternative data sources in any revision of current drug administration payments;

PHYSICIAN ENROLLMENT

- Continue pursuing alternatives to the proposed physician enrollment rule that will simplify the process and not impose new regulatory burdens on physicians who have obtained their Medicare billing number prior to 1996;

- Refrain from imposing the three-year revalidation requirement and to continue working with the physician community to resolve differences concerning all other burdensome requirements in the proposed rule;

LIMITED ENGLISH PROFICIENCY

- Consider methods for eliminating the financial burden imposed on physicians for the cost of interpretive services for LEP patients, including the creation by Medicare of a separate provider category, with adequate funding, for interpreters who would separately bill Medicare for their services;
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

- Ensure that physicians, providers and payers, are permitted, without penalty, to submit and pay “legacy claims” in addition to HIPAA compliant claims for some reasonable transition period while all continue to work diligently toward compliance; and

- Implement the contingency plan announced by CMS that would allow Medicare to accept “legacy” fee-for-service claims on or after October 16, while HIPAA issues are resolved and encourage other private and public payers to do so as well.
The American Medical Association (AMA) appreciates the opportunity to submit this statement to the Practicing Physicians Advisory Council (PPAC or the Council) concerning overview of the prescription drug benefit, revisions to the average wholesale price methodology regulation, physician enrollment, limited English proficiency (LEP) guidance, and the Health Insurance Portability and Accountability Act (HIPAA) rule.

The AMA would like to express our appreciation for the active involvement of Mr. Tom Grissom in the Council’s deliberations over the last several years. His involvement assures that senior management of the Centers for Medicare and Medicaid Services (CMS) is listening and demonstrates concern about the views of practicing physicians. Additionally, we would also like to welcome Dr. Kenneth Simon as the new Executive Director of PPAC. Dr. Simon has been an active participant in the work and deliberations of the RUC Committee and the CPT Editorial Panel. He has represented CMS well in those meetings and, by his involvement, has been able to assess for CMS physician interest and concerns on a wide variety of issues that come before these two committees. We look forward to working with him again on PPAC issues.

Further, as future PPAC meetings and agendas are planned, it would be a vast improvement in PPAC operations for CMS to publish meeting notices in the Federal Register that include not only the agenda topics, but also include the two or three questions CMS will be asking PPAC to address on each topic. Such notice helps not only PPAC members focus their attention on the questions, but the public witnesses as well. It is extremely difficult for the public to address their testimony on such agenda topics as “Divided Authority for Policies on Coverage of Procedures and Devices Results Inequities” and other broad agenda items without some insight into what CMS will be presenting and the issues to be resolved.

Accordingly, we recommend that PPAC urge CMS to ensure more specificity with regard to PPAC meeting agenda items in future Federal Register notices.

OVERVIEW OF THE PRESCRIPTION DRUG BENEFIT

The House and Senate have each passed a comprehensive Medicare prescription drug benefit bill, H.R. 1 and S. 1, the “Medicare Prescription Drug and Modernization Act of 2003,” and the “Prescription Drug and Medicare Improvement Act of 2003,” respectively. House and Senate conferees have been meeting to reconcile these bills. Although both bills would establish a Medicare drug benefit, including provisions addressing electronic prescribing, each would also address a number of other important Medicare matters, including the physician payment update, payments for rural physicians, ICD-10 coding matters, and regulatory reform.

Medicare Payment Update

The House Medicare bill contains a provision to implement a physician payment update of not less than 1.5% in each of 2004 and 2005, and the Senate bill contains a “Sense of
the Senate” provision stating that the physician payment formula is flawed and that beneficiary access to quality care may be compromised if Congress does not take action to prevent cuts in 2004 and the following years.

Due to the flaws in the sustainable growth rate (SGR) payment update formula, the physician payment crisis continues. Without Congressional action this year, Medicare payment rates for physicians and other health professionals, whose payment rates are tied to the physician fee schedule, are predicted to fall by between 4% and 5% in 2004. Although the proposed physician payment rule issued in August suggested an expected cut of at least 4.2%, it did not predict a specific number. Thus, the physician community still has no way of knowing the expected payment cuts that could be implemented as of January 1 of next year.

A cut of at least 4.2% would be the fifth cut since 1991, and would be on top of a 5.4% cut in 2002. Additional cuts are also estimated for 2005, 2006, and 2007. From 1991-2003, payment rates for physicians and health professionals fell 14% behind practice cost inflation, as measured by Medicare’s own conservative estimates.

Further, the pending Medicare legislation includes a number of provisions that, while good for patients, would increase utilization of physicians’ services. In addition to the new prescription drug coverage, the legislation proposes to establish or improve Medicare coverage of new services, such as preventive physical exams, cholesterol and lipid screenings and colorectal cancer screenings. These types of initiatives increase utilization of physicians’ services in two ways: Medicare patients will visit their physicians to obtain the newly-covered drug or other medical service, and these patients may require related follow-up care or additional care for a condition that would have gone undetected had the patient not visited his or her physician to obtain the new service. **All of the costs due to these provisions, if enacted, should be taken into account in determining payment updates for physicians’ services. Payments should not be cut due in part to increased utilization that derives from government initiatives.**

As we have previously discussed with PPAC, a number of surveys have indicated that physicians are increasingly limiting how many Medicare patients they see and that more will be forced to do so if payments are cut again. Cuts in Medicare payments also jeopardize access to medical care for military retirees and dependents because their TRICARE insurance ties its payment rates to Medicare.

**The AMA applauds CMS’ and Congress’ commitment to protecting access to needed medical care for senior and disabled Americans. We urge PPAC to recommend that CMS continue efforts to ensure such continued access by supporting the inclusion of physician payment update provisions in any final conference report for the pending Medicare prescription drug legislation that, at a minimum, mirror those contained in H.R. 1.**

Finally, the pending Medicare legislation contains various provisions that would provide additional dollars to rural physicians, including provisions relating to geographic
payment disparity and physician scarcity areas. We urge PPAC to recommend that CMS also support inclusion of provisions in any final conference agreement that address documented geographic payment disparities.

Electronic Prescribing

Both H.R. 1 and S. 1 contain provisions addressing electronic prescribing. Specifically, H.R. 1 would require that all prescriptions be written and transmitted electronically (other than by fax), except in emergency cases and other exceptional circumstances. Uniform standards for the electronic prescription drug program would be developed by the Administrator. S. 1, in contrast, would require the Secretary of the Department of Health and Human Services (HHS) to develop and adopt standards to enable the electronic transmission of medication history, eligibility, benefit and other prescription information. Only individuals and entities that choose to transmit or receive prescriptions electronically would be required to comply with the standards adopted.

While electronic prescribing shows promise toward reducing medical errors and improving patient safety, current technology is in its infancy and remains unproven. We urge PPAC to recommend that CMS support the following principles as part of any final conference agreement:

Recommendation #1: Adopt the Senate framework - develop uniform standards without a requirement to transmit or receive prescriptions electronically

The creation of uniform national standards will help facilitate the dissemination of electronic prescribing. However, physicians should have the opportunity to weigh the costs and benefits, both clinical and financial, of the use of this technology. Voluntary adoption of electronic prescribing technology would enable practices to consider critical factors such as efficient integration into management software and electronic medical record systems. Like other small businesses, each physician practice is unique. The Senate framework will provide physicians with the flexibility to incorporate electronic prescribing technology without disrupting patient care.

Conversely, federally mandated electronic prescribing would place an additional costly unfunded mandate on physicians, forcing them to rush to purchase an expensive, untested technology. The financial burden would be highest on small practices, which would be unable to benefit from economies of scale in implementing this new mandate. The burden would be disproportionately heavy on rural practices and may not be possible at all in those areas without access to high-speed data service providers and the trained information technology experts needed to maintain and update electronic prescribing systems.

Recommendation #2: Allow for a deliberative development process for electronic prescription standards
Although the concept of uniform standards for electronic prescribing appears simple, design and implementation will be extraordinarily complicated. Broad scale electronic prescribing as envisioned in this legislation does not yet exist in the ambulatory setting. Some hospitals and large practices can electronically communicate with on-site pharmacies via closed systems, but two-way, interoperable, and secure external systems are in extremely limited use. Development of a single set of standards appropriate for all health care settings, while meritorious, would be a significant undertaking.

Given the early development stage of electronic prescribing, the unrealistic January 1, 2006 statutory deadline for standards that currently exists in the pending Medicare legislation should be removed. Difficulties and delays in implementing the HIPAA Transaction and Code Set Standards are a case in point. Congress passed HIPAA in 1996, and these standards have yet to be fully implemented. Development of electronic prescribing will be equally complicated. Instead of rushing to meet an arbitrary deadline, the standards development process should include appropriate studies and pilot tests to ensure the efficacy of the standards before implementation.

**Recommendation #3: Involve practicing physicians in the standards development process**

The process to develop electronic prescription standards should be inclusive. Particularly important is input from practicing physicians and groups, which will use this new technology at the point of care. An effective electronic prescription system should provide the physician with access to independent, up-to-date, evidence-based information on the drugs he or she is prescribing and an accurate patient history. Voluntary standards should be compatible with electronic health record standards currently under development by HHS. Given the important clinical and practical issues to be resolved, involving practicing physicians in the standards development process is critical to ensure the effectiveness of electronic prescribing.

Careful and deliberative development is critical to achieving electronic prescribing’s potential of improving patient safety and reducing medical errors.

**ICD-10 Coding**

*H.R. 1 contains a provision addressing use of the ICD-10 code set, and the AMA urges PPAC to recommend that CMS support a modification of this provision in any final Medicare conference agreement to clarify that the new code set would replace only the current uses of ICD-9-CM.*

The physician community is united in its concern that application of the ICD code set in all settings, and not just as currently used, would create chaos and a dramatic increase in administrative hassles associated with coding for physicians. For example, moving from the CPT coding system, with 8,000 codes for physician services, to an ICD coding system, with more than 170,000 codes, would result in a massive upheaval in claims processing systems for physicians and other Part B providers. In addition, many
physicians’ services are not even included in ICD-10, and this system uses language that is confusing and inconsistent with the language generally used by physicians.

Additional details concerning the ICD-10 issue are attached in Appendix A.

**REVISIONS TO THE AVERAGE WHOLESALE PRICE METHODOLOGY REGULATION**

Both H.R. 1 and S. 1 contain provisions that would revise the current average wholesale price (AWP) payment methodology for Part B covered drugs and biologicals. In addition, CMS recently issued a proposed regulation that would revise the AWP methodology, based on one of four approaches. Medicare currently covers more than 400 physician-administered drugs. About 20 medical specialties administer these drugs to millions of patients suffering from a variety of debilitating conditions, including cancer, rheumatoid arthritis, Crohn’s disease, chronic pain, autoimmune diseases and macular degeneration.

The AMA recently sent a letter, along with a number of medical specialty societies, to all House and Senate conferees requesting that conferees adhere to the following principles concerning any modifications to AWP in any final Medicare conference agreement. We recommend that PPAC urge CMS to adhere to these same principles:

**Recommendation #1:** Medicare payments for drug products should fully cover the physician’s acquisition cost.

While Medicare reimbursement for drugs exceeds the physician’s acquisition cost, the margin between payment and cost varies by drug, location, and practice size. A significant across-the-board cut would have an uneven impact with potentially disastrous consequences for those products or practices with little margin. Payments based on newly-determined sales prices would have the advantage of differentiating between types of drugs and if properly constructed could be more appealing. Additional adjustments would be needed, however, to protect physicians with above-average costs due to practice size or location.

**Recommendation #2:** Any reductions in Medicare payments for drugs must be accompanied by adequate increases in what the program pays physicians to administer the drug.

In addition to paying for the drug itself, physicians also incur costs for storing, preparing and administering the drug. Both CMS and the General Accounting Office have reported that physicians use profits on the drug to subsidize inadequate drug administration payments. Without more realistic reimbursement for the practice costs associated with drug administration, cuts in drug payments could force many physicians to stop providing drugs in the office and send patients to hospital outpatient departments instead.
**Recommendation #3:** Increases in drug administration payments should not be limited to specific specialties, specific classes of drugs or specific remedies.

As previously noted, about 20 specialties administer drugs to Medicare patients. Costs vary depending on the type of drug, mode of administration (infusion or injection), need for physician management, clinical staff involved, and degree of patient education and follow-up required. The most appropriate way to improve drug administration payments will vary by drug and could involve new or modified codes for describing the services as well as increases in the work and/or practice expense values assigned to the codes. Legislative language dealing with payment improvements should permit other options in addition to increases in practice expense.

**Recommendation #4:** Improvements in drug administration payments should not trigger pay cuts for other services.

Due to complexities in Medicare’s payment methodology, changes in the calculation of chemotherapy payments are likely to generate cuts for certain other technical services performed by clinical staff rather than physicians. In addition, budget neutrality requirements generally require that any increases in values for some physician services must be offset by reductions elsewhere in the system. However, a budget neutrality offset is not appropriate in this case because the legislation under consideration would reduce, rather than increase, total spending on physician administered drugs. Budget neutrality should therefore be waived and such waiver should be broad enough to cover a variety of changes, some of which might not be fully effective until 2006. The waiver should also include the cost of completely—not partially—protecting other technical services from unintended consequences.

**Recommendation #5:** Medicare officials should explore the use of alternative data sources in any revision of current drug administration payments.

CMS currently plans to use survey data provided by oncologists to increase practice expense values for drug administration codes. While these changes would benefit other physicians as well as oncologists, additional data likely will be needed to further refine drug administration payments. In making these refinements, CMS should consider the financial burden attached to comprehensive specialty surveys and explore the use of alternative data developed by the affected specialties.

Over the past decade, medicine, aided by innovative new break-through drugs, has made enormous advancements in the treatments of many life-threatening diseases that are prevalent among the elderly. To continue providing these drugs, physicians must have a stable payment system that covers both acquisition and administration costs.

**We urge CMS to support the principles outlined above to ensure appropriate payments for all concerned.**
PHYSICIAN ENROLLMENT

In late April, CMS issued a proposed rule on the Medicare enrollment process, which, if finalized as proposed, would create a new regulatory burden on physicians and require many additional hours of paperwork hassle. In AMA comments submitted to CMS on the proposed rule, we expressed our overall appreciation for the Bush Administration’s and CMS’ commitment to improving communication with physicians, reducing Medicare’s complexity, and making Medicare’s rules fairer and less burdensome.

Nevertheless, we also expressed that because the Administration has made such great strides in its regulatory relief efforts to date, it would be a serious mistake to impose the new and burdensome enrollment requirements, without significant modification.

If finalized as proposed, the more than 300,000 physicians who obtained their Medicare billing numbers before 1996 and, hence, were not previously required to complete an 855 enrollment form, would be required to do so just to maintain their current Medicare billing privileges. Failure to complete the process could lead to revocation of the physician’s Medicare number. The new rule also proposes that the billing numbers of any enrolled physicians who do not bill the program for two consecutive quarters be deactivated and that these physicians reenroll once they wish to begin submitting claims again. Finally, physicians would be required to report changes to the information on the form on an ongoing basis as they occur, and to revalidate their enrollment information every three years. Such an enormous new regulatory burden would undermine much of the progress made to date on regulatory reform.

Other comments by the AMA were as follows:

- In November 2001, CMS revised the 855 form to ease the enrollment of qualified providers into Medicare. The application is now a set of four individualized forms, each directed toward a specific provider or supplier type based on the applicant. Although these revisions improved the application process in several respects, the process has continued to present numerous challenges, which were demonstrated by the results of a CMS customer service survey presented to PPAC in December 2002. Key among the objectives identified by respondents as needing improvement were: (i) appropriate number of hours spent on process and effort required to complete 855 form, (ii) information requested by 855 form in a user-friendly manner, (iii) helpfulness of CMS regional office and consistent answers received to questions, (iv) ease in finding out status of 855, (v) carrier minimized number of times 855 was returned for corrections, and (vi) prompt notification provided by carrier of provider number. In light of this customer service survey, we believe CMS should reconsider any major expansion of the enrollment.

- The proposed rule did not provide a sufficient rationale for imposing these new administrative burdens on physicians. The current 855 form encompasses 27
pages, and, as discussed above, changes must be submitted every time data on the
form changes, and then the form must be periodically revalidated.

- We have also been concerned about how the enrollment process will be
accomplished. In particular, it is difficult to envision how carriers could possibly
process all of the forms for physicians who already have a Medicare billing
number, but who were not previously required to complete an 855 form, while
continuing to process applications for physicians enrolling in the program for the
first time.

In meetings with CMS, agency staff have been very receptive to the concerns expressed
by the physician community, and we understand the agency is pursuing alternatives to the
specific requirements, as set forth in the proposed rule. CMS is attempting to ensure that
any new requirements will be as simple and efficient as possible for physician practices,
without imposing new paperwork burdens. For example, CMS is making an effort to
implement a comprehensive enrollment database that would allow physicians to view
online the information they have already submitted to Medicare and to validate its
accuracy and completeness electronically, instead of being required to complete a lengthy
paper form. The AMA appreciates CMS’ efforts to avoid imposing any new burdens on
physician practices and to pursue an alternative enrollment approach.

We recommend that PPAC urge CMS to continue pursuing alternatives to the
proposed enrollment rule that will simplify the process and not impose new
regulatory burdens on physicians who have obtained their Medicare billing number
prior to 1996. Further, we recommend that PPAC urge that CMS refrain from
imposing the three-year revalidation requirement and to continue working with the
physician community to resolve differences concerning all other burdensome
requirements in the proposed rule.

LIMITED ENGLISH PROFICIENCY

In August 2000, the Clinton Administration issued Executive Order 13166, which
requires all federal agencies to develop a system for providing LEP patients with
meaningful access to federal services, including health care services. In August 2000 and
February 2002, HHS’ Office of Civil Rights (OCR) published a notice that sets forth a
comprehensive list of requirements with which health care organizations must comply
when treating LEP patients. The OCR requirements require all physicians who receive
any Medicaid dollars (or any other funds that constitute “federal financial assistance”) to
provide, at their own expense, a trained clinical interpreter for all their LEP patients,
regardless of whether the patient is insured by Medicaid, Medicare or a private payer.
Physicians also must meet numerous other requirements under the OCR notice, including
(i) ensuring that interpreters are trained and demonstrate competency as interpreters, and
(ii) providing the interpreter with orientation and training that includes skills and ethics of
interpreting.
On August 8, 2003, OCR issued new guidance for physicians and other health care entities that treat LEP patients. This guidance was issued pursuant to a directive by the Department of Justice (DOJ), which issued a memo in July 2003 to all federal agencies expressing the need for consistency across federal agency LEP guidance documents.

The AMA appreciates the recognition by both HHS and DOJ, as expressed in the new LEP guidance, of the need to find constructive methods to reduce the costs of LEP requirements on small businesses. For example, DOJ has set forth several principles to which LEP guidance documents need to adhere, including that the goal of ensuring access for LEP patients must be achieved “while finding constructive methods to reduce the costs of LEP requirements on small businesses, small local governments, or small non-profits that receive federal financial assistance.” Further, HHS plans to provide assistance to LEP persons and entities covered by the guidance to identify model plans, examples of best practices and cost-saving approaches. It will also explore how certain approaches, including cost containment approaches, with respect to federal programs can be shared or made available to entities such as small businesses.

Other statements in the new LEP guidance also appear to allow flexibility for physician practices: Although the guidance provides that covered entities must consider LEP populations that may be underserved because of language barriers, it also states that “for most individual physicians or dentists, outreach may not be necessary.” In addition, the guidance allows that it may be permissible to use telephone language lines or a commercially available telephonic interpretation services. Finally, the guidance recognizes that smaller entities with more limited budgets are not expected to provide the same level of language services as larger entities with larger budgets, and “reasonable” steps may not be “reasonable” where the costs imposed substantially exceed the benefits.

While this more flexible approach to the LEP requirements is a step in the right direction, the AMA remains concerned about the bottom-line cost burden that the LEP guidance ultimately imposes on physician practices. The AMA has long-emphasized that clear, direct communication and understanding is the bedrock of the physician-patient relationship, and thus very important in providing quality medical care to all patients. When physicians are required, however, to fund written and oral interpretation services for LEP patients in their practice, as remains the case under the new guidance, this can impose severe economic losses that are difficult to sustain, especially when the cost of providing the LEP services far exceeds the payment for treating the LEP patient. This could create serious access problems for LEP patients.

**AMA policy supports elimination of the financial burden imposed on physicians for the cost of interpretive services for LEP patients, and we recommend that PPAC urge HHS and CMS to consider methods for covering the costs of interpreter services.** The AMA also supports the creation by Medicare of a separate provider category, with adequate funding, for interpreters who would separately bill Medicare for their services. This would help defray some of the costs of this unfunded mandate imposed on physicians by the LEP guidance.
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

HIPAA Enforcement

Compliance with HIPAA Transaction and Code Sets Rule (Transactions Rule) is required after October 16, 2003. The health care community has made considerable efforts and progress towards meeting the requirements of the Transactions Rule in a timely manner. Unfortunately, however, because of the enormity of the task, and compounded by the additional challenge of concurrently working to come into compliance with the Privacy Rule last April, a substantial portion of the community will likely not be ready to conduct compliant transactions by October 16th.

In fact, the AMA conducted an on-line survey of more than 500 physicians from July 25, 2003, to August 14, 2003, to attempt to assess physician knowledge of and readiness for the Transaction and Code Set Standards. The results, summarized in Appendix B, confirmed that many physicians and others in the health care community may not be ready to conduct compliant transactions by October 16th.

AMA policy supports implementation of necessary legislative and/or regulatory changes to mandate that health plans continue to accept non-standard electronic claims (“legacy claims”) from physicians during a reasonable transition period following October 16, 2003. Further, the AMA has been actively participating in a provider and payer coalition, which has been advocating to HHS and CMS the need for such flexibility in enforcement of the Transactions Rule to avoid extensive claims processing problems.

CMS has indicated that the agency has not yet determined if “legacy claims” will be acceptable without penalties by either Medicare or private payers during a transition period after October 16th. On a July 24th national conference call with the health community, CMS stated that the law does not permit the agency to provide a safe harbor for health plans to accept “legacy claims” after October 16, 2003 (although private sector attorneys have argued otherwise.) Nevertheless, at this time, CMS released a Guidance document on compliance with the rule detailing a flexible approach to enforcement of the rule. (CMS indicated additional guidance may be released in late September or early October.) Enforcement will be driven by a complaint-driven approach, similar to the enforcement approach for the Privacy Rule. CMS will determine on a case-by-case basis if the entity is making a good faith effort to come into compliance. If so, CMS will refrain from imposing fines and penalties. CMS will seek corrective action plans from those not in compliance. This Guidance was a very important step in the right direction.

The provider/payer coalition remains hopeful that CMS will allow physicians, providers and payers, without penalty, to submit and pay “legacy claims” in addition to HIPAA compliant claims for some reasonable transition period while all continue to work diligently toward compliance, and we recommend that PPAC urge CMS to ensure that this occurs.
Toward that end, we are very pleased that Tom Grissom, Director of the Center for Medicare Management within CMS, on September 4th sent a message to the health care community which further refines (and improves) CMS’s plans for HIPAA compliance. He stated that CMS has a contingency plan that would allow Medicare to accept “legacy” fee-for-service claims on or after October 16, while remaining HIPAA issues are resolved. The decision to implement the contingency plan will come after CMS assesses the readiness of the health care community, but by September 25, 2003. This is a very important decision by CMS. We hope it will be very influential and perhaps precedent setting with other private and public payers. We recommend that PPAC urge CMS to implement this contingency plan and to encourage other private and public payers to do so as well.

New Requirement for Submission of Electronic Claims to Medicare

On August 15, the Administration published an interim final rule implementing the new requirement for the electronic submission of Medicare claims starting October 16, 2003, pursuant to the Administrative Simplification Compliance Act. The rule also provides an important exemption process for a small physician practice of fewer than 10 full-time equivalent employees. CMS estimates that 83 percent of physicians, practitioners and suppliers already submit electronic claims to Medicare. That still leaves a large number of entities that do not file electronic claims and that will potentially be affected by this requirement.

CMS has indicated there is no requirement for small practices or providers to submit a waiver in order to be exempt, but instead may audit those practices who do not submit claims electronically. The AMA is hopeful that the exemption process will function smoothly. To be certain, we will monitor the exemption process and would be pleased to work with CMS to identify problems or questions raised by the physician community.

Again, the AMA appreciates the opportunity to present our views on these important matters to PPAC, and we look forward to working further with PPAC and CMS to ensure successful implementation of the recommendations set forth above.
As you continue the Committee’s hearings on the Fiscal Year 2003 Budget for the Department of Health and Human Services, the American Medical Association (AMA) would like to share its insights on the Administration’s Fiscal Year 2003 Budget Proposal submitted to Congress. As the Committee moves forward in considering the Administration’s requests, we hope you will seriously weigh our concerns related to the issues listed below.

User Fees

Through its budget proposal, the Administration has proposed user fees for physicians who submit claims on behalf of their patients. As background, several years ago, Congress enacted legislation requiring physicians treating Medicare patients to submit these claims to the Medicare program on behalf of their patients. Congress has repeatedly rejected the Administration’s attempts to shift such additional Medicare program costs onto physicians through user fees. These user fees are nothing but a tax on the physician community, which is currently facing unprecedented payment cuts from the Medicare program, and we urge you to again reject these fees.

The Administration’s budget would tax physicians $1.50 for each paper claim submission. This has the potential to impact up to 21% of all Part B Medicare claims, and along with the tax cited below would impose $130 million in fees on physicians in FY 2003. This would be an extraordinary cost for physicians to bear simply because their offices have not been linked to an electronic network. This tax is especially unwarranted since many physicians may feel more comfortable submitting hard copies of claims to their carriers given the negative experiences that some physicians have had with their carriers and the issues surrounding confidentiality of patient records. The budget proposal would also penalize physicians by taxing them $1.50 for each resubmitted claim even when payment was seriously overdue or when the contractor has rejected the claim for trivial or inappropriate reasons. The AMA objects to requiring a physician to pay to resubmit claims to the Medicare program. The AMA strongly urges the Committee to reject these user fees.
Loan Consolidation

The AMA is adamantly opposed to any proposal that would end fixed-rate consolidation of federal student loans. If implemented, this proposal would prevent thousands of student loan borrowers from consolidating their education loans at significantly lower interest rates.

Physicians enter their residency with an average of $97,750 in student loan debt. At 4.5% (the projected 2002 fixed rate for student loan consolidation), borrowers with a debt of $106,000, and a standard 10-year repayment period, pay $1,098 per month or a total of $131,828 ($25,828 in interest) over the life of the loan. At a rate of 6.8%, (projected variable rate based on Congressional Budget Office projections over the next 10 years) these same borrowers would pay $1,220 per month or a total of $146,382 ($40,382 in interest) over the life of the loan. This increase would be unjustified and would rest squarely on the backs of our nation’s students.

The AMA believes that students should be able to avail themselves of the best possible loan terms when seeking to refinance their debt. The high level of educational indebtedness serves as a deterrent for many medical school graduates considering whether to practice medicine in an underserved area, enter the public health service, or start a career in medical education or research. We strongly urge the Committee to reject this proposal as it would effectively raise the interest on education loans for millions of American students.

Limited English Proficiency Requirements

The previous Administration issued guidance stating that since physicians treating Medicaid patients receive “federal financial assistance,” they are required to provide medical interpreters for all of their non-English speaking patients. Since the cost of providing interpreter services usually exceeds the payment made for the physician visit, many physicians may simply opt not to treat the most needy patients because of this requirement. The AMA believes that the Center for Medicare and Medicaid Services (CMS) should instead fund toll-free interpreter services that would be available to patients or physicians needing interpreter services. The AMA believes that action on this item is imperative to ensure that it does not become an economic disincentive for physicians to provide care to non-English speaking patients.

Bioterrorism and Emergency Preparedness

The events of September 11th and the subsequent anthrax attacks have demonstrated that it is imperative for our nation to invest in its public health infrastructure and disaster response system, including an investment in the readiness of our nation’s physicians. The AMA has identified the following critical steps to ensure that our health care system is prepared to respond to any future threat. We urge the Committee to recognize the role of organized medicine in:

(1) The adaptation of existing medical education curricula on disaster medicine, the medical response to terrorism, and the development of information resources for civilian physicians and other health care workers. As curricula teaching the medical response to terrorism and
other disasters already exist, the need is to adapt curricula to physician audiences and then disseminate to target audiences, as well as to support the costs of continuing medical education (CME) programs. Congress should support this effort by ensuring that organized medicine has adequate funding via federal education and training grants;

(2) The development of model plans for community medical response to disasters, including terrorism, that incorporate physicians into community planning efforts; and

(3) The development of a national communications infrastructure that will address the issues of reliable, timely and adequate sharing of information on dangerous diseases by community physicians to public health authorities. This effort should rely to the largest extent possible on existing systems. Any such system also must take into account the burdens placed on physicians and hospitals in reporting such information.

The appropriate level of funding should also be dedicated to ensuring that increased stockpiles of vaccines and antibiotics are available, that more research occurs, and to support an industrial base to insure the production of new antiviral and antibiotic treatments. The AMA also requests the Committee to give careful consideration to funding mental health services for those affected by terrorism.

Liability for Physician Volunteers

In 1996, the Congress wisely enacted legislation which promotes free clinics around the country by reducing the professional liability exposure of physicians who volunteer their time and medical skills. The AMA urges the Committee to appropriate the necessary funds for the implementation of Section 194 of the “Health Insurance Portability and Accountability Act of 1996” (HIPAA) as soon as possible. This Section designates physicians who work in free clinics without receiving reimbursement as federal Public Health Service employees. As such, if a medical malpractice claim arises, the physician’s legal defense is assumed by the federal government. Without this provision, the enormous increases in malpractice insurance may force physicians to stop volunteering at these free clinics, many of which are in areas with physician shortages.

The AMA believes that it is especially important to encourage physician volunteerism in free clinics and in other critical need areas, and we hope the Committee will appropriate the funds authorized under Section 194 of HIPAA, which are necessary to implement this important program and promote free clinics.

HIPAA Educational Efforts –

Beginning in October of 2002, physicians and other covered entities will be required to make major changes to their administrative systems to accommodate the provisions of the privacy portion of HIPAA and the transaction and code set standards established as a result of HIPAA. Significant educational efforts will be necessary to ensure effective implementation of the new standards. The AMA believes that the Department should devote an appropriate level of resources (the level spent on Y2K educational efforts may be a suitable guide) to ensure that the health care community properly submits and receives payments based on the new HIPAA rules.
Title VII/Title VIII Funding for Physician Training

Through loans, loan guarantees, and scholarships to students, and grants and contracts to academic institutions and non-profit organizations, Title VII and VIII health professions programs are designed to:

• meet the nation's needs to increase the supply of primary medical and dental care providers, public health and allied health professionals, and nurses;
• educate and train more health professionals in fields experiencing shortages, such as the current shortages in nursing, pharmacy, dentistry, public health, and allied health;
• improve the geographic distribution of health professionals and nurses;
• increase access to health care for underserved populations; and
• enhance minority representation in the practicing health professional workforce.

The AMA strongly urges the Committee to retain or increase Fiscal Year 2002 levels for the Title VII and Title VIII programs. The Administration’s budget proposal would zero out funding for the Primary Care Medicine and Dentistry Program and would cut the Health Professions Program by 75% (from $378 million to a total of $94 million). Title VII is the only federal program designed to increase the number of primary care physicians and to increase the number of individuals providing health care to underserved populations. In fact, a study by the Robert Graham Center for Policy Studies shows that medical schools receiving Title VII funds produced higher numbers of students that practiced family medicine or primary care, practiced in rural areas, or practiced in a whole county primary care health professions shortage area. We urge the Committee to act to ensure continued funding of the Title VII and Title VIII programs.

Pilot Testing New Evaluation and Management (E&M) Procedure Codes –

Payments for E&M codes represent approximately one-third of all payments made to the physician community. A private sector workgroup has been working with CMS to refine these codes. However, it will be necessary to pilot test any new documentation guidelines prior to national implementation. We urge the Committee to provide CMS with specific funding to pilot test any new E&M documentation guidelines.

National Health Service Corps

The AMA has been a long time supporter of the National Health Service Corps (NHSC), a program that recruits and retains primary care physicians and other healthcare providers into underserved rural areas within our great nation. The AMA is extremely committed to the continuation of the NHSC and its objectives.

The NHSC recruits, prepares, and supports dedicated students and clinicians through a variety of programs and services. In fact, more than 2,300 NHSC clinicians provide primary and preventive health care to some 3.6 million people in rural and urban communities. The goal is not only to recruit physicians and health care professionals to remote areas, but to retain them in these areas. To date, more than 50% of physicians and health care providers remain in underserved areas.
The AMA strongly supports the Administration’s request for a 32% increase in the Fiscal Year 2003 NHSC budget. This funding level is extremely important to the millions of individuals who will be well served through the NHSC’s preservation and growth.

Agency for Healthcare Research and Quality (AHRQ)

The AMA is very concerned about the Administration’s proposal to decrease AHRQ funding by $48 million or 16% of its Fiscal Year 2002 budget. AHRQ has played a vital role in improving patient safety and reducing medical errors, providing health care access for persons with chronic disorders, and reducing health care costs. The AMA believes that the agency’s work is extremely valuable to both patients and to the health care system on a larger scale.

The proposed budget would result in AHRQ not being able to undertake any new projects and would mean that non-patient safety research spending would be reduced by 50%. This reduction in research would significantly reduce the knowledge and understanding of how to provide cost-effective quality health care. We strongly urge the Committee to restore the AHRQ budget to its FY2002 level to ensure the continuation of its essential work.

Office on Smoking and Health at the Centers for Disease Control and Prevention (CDC)

The AMA strongly encourages the Committee to increase CDC funding from its FY2002 level to ensure that it has an appropriate level of funds to conduct its tobacco work. The CDC would use additional funding to expand the scope of its current activities to study the effects of exposure to environmental tobacco smoke (ETS) and to educate the public about the benefits of reducing ETS exposure. Additional funds would be used by CDC to learn more about ETS, educate the public about exposure to ETS, and evaluate which programs work to reduce ETS exposure. Additional funds would be used to research cessation techniques, establish a “tobacco quitline,” and to evaluate and expand tobacco cessation programs. We strongly urge the Committee to increase CDC funding to ensure the expansion of these programs.

Medicare Contractor Reform Impact Analysis –

In December, the House of Representatives passed H.R. 3391, the “Medicare Regulatory and Contracting Reform Act of 2001” which could significantly alter the number of Medicare carriers and intermediaries and how they pay, review, and serve physicians and providers of care. The AMA strongly supports this legislation, and we believe that the CMS should conduct an impact analysis prior to changing the number and responsibilities of Medicare contractors. This analysis would aid in avoiding unnecessary disruptions in the way the program is administered.

In addition, we urge the Committee to ensure that local carrier advisory committees (CACs) continue to function in each state to ensure that local medical review policy reflects the consensus of the local physician community. All changes in local medical review policy (whether through a change in contractor or through the consolidation of existing contractors) should be subjected to the normal review and comment process with the local CAC. This would prevent a new contractor from simply transporting a new policy from one geographic region to another without subjecting that policy to CAC review in the new geographic area.
Immunization Activities

The AMA supports the CDC’s efforts to expand the nation’s immunization system. The CDC provides technical assistance, training, and education for health care practitioners providing vaccines. Among its many immunization activities, the Center also provides grants to all fifty states, six cities, and eight current or former territories to reduce the instances of disability and death from vaccine-preventable diseases.

The AMA believes that vaccines are one of the best methods of protecting children and the general population from vaccine-preventable diseases. It is inexcusable that one million two-year olds in the United States have not received all of the recommended vaccinations. In the adult population, more than 38,000 adults die annually from complications associated with hepatitis B, influenza, and pneumococcal infections – despite the availability of vaccines.

We urge you to ensure that CDC receives increased funding to safeguard its current program activities and to expand its functions so as to guarantee that an ever-diminishing proportion of our population falls victim to these devastating diseases.

Antimicrobial Resistance

The appearance of numerous bacterial and viral species resistant to the very treatments that, in the past, effectively cured patients, has left physicians with a decreased number of options in the battle against diseases caused by organisms such as salmonella, staphylococcus, streptococcus, and HIV. The AMA has had a longstanding interest in the problem of antimicrobial resistance and supported the Public Health Action Plan to Combat Antimicrobial Resistance, which coordinated the different federal agencies’ efforts to combat this important public health problem.

The AMA believes that antimicrobial resistance can only be solved through coordinated, cooperative efforts involving both public and private sectors. This activity must receive appropriate funding for the Food and Drug Administration (FDA) and the CDC to execute its action items under the Action Plan. There is very strong support among the medical and public health communities for efforts to combat antimicrobial resistance, and we urge you to support CDC funding levels and to ensure that such activities occur.

We appreciate the opportunity to submit this statement to the Committee, and we look forward to working with the Committee as this process moves forward. Please feel free to contact our Washington DC office with any questions you may regarding these or other matters.
Whereas, Public will and strong political forces are pushing to change the system of American medicine; and

Whereas, The practice of medicine has always been and should remain in the control of physicians; and

Whereas, The practice of medicine, both traditionally and practically, has been carried out as a private business enterprise under the control of the physician; therefore be it

RESOLVED, That our American Medical Association adopt policy that government involvement in the practice of medicine must not force the participation of physicians, allowing their participation to remain voluntary (New HOD Policy); and be it further

RESOLVED, That our AMA take action to officially reject any future attempt by individual state and/or federal legislative bodies to require acceptance of any private or government third party payments or contracts as a condition of licensure. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $12,000.

Received: 05/05/09
**H-165.985 Opposition to Nationalized Health Care**

Our AMA reaffirms the following statement of principles as a positive articulation of the Association's opposition to socialized or nationalized health care: (1) Free market competition among all modes of health care delivery and financing, with the growth of any one system determined by the number of people who prefer that mode of delivery, and not determined by preferential federal subsidy, regulations or promotion. (2) Freedom of patients to select and to change their physician or medical care plan, including those patients whose care is financed through Medicaid or other tax-supported programs, recognizing that in the choice of some plans the patient is accepting limitations in the free choice of medical services. (Reaffirmed: BOT Rep. 1-93-25; Reaffirmed: CMS Rep. 1-93-5) (3) Full and clear information to consumers on the provisions and benefits offered by alternative medical care and health benefit plans, so that the choice of a source of medical care delivery is an informed one. (4) Freedom of physicians to choose whom they will serve, to establish their fees at a level which they believe fairly reflect the value of their services, to participate or not participate in a particular insurance plan or method of payment, and to accept or decline a third party allowance as payment in full for a service. (5) Inclusion in all methods of medical care payment of mechanisms to foster increased cost awareness by both providers and recipients of service, which could include patient cost sharing in an amount which does not preclude access to needed care, deferral by physicians of a specified portion of fee income, and voluntary professionally directed peer review. (6) The use of tax incentives to encourage provision of specified adequate benefits, including catastrophic expense protection, in health benefit plans. (7) The expansion of adequate health insurance coverage to the presently uninsured, through formation of insurance risk pools in each state, sliding-scale vouchers to help those with marginal incomes purchase pool coverage, development of state funds for reimbursing providers of uncompensated care, and reform of the Medicaid program to provide uniform adequate benefits to all persons with incomes below the poverty level. (8) Replacing the present Medicare program with a system developed by the AMA of pre-funded vouchers to older persons to purchase health insurance with comprehensive benefits, including catastrophic coverage. (9) Development of improved methods of financing long-term care expense through a combination of private and public resources, including encouragement of privately pre-funded long-term care financing to the extent that personal income permits, assurance of access to needed services when personal resources are inadequate to finance needed care, and promotion of family caregiving. (BOT Rep. U, I-88; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: Sub. Res. 110, A-94; Reaffirmed: CMS Rep. 7, I-97; Reaffirmed by CMS Rep. 9, A-98; Reaffirmed: CMS Rep. 4, A-99; Reaffirmation I-07; Modified: CMS Rep. 8, A-08; Reaffirmed in lieu of Res. 813, I-08)

**H-390.961 Opposition to Mandatory Acceptance of Medicare**

The AMA (1) continues to actively oppose, through appropriate political and legal means, any and all actions by any government body or legislative body, which would require mandatory acceptance of Medicare assignment; and (2) encourages all concerned physicians to join with the AMA in the active opposition to such oppressive action. (Res. 114, I-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CMS Rep. 9, A-07)

**H-275.963 Mandatory Medicare Assignment or Determination of Fee Levels**

Our AMA supports federal legislation that would prohibit states from enacting legislation to require that acceptance of Medicare assignment or the Medicare allowance of reimbursement be a condition of medical licensure, or used in determinations of unprofessional conduct, or made effectively mandatory in any other fashion. (Sub Res. 75, A-89; Reaffirmed: Sunset Report, A-00)
WHEREAS, Our American Medical Association is working actively to represent the physicians and patients throughout our nation in the debate on health system reform; and

WHEREAS, The primary goals of this debate are to improve health care by extending affordable, essential health insurance to all Americans, improving patient access to physicians and related health care resources, and moderating the costs of care through prevention and early detection; and

WHEREAS, A hostile medical litigation climate, left unchecked, could negate many of the quality improvements and savings promised by comprehensive health system reform; and

WHEREAS, The AMA’s Prescription for Health System Reform cites medical liability reforms as a key cost-saving policy component that will reduce “defensive” medicine; and

WHEREAS, Medical liability reform will also encourage physicians to continue and return to practice high-risk specialties, providing greater access to needed specialists; and

WHEREAS, Several options exist for effective medical liability reforms, including potential transition to a Veterans’ Administration-style system of dispute resolution; adoption of a health courts model for hearing medical malpractice cases; a host of traditional, well-proven state tort reforms such as non-economic damages caps, certificates of merit, etc; along with other policy ideas; and

WHEREAS, The Obama Administration has publicly indicated willingness to consider medical litigation reform as part of the larger challenge of improving the nation’s health system; therefore be it

RESOLVED, That our American Medical Association press vigorously and creatively for inclusion of effective medical litigation reforms as part of the comprehensive federal health system/insurance reform debate now underway in Washington, DC (Directive to Take Action); and be it further

RESOLVED, That our AMA consider and, as necessary, negotiate with federal policymakers on a wide range of litigation reform policy options to gain inclusion of a remedy in the health system reform package. These options might include traditional tort reforms, recovery limitations similar to those of the Veterans Administration (VA) system, demonstration/pilot programs on alternate dispute resolution systems such as the VA model and health courts, and/or other effective options to preserve patient access to care. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $12,000.

Received: 05/05/09
H-435.978 Federal Medical Liability Reform
Our AMA: (1) supports federal legislative initiatives implementing the following medical liability reforms: (a) limitation of $250,000 or lower on recovery of non-economic damages; (b) the mandatory offset of collateral sources of plaintiff compensation; (c) decreasing sliding scale regulation of attorney contingency fees; and (d) periodic payment for future awards of damages; (2) reaffirms its support for the additional reforms identified in Report L (A-89) as appropriate for a federal reform vehicle. These are: (a) a certificate of merit requirement as a prelude to filing medical liability cases; and (b) basic medical expert witness criteria; (3) supports for any federal initiative incorporating provisions of this type would be expressly conditional. Under no circumstances would support for federal preemptive legislation be extended or maintained if it would undermine effective tort reform provisions already in place in the states or the ability of the states in the future to enact tort reform tailored to local needs. Federal preemptive legislation that endangers state-based reform will be actively opposed. Federal initiatives incorporating extended or ill-advised regulation of the practice of medicine also will not be supported. Effective medical liability reform, based on the California Medical Injury Compensation Reform Act (MICRA) model, is integral to health system reform. (BOT Rep. S, I-89; BOT Rep. I-93-53; Reaffirmed: BOT Rep. 8, I-98; Reaffirmation A-00; Reaffirmation I-03; Reaffirmed: Sub. Res. 910, I-03)

(1) It is the policy of the AMA that effective medical liability reform, based on the California Medical Injury Compensation Reform Act (MICRA) model, is integral to health system reform. The AMA’s MICRA-based federal tort reform provisions include: (a) a $250,000 ceiling on non-economic damages, (b) the offset of collateral sources of plaintiff compensation, (c) decreasing incremental or sliding scale attorney contingency fees, (d) periodic payment of future awards of damages, and (e) a limitation on the period for suspending the application of state statutes of limitations for minors to no more than six years after birth. (2) Our AMA also supports federal reform to achieve: (a) a certificate of merit requirement as a prerequisite to filing medical liability cases; (b) statutory criteria that outline expert witness qualifications; and (c) demonstration projects to implement potentially effective alternative dispute resolution (ADR) mechanisms. (3) Our AMA supports medical product liability reform, applicable to the producers of pharmaceuticals and medical devices, as an important state and federal legislative reform objective. (4) Any health system reform proposal that fails to include MICRA type reform, or an alternative model proven to be as effective in a state, will not be successful in containing costs, providing access to health care services, and promoting the quality and safety of health care services. Under no circumstances would support for federal legislation be extended or maintained if it would undermine effective tort reform provisions already in place in the states. Federal preemptive legislation that endangers effective state-based reform will be actively opposed. (BOT Rep. 53, I-93; Reaffirmation A-00; Reaffirmation I-03; Reaffirmed: Sub. Res. 910, I-03; Reaffirmation A-04)

Our AMA: (1) reaffirms its support for investigating promising Alternative Dispute Resolution (ADR) mechanisms, in the context of demonstration projects designed to evaluate whether they resolve medical liability claims fairly and in a more timely and cost-effective manner. (2) The AMA strongly recommends that if cost containment goals are to be achieved, ADR proposals designed to provide greater access to legal process must incorporate effective mechanisms to: (a) identify non-meritorious claims and dispose of them; (b) decrease the proportion of cases being litigated; (c) increase the portion of any settlement payment received by the patient; and (d) identify appropriate guidelines for the payment of damages; and (3) continues to monitor and disseminate information to state and component medical societies about state and federal initiatives that address the issue of protections from liability risks for physicians who provide volunteer activities and care of the indigent, as well as the effectiveness of those initiatives. Effective medical liability reform, based on the California Medical Injury Compensation Reform Act (MICRA) model, is integral to health system reform. (BOT Rep. M, I-92; BOT Rep. I-93-53; Modified: Sub. Res. 205 and Reaffirmation A-00; Reaffirmation A-04; Reaffirmation A-06)
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. (BOT Rep. 15, A-07)
Statement

of the

American Medical Association

to the

Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives

Re: “Innovative Solutions to Medical Liability”

July 13, 2006
The American Medical Association (AMA) appreciates the opportunity to submit our statement for the record on alternatives to medical liability reform. The AMA strongly agrees with the premise of the hearing that innovative solutions to the current medical liability system are desperately needed and applauds the Committee’s continued interest in exploring solutions. The AMA remains committed to proven, effective reforms based on California’s successful model, MICRA, (the “Medical Injury Compensation Reform Act of 1975”) that includes a $250,000 cap on non-economic damages. We appreciate the House of Representatives’ continuing commitment to these reforms while investigating the efficacy of other alternatives.

Various states have passed effective medical liability reforms that, in addition to including a cap on non-economic damages and other MICRA-based reforms, also contain innovative approaches. While the AMA strongly favors a $250,000 limitation on non-economic damages as the optimal solution to the medical liability issue, we believe it is worth exploring state or local-based demonstration programs to collect information on whether other approaches may also have the potential to improve the current litigation climate.

**THE CURRENT SYSTEM FAILS BOTH PATIENTS AND HEALTH CARE PROFESSIONALS**

The medical liability litigation system needs reform. It is neither fair nor cost effective in compensating patients. It has become an increasingly irrational system driven by open-ended non-economic damage awards. It is also an extremely inefficient mechanism for compensating patients harmed by negligence where court costs and attorney fees often consume a substantial amount of any compensation awarded to patients.

Patient access to health care services is also being affected. Escalating jury awards and settlements, and the high cost of defending against lawsuits, even those without merit, are
driving medical liability insurance premiums to unprecedented levels.\textsuperscript{1} As insurance becomes unaffordable or unavailable, physicians are being forced to relocate, close their practices, or drop vital services—all of which seriously impede patient access to care. The situation may also have long-term consequences. Almost half of America’s medical students in their third or fourth year of medical school indicate the liability climate is a factor in their choice of specialty, threatening America’s future access to high-risk medical services such as surgical and obstetrical care.\textsuperscript{2} Also, the cost of the liability system is borne by everyone and adds billions of dollars to the cost of health care each year.\textsuperscript{3} These resources would be better applied to caring for injured patients.

**PROVEN SOLUTIONS**

**California**

The AMA strongly supports federal legislation based on California’s MICRA, which has been proven to stabilize the medical liability insurance market in California—increasing patient access to care and saving more than $1 billion per year in liability premiums—and has reduced the time it takes to settle a claim by 33 percent. MICRA is also saving California from the current medical liability insurance problems experienced in many states that lack similar reforms. In fact, the gap between medical liability insurance rates in California and those in the largest states that do not limit non-economic awards is substantial and growing. Data from the National Association of Insurance Commissioners (NAIC) shows that total liability premiums in California increased only 309 percent between 1976 and 2004, compared to 1,011 percent for the rest of the U.S.

**Texas**

Texas also provides a compelling example of how successful tort reforms improve patient access to care and reduce escalations in medical liability premiums. From 1995 to 2002,

\textsuperscript{1} A compendium of data supporting medical liability reform and debunking arguments against reform is available on the AMA Web site at http://www.ama-assn.org/go/mlrnw.
\textsuperscript{2} AMA Division of Market Research and Analysis, November, 2003
\textsuperscript{3} According to estimates by the U.S. Department of Health and Human Services (HHS), medical liability adds $70 billion to $126 billion to the cost of health care each year. These are the costs attributed to defensive medicine, which could be significantly reduced by effective medical liability reforms. These costs mean higher health insurance premiums and higher medical costs for all Americans as well as higher taxes. Taxpayers bear a substantial burden, given that one-third of the total health care spending in our country is paid by the federal government through the Medicare and Medicaid Programs. (Office of the Assistant Sec’y for Planning and Evaluation, U.S. Dept. of Health and Human Servs., Confronting the New Health Care Crisis, Improving Health Care Quality & lowering Costs by Fixing Our Med. Liability Sys. 8 (2002), available at http://aspe.hhs.gov/daltcp/reports/litrefm.pdf). Also, an April 2002 Price Waterhouse Coopers study, “The Factors Fueling Rising Health Care Costs,” concluded that litigation accounted for seven percent of the increase in rising costs of health insurance premiums. The median jury award in medical liability cases nearly tripled from 1997 to 2004, increasing from $157,000 to $439,400. Overall, 75 percent of medical liability claims in 2004 were closed without payment to the plaintiff. Of the seven percent of claims that resulted in a jury verdict, the defendant won 83 percent of the time. However, physicians who are found not liable for negligence still have large fees to pay for their defense. Average defense costs were $93,559 per claim in cases where the defendant prevailed at trial. In cases where the claim was dropped or dismissed, the cost to defendants averaged $18,774.
claims against Texas doctors occurred at nearly twice the national average.\textsuperscript{4} From 1989 to 1999, the average non-economic damage award quadrupled from $318,666 to $1,379,203.\textsuperscript{5} Thirteen physician liability insurance companies began withdrawing from this line of insurance or left the state entirely because of unprecedented losses.

In 2003, the Texas legislature enacted comprehensive medical liability insurance reform, which included a “stacked cap” on non-economic damages. Under the Texas law, in addition to recovering unlimited economic damages, an injured patient may recover up to $750,000 in non-economic damages in a health care lawsuit against multiple defendants.\textsuperscript{6} The Texas reforms created three separate caps, one for health care providers (including physicians) and two for health care institutions (including hospitals). One cap provides a $250,000 limitation on non-economic damages in lawsuits against all health care providers named as defendants in a lawsuit. For institutions, the Texas law also includes a cap of $250,000 on non-economic damages against any one institution, while also permitting a third cap of $250,000 in those instances where more than one institution is found negligent.

As a result, Texas medical liability insurance rates have seen impressive decreases. The average rate cut for Texas physicians was 13.5 percent in 2005.\textsuperscript{7} Texas physicians will save an estimated $49 million on their 2006 premiums.\textsuperscript{8} The number of medical liability insurers in Texas has also increased by 23.\textsuperscript{9} Texas patients benefited from these reforms, too. Texas experienced an increase of physicians, particularly specialists, and there has been an influx of physicians to medically underserved communities.\textsuperscript{10}

STATE REFORMS AND OTHER PROPOSALS

The AMA remains committed to finding a solution to the broken medical liability system. The AMA is steadfast in its support of time-tested reforms, such as the non-economic damage limitations enacted in California and other states since 1975. In addition to MICRA-based reforms, various states have enacted alternative reforms that have demonstrated potential to

\textsuperscript{4} 2003 Texas Medical Association Closed Claim Liability Study
\textsuperscript{5} Id.
\textsuperscript{6} On September 13, 2003, Texas voters passed Proposition 12. This ballot initiative amended the state constitution to specifically allow the legislature to enact laws that place limits on non-economic damages in health care liability cases.
\textsuperscript{7} Texas Department of Insurance
\textsuperscript{8} The Doctor’s Company announced an 18 percent rate cut on March 23, 2005. Since the passage of state reforms, the carrier decreased its rates by 24.5 percent. Medical Protective announced a six percent rate cut, a third reduction in the past twelve months. American Physicians Insurance Exchange implemented a 13 percent rate cut in December, 2005.
\textsuperscript{9} Id.
\textsuperscript{10} Texas had experienced a net loss of 9 orthopaedic surgeons from 2000 to 2003. Since then, the state has experienced a net gain of 93 orthopaedic surgeons. Texas had lost 14 ob-gyns from 2001 to 2003 and subsequently experienced a net gain of 91. From 1991 to 2002, Texas experienced a net loss of one neurosurgeon. Since the enactment of the 2003 reforms, the state has experienced a net gain of 24. The number of physicians serving the state’s most populous county, Harris County, has grown by 762. Among the additions to the Houston medical community are 65 emergency physicians, 8 orthopaedic surgeons, 16 neurologists, 8 neonatalogists, 6 pediatric cardiologists, 22 kidney specialists, and 9 rheumatologists. (Texas Medical Board, May 2005 reports)
help improve the medical liability system. Accordingly, the AMA favors state-based demonstration programs on these alternative reform models as a method to gather additional information regarding their efficacy.

Numerous alternatives are receiving increasing scrutiny within academic circles and by policymakers. Several may show promise after further analysis. However, it is imperative that these models be thoughtfully developed after considerable input from stakeholders, including physicians, with extensive practical experience and specialized knowledge on the medical liability system before their merits are assessed.

**ALTERNATIVE DISPUTE RESOLUTION MODELS**

Under an early disclosure and compensation model, providers would be required to notify a patient of an adverse event within a limited period of time. Notification would not constitute an admission of liability. Providers offering to compensate for injuries in good faith would be provided immunity from liability. Payments for non-economic damages would be paid based on a defined payment schedule developed by the State in consultation with relevant experts and with the Secretary of Health and Human Services (HHS).

Another alternative is the administrative determination of compensation model. A state’s administrative entity would be charged with resolving claims for scheduled injuries, setting a schedule for injuries, and establishing compensation based on the patient’s net economic loss, subject to periodic payment and offset by collateral payments from sources such as insurance. The model would have to provide for an appeals process and establish procedures to coordinate settlement payments with other sources. Non-economic damages would also be subject to a schedule and reasonable attorneys fees would be paid.

A third model, health courts, would provide a forum where medical liability actions could be heard by judges specially trained in medical liability matters and who hear only medical liability cases. In the state-based system, medical liability claims would first be filed with an administrative board, in a model commonly utilized in workers compensation cases. Claims that cannot be easily resolved at the administrative level would then be heard by the health court. The distinctions between health courts and regular civil courts are noteworthy. Expert witnesses would be hired by the court, not by the parties to the case. Most proposals would also eliminate the jury and rely instead on the expertise of the specially trained judge. The judge would make binding rulings on causation, compensation, standards of care, and related issues. Compensation would be determined by a fixed schedule of benefits (the functional equivalent of a cap) developed by medical experts that would be annually updated and refined.

Potential advantages of these models include the reduction in the number of meritless claims filed and the reduction of costs associated with litigating claims. In addition, the merits of liability claims would be determined on a more consistent basis, tempering the unpredictable nature of our current medical liability system. However, research on these models must be rigorous and experience-based to avoid unintended consequences such as lowering the burden of proof or the evidentiary requirements claimants must meet. Likewise, it will be critical to
ensure that existing peer review and quality improvement protections are not inadvertently jeopardized.

ADDITIONAL REFORMS

In addition to demonstrations that would create new systems to resolve disputes, there are other reforms that could be studied to measure their efficacy to improve the medical liability system. Below are a few examples.

Expert Witness Qualifications

Several states have amended the statutory qualifications for those who may serve as medical expert witnesses at trial. Jury findings of liability frequently hinge on testimony that medical expert witnesses provide. The complexity of the issues at stake and the particular specialized knowledge necessary to opine on appropriate treatment also make it difficult for the average lay juror to determine the accuracy and reliability of the medical expert witness testimony they receive. Some states (e.g., Georgia, Texas, and Illinois) have created additional standards that medical expert witnesses must meet in order to ensure the testimony juries receive is presented by an individual with particularized expertise in the matter in question. AMA policy supports reforms that would require a medical expert witness to meet the following criteria: licensure as a physician; training or experience in the same or similar field as the defendant physician; certification by a board recognized by the American Board of Medical Specialties, the American Osteopathic Association, or by a board with equivalent standards; and engagement in active medical practice in the same or similar specialty as the defendant physician within five years of the occurrence giving rise to the claim, or substantial time teaching at an accredited medical school or in university-based research related to the medical care at issue.

“I’m Sorry” Legislation

The current litigation system discourages health care professionals from expressing an apology or remorse over an unanticipated outcome because of the fear it will be used as evidence in a lawsuit. Patients cite anger over a professional’s lack of remorse or empathy as a reason for filing suit. The purpose of “I’m sorry” laws is to encourage open communication between patients and physicians without fear of reprisal. Generally, these laws protect health care professionals who express sympathy to a patient for an unanticipated outcome from having the statement used against them in litigation. It would be imperative to ensure that such a provision would be carefully crafted with due consideration for the complexity of the rules of evidence to ensure its protections are sufficiently expansive.

Sanctions for Filing Frivolous Suits

Rule 11 of the Federal Rules of Civil Procedure is designed to deter frivolous litigation. In its current form, however, Rule 11 is an inadequate deterrent to attorneys who file cases without a good faith basis or otherwise rely on the nuisance factor of threatened litigation to force settlements of dubious claims. There have been numerous proposals that would raise the
standards under Rule 11 and mandate penalties for attorneys who engage in abusive litigation practices. For example, the AMA supports H.R. 420, which passed the House of Representatives in October 2005. This bill would mandate sanctions against attorneys who file frivolous lawsuits, precludes the withdrawal of pleadings by attorneys to avoid sanctions under Rule 11, and requires courts to award parties prevailing on Rule 11 motions reasonable expenses and legal fees. The bill also would require a district court to suspend for one year an attorney violating Rule 11 more than three times. It would further create the rebuttable presumption that an attempt to litigate, in any forum, a claim or defense involving the same plaintiff and defendant that has been litigated and lost on three consecutive prior occasions violates Rule 11.

CONCLUSION

The AMA applauds the Committee’s continued interest in exploring innovative solutions to America’s broken medical liability system. While the AMA remains committed to MICRA-style reforms that include a $250,000 limitation on non-economic damages, we support the Committee’s examination of other approaches that hold the potential for improving the current dispute resolution climate. The AMA appreciates the leadership of the Committee and looks forward to working with you on enacting effective and proven reforms to fix the broken medical liability system.
The case for medical liability reform

The American Medical Association (AMA) is an outspoken advocate for medical liability reform as a means of protecting patients’ access to care and slowing the rising cost of health care. In many states, medical liability premiums remain at or near all-time highs. Where states have been unable to enact effective reforms, a federal solution is needed. The AMA is committed to working on this issue until the medical liability crisis is solved at both the federal and state levels.

Liability costs affect everyone.

Through its impact on defensive medicine, liability pressure increases health system costs by between $84 and $151 billion per year.

More than 60 percent of liability claims against physicians are dropped, withdrawn or dismissed without payment. However, even these cases have a price, costing an average of more than $18,000 to defend in 2007. Physicians are found not negligent in over 90 percent of cases that go to trial—yet more than $100,000 per case is spent on defending those claims.

Medical liability premiums in many states, including Pennsylvania, New Jersey and Connecticut, are at levels more than double those of just a few years ago.

Access to care is affected by liability concerns.

One in 12 obstetricians who have reported changes in their practice as a result of the risk or fear of professional liability claims have stopped delivering babies.

In Massachusetts, 48 percent of physicians have altered or limited their services because of liability concerns.

Numerous independent research articles show that over the long term, patients have greater access to physicians in areas with reforms, such as caps on noneconomic damages, than in areas without.

(Continued on next page)
Reforms work.

Medical liability premiums increased more than 1,029 percent throughout the country from 1976 through 2007—except in California. There, premiums grew by less than one third of that amount during the same span, thanks to reasonable limits on noneconomic damages that have been in place for more than three decades.

Since Texas enacted reforms in 2003, the state’s physicians have seen their liability rates cut by an average of 27 percent. Texas also has experienced a statewide increase of physicians, particularly specialists.

Recent changes in states that have enacted significant reforms, and the long-term trends in California, are supported by a growing body of economic research that links tort reforms, such as caps on noneconomic damages, to slower growth in indemnity payments and premiums.

What the AMA is doing.

The AMA is leading an aggressive campaign to solve the medical liability crisis and protect patients’ access to care by

- Working in concert with state medical associations to enact and defend strong medical liability reform laws.
- Continuing to advocate for federal reforms based on proven state solutions such as California’s, which limit noneconomic damages in medical liability cases to $250,000.

Learn more about the AMA’s solutions to reform the nation’s medical liability system and protect patients’ access to health care.

www.ama-assn.org/go/liability
Health Courts

Background

Since the first medical liability crisis in the 1970s, policy makers have been seeking solutions to this recurring problem. California’s Medical Injury Compensation Reform Act of 1975 (MICRA) halted California’s crisis after its enactment, and it has kept California’s medical liability premiums in check while they have increased sharply in other parts of the country. MICRA’s $250,000 cap on non-economic damages has been the cornerstone of organized medicine’s attempts to ensure a litigation system that does not hinder patient access to care. To date, close to 30 states have enacted caps with varying limits and exceptions. Limiting non-economic damages has remained politically elusive in the other states and at the federal level as well.

While MICRA-based reforms continue to be the best option for fixing the medical liability crisis, other reforms should be explored and tested as well. AMA policy indicates that health courts are a promising reform proposal that merits further investigation (Board of Trustees Report 32 (A-03) and D-435.987). The concept is receiving more attention from policy makers and the media, and this may lead to the implementation of a health court pilot project at the state or local level.

If properly constructed, health courts should have several positive effects. They should lead to a fairer and more expedited resolution of medical liability claims. Verdicts should be based more on whether or not there was a deviation from the standard of care and less on emotional appeals to juries. A higher percentage of victims of medical negligence should receive compensation, and a higher percentage of frivolous claims should be dismissed. Health courts provide an opportunity to create a system that resolves medical liability claims in a more balanced and equitable fashion than the current system. On the other hand, the costs of establishing health courts are unknown and could potentially be borne by physicians. Therefore, 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.

AMA Policy

D-435.987 Medical Courts
Our AMA will draft an alternative judicial model for addressing medical liability claims based on special medical courts that are composed of judges trained in medical standards that could render more accurate decisions regarding whether medical malpractice has
actually occurred and, if so, render a judgment as to the amount of monetary damages to be awarded.

**Principles for Health Courts**

The AMA supports the following six key principles. 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 for each category.
- 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 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 discipline or school of practice 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 discipline or school of practice 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.

Adopted by AMA House of Delegates June 2007
June 6, 2007

The Honorable Phil Gingrey, MD  
U.S. House of Representatives  
119 Cannon House Office Bldg.  
Washington, DC  20515

Dear Dr. Gingrey:

The undersigned national organizations representing physicians are writing to express our strong support for the Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act of 2007. We applaud your continued efforts to fix our broken medical liability system.

Unfortunately, the current system fails both patients and health care professionals. Escalating jury awards and settlements have resulted in unsustainable increases in medical liability insurance premiums, eroding access to health care services, and increasing health care costs. Every dollar that goes toward medical liability costs and defensive medicine is a dollar that does not go to patients who need care, nor toward investment in patient safety improvement or much-needed modern health information technology systems.

We believe that the proven reforms contained in this bill would help resolve the medical liability crisis, while ensuring that patients who have been injured receive just compensation. The HEALTH Act provides the right balance of reforms -- maintaining access to courts and unlimited compensation for economic damages, while limiting non-economic damages to a quarter of a million dollars. The HEALTH Act also promotes speedier resolutions to disputes, ensures fair allocation of responsibility, prevents double recovery of awards, and helps to maximize patient recovery of damage awards.

Similar reforms have been in place in California for more than 30 years, standing the test of time in keeping medical liability insurance premiums stable. Texas law also provides a compelling example of how successful tort reforms can improve patient access to care and reduce escalations in medical liability premiums. All major physician liability carriers in Texas have cut their rates since the passage of comprehensive liability reforms in 2003, most by double-digits. Two-thirds of Texas doctors have seen their rates slashed a quarter or more. Patients have also benefited from these reforms with an influx of specialists and physicians practicing in medically underserved communities in Texas. The state has added more than 4,500 physicians since passage of the 2003 reforms and is licensing an average of 400 more doctors per year than in the pre-reform years. The success of reforms in California and Texas could be achieved nation-wide with passage of the HEALTH Act.

We thank you for your continued leadership in striving to enact meaningful professional liability reform legislation that will make rational changes to the current system and preserve patients’ access to medical care.

Sincerely,

American Academy of Dermatology Association  
American Academy of Facial Plastic and Reconstructive Surgery  
American Academy of Family Physicians  
American Academy of Hospice and Palliative Medicine  
American Academy of Neurology  
American Academy of Ophthalmology
Medical Liability Reform

The AMA is committed to enacting and defending proven medical liability reforms at the federal and state levels. The current medical liability litigation system is neither fair nor cost-effective in compensating patients. It has become an increasingly irrational system driven by open-ended non-economic damage awards. It is also an extremely inefficient mechanism for compensating patients harmed by negligence where court costs and attorney fees often consume a substantial amount of any compensation awarded to patients. Various states have passed effective medical liability reforms that, in addition to including a cap on non-economic damages, also contain innovative approaches. While the AMA strongly favors a $250,000 limitation on non-economic damages as the optimal solution, we support the exploration of state or local-based demonstration programs to collect information on the efficacy of alternative reforms that have the potential to improve the current litigation climate.

Proven Reforms

The AMA supports effective medical liability reform, based on California’s Medical Injury Compensation Reform Act (MICRA) model that includes a $250,000 cap on non-economic damages. A large and growing body of research shows that caps on non-economic damages lead to improved patient access to care, lower medical liability premiums, and lower health care costs.

California’s MICRA and Texas’ recent liability reform laws illustrate that reforms can stabilize the liability climate by allowing patients to recover unlimited economic damages while capping pain and suffering damages at reasonable and predictable levels. Medical liability premiums increased more than 1,029 percent throughout the country from 1976 through 2007—except in California. There, premiums grew by less than one third of that amount during the same span, thanks to reasonable limits on non-economic damages that have been in place for more than three decades. Since Texas enacted reforms in 2003, the state’s physicians have seen their liability insurance premiums cut by an average of 27 percent. Texas also has experienced a statewide increase in the number of physicians, particularly specialists. Recent changes in states that have enacted significant reforms, and the long-term trends in California, are supported by a growing body of economic research that links tort reforms, such as caps on non-economic damages, to slower growth in indemnity payments and premiums.

Alternative Reforms

While the AMA continues to advocate for proven reforms like MICRA, we are also committed to finding innovative solutions to the broken medical liability system such as offering of grants to states to pursue alternatives to current tort litigation. These alternatives include:

- **Health Courts.** Health courts would provide a forum where medical liability actions could be heard by judges specially trained in medical liability matters and who hear only medical liability cases. The AMA developed and adopted health court principles in 2007
to assist state and local governments, insurers, hospitals and other entities interested in exploring this option for medical liability reform.

- **Early Disclosure and Compensation Programs.** Under an early disclosure and compensation model, providers would be required to notify a patient of an adverse event within a limited period of time. Notification does not constitute an admission of liability. Providers offering to compensate for injuries in good faith would be provided immunity from liability. Payments for non-economic damages would be based on a defined payment schedule developed by the state in consultation with relevant experts and with the Secretary of Health and Human Services (HHS).

- **Administrative Determination of Compensation Model.** A state’s administrative entity would be charged with setting a compensation schedule for injuries, resolving claims for injuries, and establishing compensation based on the patient’s net economic loss, subject to periodic payment and offset by collateral payments from sources such as insurance.

- **Expert Witness Qualifications.** Several states have amended the statutory qualifications for those who may serve as medical expert witnesses at trial. Some states (e.g., Georgia, Texas, and Illinois) have created additional standards that medical expert witnesses must meet in order to ensure the testimony juries receive is presented by an individual with particularized expertise in the matter in question.

The AMA is committed to finding a solution to the challenges of the broken medical liability system, including federal reforms based on proven state solutions like California and Texas as well as alternative liability reforms like health courts. The AMA also supports protecting patients’ access to care by working in concert with state medical associations to enact and defend strong medical liability reform laws.
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 210
(A-09)

Introduced by: Iowa Delegation

Subject: Geographic Devaluation of Medicare Payments for PQRI

Referred to: Reference Committee B
(Monica C. Wehby, MD, Chair)

Whereas, All physicians should be paid equally for equal work and equal expenses; and

Whereas, Geographic Practice Cost Index (GPCI) adjustments result in rural physicians being paid less for their work, less for their E-prescribing, less for their quality by the Physician Quality Reporting Initiative (PQRI), and less for their practice expenses despite the fact that no practice expense survey has ever shown any differences; and

Whereas, The Centers for Medicare & Medicaid Services is paying 2% of the GPCI-adjusted total Medicare payments for the PQRI bonus payments; and

Whereas, The work effort for performing and reporting quality measures is the same in all regions; and

Whereas, There are no differences in practice expenses to submit PQRI data; and

Whereas, The geographic adjustment could be eliminated by applying the highest calculated Geographic Adjustment Factor (GAF) to a payment locality’s Physician Quality Reporting Initiative (PQRI) payment (e.g., Iowa’s GAF would increase from 0.921 to 1.288, thereby increasing Iowa’s payment for PQRI by 39.8%). This method would not decrease payments to any geographic payment locality’s PQRI payments; therefore be it

RESOLVED, That our American Medical Association reaffirm the concept of equal pay for equal work (Reaffirm HOD Policy D-400.989); and be it further

RESOLVED, That the American Medical Association affirm the concept of equal pay for equal quality (New HOD Policy); and be it further

RESOLVED, That our AMA lobby Congress and the Centers for Medicare & Medicaid Services to prohibit geographic adjustments from being applied to Physician Quality Reporting Initiative payments. (Reaffirm HOD Policy D-400.985).

Fiscal Note: Implement accordingly at estimated staff cost of $4,580.

Received: 05/06/09
Whereas, Medicare payments for E-prescribing are 2% of physicians’ Medicare total allowable charges; and

Whereas, Geographic Practice Cost Index (GPCI) adjustments to physician Medicare fees make the differential payments to physicians as high as 30-41%; and

Whereas, This GPCI adjustment of E-prescribing payments ignores the fact that the cost of E-prescribing equipment and supplies are the same geographically; and

Whereas, Vendors do not offer geographic discounts for E-prescribing or other health information technology equipment; and

Whereas, The physician work effort for E-prescribing is the same in all geographic regions; and

Whereas, All physicians should be paid equally for equal work and equal expenses; and

Whereas, GPCI adjustments result in rural physicians being paid less for their work, less for their E-prescribing, less for their quality by the Physician Quality Reporting Initiative, and less for their practice expenses despite the fact that no practice expense survey has ever shown any differences; and

Whereas, The geographic adjustment could be eliminated by applying the highest calculated Geographic Adjustment Factor (GAF) to a payment locality’s E-prescribing payment (e.g., Iowa’s GAF would increase from 0.921 to 1.288, thereby increasing Iowa’s payment for E-prescribing by 39.8%). This method would not decrease payments to any geographic payment locality’s e-prescribing payments; therefore be it

RESOLVED, That our American Medical Association lobby Congress and the Centers for Medicare & Medicaid Services to prohibit geographic adjustments for E-prescribing payments. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $4,580.

Received: 05/06/09
Whereas, Geographic Practice Cost Index (GPCI) adjustments for Medicare physician professional fees result in differentials of 30-40% between areas of the country; and

Whereas, GPCI adjustments for Medicare technical fees for imaging studies show even larger differences, as much as 43% less in some rural areas (i.e. 73% higher in some urban areas); and

Whereas, Many rural areas of the country are at risk of losing imaging services because they are so poorly reimbursed by Medicare; and

Whereas, Practice expense GPCI adjustments for imaging technical fees are based on limited data from indirect sources, such as apartment rental rates for the office rent category of the GPCI and only four occupations for the wage category; and

Whereas, Other credible data sources have not been used, such as practice expense surveys from the Medical Group Management Association and Medical Economics; and

Whereas, The Medical Economics 2007 survey shows rural physician practice expenses are $250,000 per year compared to urban ($210,000) and inner city ($180,000) practice expenses; and

Whereas, The Centers for Medicare & Medicaid Services has never used a survey to measure actual physician expenses for GPCI determination but instead uses proxies which have never been shown to be accurate or reliable; and

Whereas, The GPCI adjustments to imaging technical fees use a constant percentage weighting of rent (28%), equipment and supplies (29%), and wages (43%) that is far from accurate, especially considering that the cost of imaging equipment and supplies can be over 78% of the total cost of running imaging procedures; and

Whereas, Vendors do not offer discounts on purchases of imaging equipment and supplies for rural areas (geographic location); and

Whereas, With lower volumes of imaging procedures, practice costs for imaging may actually be higher in rural areas; therefore be it
RESOLVED, That our American Medical Association advocate Congress to immediately eliminate the inaccurate Geographic Practice Cost Index (GPCI) adjustment for the technical component of imaging studies (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate Congress to bring about a 1.0 floor for all Geographic Practice Cost Index (GPCI) practice expense adjustments. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $9,294.

Received: 05/06/09
D-400.985 Geographic Practice Cost Index
Our AMA will: (1) use the AMA Physician Practice Information Survey to determine actual differences in rural vs. urban practice expenses; (2) seek Congressional authorization of a detailed study of the way rents are reflected in the Geographic Practice Cost Index (GPCI); and (3) advocate that payments under physician quality improvement initiatives not be subject to existing geographic variation adjustments (i.e., GPCIs). (Sub. Res. 810, I-08)

H-400.972 Physician Payment Reform
It is the policy of the AMA to (1) take all necessary legal, legislative, and other action to redress the inequities in the implementation of the RBRVS, including, but not limited to . . . . (c) defects in the Geographic Practice Cost Indices and area designations; (d) inappropriate Resource-Based Relative Value Units; (f) the need for restoration of the RBRVS conversion factor to levels consistent with the statutory requirement for budget neutrality; . . . . (8) support further study of refinements in the practice cost component of the RBRVS to ensure better reflection of both absolute and relative costs associated with individual services, physician practices, and medical specialties, considering such issues as data adequacy, equity, and the degree of disruption likely to be associated with any policy change; . . . . (10) support the concepts of HR 4393 (the Medicare Geographic Data Accuracy Act of 1992), S 2680 (the Medicare Geographic Data Accuracy Act of 1992), and S 2683 (Medicare Geographic Data Accuracy Act) for improving the accuracy of the Medicare geographic practice costs indices (GPCIs) and work with CMS and the Congress to assure that GPCIs are updated in as timely a manner as feasible and reflect actual physician costs, including gross receipt taxes; (11) request that CMS refine relative values for particular services on the basis of valid and reliable data and that CMS rely upon the work of the AMA/Specialty Society RVS Updating Committee (RUC) for assignment of relative work values to new or revised CPT codes and any other tasks for which the RUC can provide credible recommendations; (12) pursue aggressively recognition and CMS adoption for Medicare payment schedule conversion factor updates of an index providing the best assurance of increases in the monetary conversion factor reflective of changes in physician practice costs, and to this end, to consider seriously the development of a "shadow" Medicare Economic Index; (13) continue to implement and refine the Payment Reform Education Project to provide member physicians with accurate and timely information on developments in Medicare physician payment reform; and (14) take steps to assure all relative value units contained in the Medicare Fee Schedule are adjusted as needed to comply with ever-increasing federal and state regulatory requirements. (Sub. Res. 109, A-92; Reaffirmed: I-92; Reaffirmed by CMS Rep. 8, A-95 and Sub. Res. 124, A-95; Reaffirmation A-99 and Reaffirmed: Res. 127, A-99; Reaffirmation A-02; Reaffirmation A-06; Reaffirmation I-07; Reaffirmed: BOT Rep. 14, A-08)

D-400.989 Equal Pay for Equal Work
Our AMA: (1) shall make its first legislative priority to fix the Medicare payment update problem because this is the most immediate means of increasing Medicare payments to physicians in rural states and will have the greatest impact; (2) shall seek enactment of legislation directing the General Accounting Office to develop and recommend to Congress policy options for reducing any unjustified geographic disparities in Medicare physician payment rates and improving physician recruitment and retention in underserved rural areas; and (3) shall advocate strongly to the current administration and Congress that additional funds must be put into the Medicare physician payment system and that continued budget neutrality is not an option. (BOT Rep. 14, A-02; Reaffirmation A-06; Reaffirmation I-07; Reaffirmation A-08; Reaffirmed: Sub. Res. 810, I-08)

H-400.988 Medicare Reimbursement, Geographical Differences
The AMA reaffirms its policy that geographic variations under a Medicare payment schedule should reflect only valid and demonstrable differences in physician practice costs, especially liability premiums, with further adjustments as needed to remedy demonstrable access problems in specific geographic areas. (Sub. Res. 82, A-89; Reaffirmed: BOT Rep. DD, I-92; Reaffirmed: CMS Rep. 10, A-03; Reaffirmation A-06; Reaffirmation I-07; Reaffirmation A-08)
H-390.945 Legal Action to Resolve Medicare Reimbursement Disparities
Our AMA believes that: (1) current geographic inequities in Medicare payments for physician services pose a serious threat to access to care for many Medicare beneficiaries; and; (2) such payment inequities must be addressed and remedied in a timely manner, without awaiting implementation of a new Medicare indemnity physician payment system. (Sub. Res. 69, I-88; Reaffirmed: Sunset Report, I-98; Reaffirmation A-06; Reaffirmed in lieu of Res. 921, I-06; Reaffirmation I-07)

H-400.952 Consolidation of Medicare Fee Schedule Areas
The AMA will continue to petition CMS to improve the accuracy of the Geographic Practice Cost Indices (GPCIs) through the use of accurate practice costs and timely data; and will petition CMS and, if necessary, the Congress to retain as distinct Medicare localities, cities where recent inclusion in state-wide localities by CMS is based on criteria that do not allow for appropriate recognition of the higher costs associated with practice in these areas. (Res. 118, I-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmed in lieu of Res. 921, I-06; Reaffirmation I-07)

H-400.990 Refinement of Medicare Physician Payment System
The AMA: (1) reaffirms its support for development and implementation of a Medicare indemnity payment schedule according to the policies established in Policy 400.991; (2) supports reasonable attempts to remedy geographic Medicare physician payment inequities that do not substantially interfere with the AMA's support for an RBRVS-based indemnity payment system; . . . . (BOT Rep. BBB, A-89; Reaffirmed: I-92; Reaffirmed and Modified: CMS Rep. 10, A-03)

D-390.989 Equal Pay for Equal Work
Our AMA will work to eliminate the unfairness inherent in the current wide geographic disparity in physician Medicare reimbursement. (BOT Rep. 14, A-02)

H-400.984 Geographic Practice Costs
Our AMA will work to ensure that the most current, valid and reliable data are collected and applied in calculating accurate geographic practice cost indices (GPCIs) and in determining geographic payment areas for use in the new Medicare physician payment system, with data collected from rural practice sites for this purpose. (Sub. Res. 25, A-90; Modified: Sunset Report, I-00)
WHEREAS, The US Food and Drug Administration (FDA) has the power to fine the pharmaceutical companies; and

WHEREAS, The FDA has played a crucial role in the $634 million in fines imposed on Purdue Pharma regarding its pain killer Oxycontin; and

WHEREAS, The FDA has imposed a fine of $4.2 million on the Red Cross for failure to comply with requirements under federal laws and FDA regulations relating to the collection of blood products; and

WHEREAS, The FDA has issued mere warning letters to Bayer AG for misleading ads on the birth control pill Yaz; therefore be it

RESOLVED, That our American Medical Association lobby the US Food and Drug Administration for stricter sanctions and monetary fines against pharmaceutical companies for flouting the guidelines regarding direct-to-consumer advertisements. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09
D-105.998 Direct to Consumer Advertising
Our AMA will request the appropriate federal agency to enforce the direct-to-consumer advertising guidelines and regulations according to AMA Policy H-105.998. (Res. 714, I-03)
Statement

of the

American Medical Association

to the

Oversight and Investigation Subcommittee
Energy and Commerce Committee
U.S. House of Representatives

RE: Direct-to-Consumer Advertising: Marketing, Education or Deception?

Presented by: Nancy H. Nielsen, MD, PhD

May 8, 2008

(202) 789-7481

25 Massachusetts Avenue, NW, Suite 600
Washington, D.C. 20001
Division of Legislative Counsel
The American Medical Association (AMA) appreciates the opportunity to provide its views regarding the role of direct-to-consumer advertising (DTCA) in health care. We commend Chairman Stupak, Ranking Member Shimkus, and members of the Subcommittee for convening this hearing. My name is Nancy H. Nielsen, MD, PhD, an internist and President-Elect of the AMA. I am also a clinical professor of medicine and senior associate dean for medical education at the State University of New York at Buffalo School of Medicine and Biomedical Sciences. We look forward to sharing our policy concerning DTCA as well as our perspective on DTCA’s impact on the patient-physician relationship, its adequacy as a source of information for patients, and its role in driving health care costs and utilization.
Background

DTCA has become ubiquitous over a very short period of time. According to a recent consumer survey, almost all Americans (91 percent) have seen or heard DTCA. In under ten years, between 1993 and 2002, the percentage of people who reported that they had seen an ad for a prescription drug on television or heard one on the radio more than doubled. Nearly a third (32 percent) of Americans have talked to a physician about a prescription drug they saw advertised.

The foregoing is not surprising since the growth in spending on DTCA between 1989 and 2004 has been explosive. In 1989, the pharmaceutical industry spent only $12 million on DTCA, and by 2004 spending had dramatically climbed to approximately $4.45 billion. Pharmaceutical companies have increased spending on DTCA faster than they have increased spending on research and development. Between 1997 and 2001, spending on DTCA increased 145 percent, while research and development spending increased only 59 percent. Spending on DTCA grew at an average annual rate of 14.3 percent from 2002 to 2005.

The sheer frequency and volume of DTCA that now appears on television in particular, including ads for drugs to treat conditions such as erectile dysfunction, has raised questions about the appropriateness of these ads for some consumers, such as children. There is growing concern that many of the television DTC ads lack fair balance; i.e., claims of benefit overwhelm risk information presented in the ads. This can result in trivialization of the safety risks of prescription drugs. Also, intense advertising for newly
approved drugs with limited safety profiles could potentially lead to significant safety problems.\textsuperscript{x} The rofecoxib (Vioxx) case is illustrative of this concern.

The AMA has been, and continues to be, concerned about the possible negative impact of DTCA on the patient-physician relationship, patient safety, and is increasingly concerned about the role that DTCA plays in fueling the increase in health care costs. It is all the more urgent now as Congress grapples with escalating costs and the need to prioritize scarce health care dollars. There is growing alarm that DTCA increases utilization of new and more expensive drugs that all too often have limited safety profiles. The AMA does not believe that the Food and Drug Administration (FDA) has adequate resources to carry out its enforcement role over DTCA since the staffing has not kept pace with the proliferation of DTCA,\textsuperscript{xi} nor has Congress provided sufficient funding to support quality, independent research on the impact of DTCA. These concerns are discussed in more detail later in this testimony.

\textit{AMA Policy and DTCA}

In June 2006, in light of the rapid proliferation of DTCA, climbing health care costs, and concerns about the negative impact of DTCA on patient-physician relations, the AMA adopted a comprehensive set of recommendations, in addition to guidelines for an appropriate DTC ad, to ensure that DTCA is properly regulated and assessed to ensure it does not adversely impact patient-physician relations, provides appropriate and balanced information, and does not artificially increase health care costs by causing overutilization.
In general, the AMA supports "help-seeking" or "disease awareness" ads (i.e., ads that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA). The AMA opposes “product-specific” DTCA, regardless of medium, that is not consistent with the following guidelines.

- **Indication-Specific and Educational.** The ad should be indication-specific and enhance consumer education about both the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.

- **Accurate and Objective Information on Risk as well as Benefit.** In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the ad should convey a clear, accurate, and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug’s or device’s approval for marketing. Risk information should be clearly stated and comprehensible to the consumer.

- **Prescription Required.** The ad should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.
• **Encourage Physician Consultation.** The ad should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as "Your physician may recommend other appropriate treatments," is recommended.

• **Fair Balance Between Risk and Benefit Information.** The ad should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well ease with which people can find, understand, remember, and use the information, should be comparable.

• **Clear Communication of Warnings, Precautions, and Potential Adverse Reactions.** The ad should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without content and devices designed to minimize or distract from risks, and will help facilitate communication between physician and patient.

• **No Actors Playing Doctor Unless Clear Disclaimer Provided.** In general, ads 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, a disclaimer should be prominently displayed.

- **No Actual Health Care Professionals Unless Clear Disclaimer Provided.** 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 ad must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.

- **Age Appropriate Placement.** The ad 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.

- **Comply with FDA Regulations.** The ad must comply with all other applicable FDA regulations, policies, and guidelines.

In addition, the AMA’s policy includes support for enhanced FDA authority to regulate DTCA. Specifically, the AMA has advocated for FDA authority to review—and pre-approve—all DTC ads for prescription drug or implantable medical device products before pharmaceutical and medical device manufacturers run the ad.

The AMA has called upon the FDA to require that all newly approved prescription drug or implantable medical device products should be subject to a DTCA moratorium until
physicians have been appropriately educated about the drug or implantable medical device. Our policy provides that the time interval for this moratorium on DTCA should be determined by the FDA, in negotiations with the drug or medical device product’s manufacturer, 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.

The 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.

To that end, the AMA also supports actions by Congress to require that the Agency for Healthcare Research and Quality (AHRQ) perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is
detrimental to the public health, then Congress should consider enacting legislation to increase DTCA regulation or, if necessary, prohibit DTCA in some or all media. (Incidentally, the Institute of Medicine has already recommended that the FDA restrict advertising for newer prescription drugs in a study of drug safety.)\textsuperscript{xii} In such legislation, every effort should be made not to violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.

AMA’s current policy recognizes that DTCA is legal and widespread. While the AMA’s guidelines for acceptable DTCA have generally been well received by both the FDA and the Pharmaceutical Research and Manufacturers of America (PhRMA), regrettably the member companies of PhRMA have not consistently complied with the AMA’s guidelines.

\textit{Key AMA Concerns about DTCA}

Significant ongoing concerns and questions about DTCA within the physician community, include: 1) does DTCA provide educational value, are ads fairly balanced, and do they adequately disclose risks to consumers; 2) what is the impact of such ads on patient-physician relationships; and 3) what is the impact of such ads on health care utilization and costs? Each of these concerns/questions is addressed below.

1. \textit{Is DTCA Educational and Balanced?}

The bedrock of AMA’s guidelines is that DTCA should be educational, and not misleading. Do most product-specific ads meet the AMA’s standard for educational
value? This is difficult to answer, since what is educational to one individual may not be to another. While good data is hard to find on this issue, the majority of physicians most likely would not agree that the ads are educational. In one study that was published in the December 2000 issue of the *Journal of Family Practice*, the researchers reviewed over 300 print ads for 101 prescription drug products in 18 popular magazines over the previous decade. They found that while the ads were informative, they lacked important educational information about the condition and the treatment for which the drug was being promoted.xiii

Similarly, researchers in another study reviewed the contents of 67 DTC ads from 10 magazines published between July 1998 and July 1999. They found that the ads rarely quantified a medication’s expected benefit, and instead made an emotional appeal.xiv In contrast, more than one-half of the ads used data to describe a drug’s side effects.xv The authors suggested that these DTC ads leave readers with the perception that the drug’s benefit is large and that everyone who uses the drug will enjoy the benefit.xvi

In yet another study, concerns were raised about the educational value of television DTC ads.xvii These investigators reviewed 23 television DTC ads and found the ads provided insufficient information about risks, and that the ads lacked fair balance between benefit and risk information.xviii They also found that the ads often used medical terminology that was not consumer-friendly, especially for patients with limited literacy.xix More recently, researchers reviewed 31 product-specific DTC TV ads and concluded the ads lacked educational value.xx These TV ads provided limited information about the causes
of a disease or who may be at risk, they show characters that have lost control over their social, emotional, or physical lives without the medication, and they minimize the value of health promotion through lifestyle changes. \textsuperscript{xxviii}

Although increased access by patients to accurate, objective information about tests to diagnose and drugs to treat illnesses is certainly important, there is the risk of confusion when commercially-driven promotional information is presented as educational. The issue is not whether consumers should obtain more information about treatment options; the real question is whether DTCA, with its aim of selling a product, can provide the type of information consumers need or should have. Advertising has been described by one economist as “the science of arresting the human intelligence long enough to get money from it.”\textsuperscript{xxi} One executive of an advertising agency that focuses on DTCA has noted that “consumers react emotionally, so you want to know how they feel about your message and what emotional triggers will get them to act…. We want to identify the emotions that we can tap into to get that customer to take the desired course of action.”\textsuperscript{xxii}

In addition to assessing the educational value of DTCA, the AMA is concerned that consumers are not consistently receiving a balanced view of the benefits and risks of a product based on advertising. The FDA has made efforts to guide manufacturers to provide consumers with risk information, based on the drug’s labeling, that is more useful and easily understood. For the most part, the AMA would concur that fair balance and adequate disclosure of risks appear in print ads, which require the “brief summary” (which usually is identical text to the risk sections [i.e., warnings, precautions and side
effects] in FDA-approved professional labeling [Package Insert, PI] to be included. Unfortunately, the “brief summary” has long been criticized by many stakeholders as too difficult for consumers to understand. The AMA has submitted comments to the FDA supporting the presentation of risk information in a more consumer-friendly way, so that key risks about prescription drug products will be better understood.

For television ads, however, studies indicate that DTCA in this medium has not provided fair balance between benefit and risk information. In one study, after viewing DTC TV ads, people were about 80 percent correct in identifying the benefits of the advertised drug, but only 20 percent correct in describing the side effects. In the same study, the researchers found that about three times more sentences were devoted to benefit information when compared to risk information, and that the placement of risk information was such that consumers would be least likely to remember it. Also, an individual would need only about a 6th grade reading level to understand the benefits of the advertised drug, but a 9th grade level for side effects. The authors concluded that the cognitive accessibility, defined as the ease with which people can find, understand, remember, and use information, was far better for benefit information when compared to risk information in DTC TV ads.

In yet another study, researchers found that the mean television DTC ad length was 46.3 seconds, but only 6.3 seconds on average discussed side effects. Also, the vast majority of the ads (90 percent) placed risk information in the middle or the end of the ad where it would be less likely to be remembered. Some of the ads also were very effective at
using pleasing, not to mention distracting, visuals as the major risk information was being
discussed in audio only.

Finally, some studies have shown that patients have potentially dangerous misperceptions
about DTCA. One research study suggested that one-half of consumers incorrectly
believed that DTC ads are pre-approved by the FDA, and 43 percent incorrectly believed
that only completely safe drugs can be advertised directly.\textsuperscript{xxv} Another study found that
consumers rated the safety and appeal of drugs described with an incomplete statement of
risks more positively than similar drugs described with a more complete statement of
risks.\textsuperscript{xxvi} These perceptions raise the question of whether widespread DTCA is giving
consumers a false sense of security that prescription drugs are risk-free.

2. \textit{What is the Impact of DTCA on the Patient-physician Relationship?}

The AMA remains concerned about the impact of DTCA on the patient-physician
relationship and the paucity of quality, independent peer-reviewed research to measure
this impact. The consumer surveys that have been conducted, such as those by the FDA,
\textit{Time}, the AARP, the National Consumers League and \textit{Prevention} magazine, suggest that
DTCA increases: (1) physician office visits; (2) new diagnoses; (3) informed discussion
between physician and patient about conditions and treatments; and, (4) unfortunately in
some cases, demand for a specific advertised drug product. In a 2002 report by the
Government Accountability Office (GAO), the authors examined a number of consumer
surveys and concluded that the percentage of consumers who, in response to a DTCA,
requested and received a prescription from their physician for a drug they were not
currently taking was generally about 5 percent. The GAO estimated that this meant that about 8.5 million consumers in 2000 received a prescription drug after viewing a DTC ad and asking their physician for the drug.\textsuperscript{xxvii}

Although DTCA might have the positive effect of increasing physician office visits, resulting in the diagnosis of previously undiagnosed conditions, and in better communication between physician and patient, many physicians complain that patients, armed with the latest DTC ad, come into their offices demanding the physician prescribe the advertised drug for them. If a medication is not necessary or appropriate, the physician is put in the uncomfortable and awkward position of defending why this is the case. Less time is available to diagnose and treat the patient if the patient has a fixation on a particular drug as a result of a commercial. This can add strain and potentially distrust to a relationship that should be completely open.

A FDA survey of physicians, strongly supported by the AMA, released in January 2003 concluded that most physicians view DTCA as one of many factors that affect their practice and their interactions with patients, both positively and in some respects, negatively. The FDA survey also found that physicians felt they had to provide additional information to patients beyond what patients retained from the DTCA. About 75 percent of physicians believed that DTCA causes patients to think the drug works better than it did, and many physicians felt some pressure to prescribe something when patients mentioned an ad. The FDA survey also found that about eight percent of physicians felt very pressured to prescribe the specific brand name drug when asked
Various surveys and limited research studies have shown that some physicians prescribe the requested drug. One would like to believe that objective treatment decisions were made in every case. However, the question needs to be raised as to whether clinical judgment is being compromised in some cases to preserve a positive relationship with the patient.

3. What is the Impact of DTCA on Health Care Costs and Utilization?

The AMA also is concerned about the impact of DTCA on health care costs and utilization. DTCA is targeted at an audience that often is not responsible for paying for the product because most prescriptions are paid for, at least in part, by private or public insurance. The key question is whether these increased costs for advertised drugs are reducing costs in other health care areas so that the net effect is more cost-effective health care. This also places the physician in a difficult situation. On the one hand, the payer expects the physician to be cost-conscious and not prescribe the most expensive drug, if not medically indicated. On the other hand, payers also grade physicians based on patient satisfaction. The physician faces pressure from the patient requesting an expensive advertised drug and pressure from the payer to prescribe comparable but less expensive alternatives.

Limited studies have concluded that DTCA does, in fact, lead to increased spending on drugs. A study by researchers at the Harvard School of Public Health, Massachusetts Institute of Technology, and Harvard Medical School for the Kaiser Family Foundation, released in June 2003, found that increases in DTCA have a significant impact on drug
spending growth. The authors estimated that in 2000, 12 percent of drug spending
growth was related to increased spending on DTCA. Each additional dollar spent on
DTCA yielding an additional $4.20 in drug sales in that year.

In 2002, the GAO also found that drugs promoted directly to consumers often were
among the best-selling drugs, and sales for DTC-advertised drugs increased faster than
sales for drugs that are not heavily advertised to consumers. Moreover, the GAO found
that most of the spending increase for heavily advertised drugs was the result of increased
utilization rather than price increases. A more recent GAO report in November 2006
also concluded that DTCA appeared to increase prescription drug spending and
utilization.

A recent Kaiser Foundation, USA Today, and Harvard School of Public Health consumer
survey found that about one-third of consumers have talked to a physician about a
prescription drug they saw advertised. Among this group, 44 percent said their
physician prescribed them a drug they asked about, and 54 percent say their physician
recommended another prescription drug (resulting in 82 percent who received a
prescription either for the drug they asked about and/or another drug).

These studies may reflect an appropriate increase in spending on drug treatments that
were previously underutilized. Alternatively, this also could reflect wasteful spending on
expensive advertised drugs for which less expensive alternatives, or no drug at all, will
work just as well. A clear answer to this important question is definitely needed.
Recommendations

The AMA offers the following conclusions and recommendations to the Subcommittee as it examines the consequences of DTCA:

1. The AMA believes there is substantial room for improvement in the educational value of DTCA. In this regard, the AMA urges the pharmaceutical and medical device industries to use and comply with the AMA’s guidelines for DTCA. Responsible DTCA that is accurate and educational to consumers, that balances benefits and risks, and that promotes good health outcomes could have a positive impact on health care.

2. The AMA believes that consumers must be better educated to understand the limitations of DTCA. The AMA stands ready to work with the FDA and consumer groups in such an educational endeavor.

3. The AMA supports more independent research on DTCA and, particularly, on its impact on the patient-physician relationship and on health outcomes and costs. In light of recent events involving aggressively marketed new drugs with significant safety risks, the need to examine the impact of DTCA on patient safety also has become a priority. The results of this research must be published in reputable, peer-reviewed journals and be available in the public domain. The AMA believes
that both industry and government have an obligation to fund this research. Such research should guide future regulation of DTCA.

4. The FDA should pre-review and approve all DTC ads, and should determine the length of any moratoriums on DTC ads for new drugs and medical devices.

5. For its part, the AMA will continue to educate physicians on their role in identifying and reporting inappropriate DTC ads, in cooperating with research studies to better understand and evaluate the impact of DTCA, and to assure they are meeting their ethical duties to their patients in recommending appropriate treatments.

The AMA is pleased to have the opportunity to share with the Subcommittee the AMA’s policy on DTCA and information on the impact it has on the patient-physician relationship, the quality of the information it provides to patients, and the role it may play in escalating health care costs. We look forward to working with the Subcommittee to promote and protect the interests of patients and consumers by ensuring that DTCA is accurate, balanced, and enhances the patient-physician relationship while not causing over utilization or promotion of expensive new drugs with limited safety profiles.

Endnotes


iii The Public on Prescription Drugs and Pharmaceutical Companies, Id.


xi Donohue 2007.

xii Id., 679.


xvi Id.

xvii Id.


xix Id.


xxiv Id.


xxvii FDA Oversight of Direct-to-Consumer Advertising Has Limitations, GAO-03-177, Government Accountability Office, October 2002

xxiii Id.
WHEREAS, Insurance companies adhere to set time limits of no more than 180 days for physicians to submit claims for care they render to their patients; and

WHEREAS, Several major insurance companies have recently employed contractors to recover payments on old claims past one year deadline for repayment; and

WHEREAS, The contractors often send letters asking for monies back erroneously and when contacted by their listed phone numbers or by mail no satisfactory explanation or appeal process is given; and

WHEREAS, The contractors essentially harass physicians improperly and provide no recourse for physicians to dispute these “recovery” claims; and

WHEREAS, The contractors are thought to be employed by the insurance companies as their listed phone number is that of the insurance companies even though their letterheads list different names; and

WHEREAS, The contractors do not always use the accepted standard for bundling and multiple procedures, but rather their own guidelines that providers are not privy to, creating generally unacceptable and egregious denial of payment for services rendered; therefore be it

RESOLVED, That our AMA seek legislation to limit insurance companies, their agents, or any contractors from requesting payment back on paid claims to no more than 90 days after payment is made (Directive to Take Action); and be it further

RESOLVED, That such legislation require insurance companies, their agents, or any contractors to have a defined and acceptable process for physicians to dispute these maneuvers to get payment back on claims already processed, verified, and paid (Directive to Take Action); and be it further

RESOLVED, That such legislation ban insurance companies, their agents or contractors from using re-pricers and re-reviewers and to adhere to their own pricing and reviewing guidelines as agreed upon in their contracts with physicians (Directive to Take Action); and be it further

RESOLVED, That our AMA pursue legislation to end ERISA preemption of state laws to regulate self-insured plans in this regard and apply the same rules to Medicare and other federal plans. (Directive to take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $3,047.

Received: 04/22/09
H-70.926 Reasonable Time Limitations on Post-Payment Audits and Recoupments by Third Party Payers
Our AMA policy is that post-payment audits, post-payment downcodes and other similar requests for recoupment by third party payers be made within one year of the date the claim is submitted or within the same amount of time permitted for submission of the claim, whichever is less. (Res. 815, A-01; Reaffirmation I-04; Reaffirmation A-08)

D-285.968 Health Insurance Code of Conduct
Our AMA will: 1. develop a Health Insurer "Code of Conduct" setting forth clear and concise principles addressing both medical care policies and payment issues; 2. seek concurrence among health insurers in complying with this "Code of Conduct;" 3. develop a mechanism to monitor compliance with this "Code of Conduct;" and 4. widely disseminate information regarding this "Code of Conduct," and health insurer compliance, to physicians and consumers. (Res. 823, I-08)

H-285.915 AMA Policy on ERISA
Our AMA will seek, through amendment of the ERISA statute, through enactment of separate federal patient protection legislation, through enactment of similar state patient protection legislation that is uniform across states, and through targeted elimination of the ERISA preemption of self-insured health benefits plans from state regulation, to require that such self-insured plans: (1) Ensure that plan enrollees have access to all needed health care services; (2) Clearly disclose to present and prospective enrollees any provisions restricting patient access to or choice of physicians, or imposing financial incentives concerning the provision of services on such physicians; (3) Be regulated in regard to plan policies and practices regarding utilization management, claims submission and review, and appeals and grievance procedures; (4) Conduct scientifically based and physician-directed quality assurance programs; (5) Be legally accountable for harm to patients resulting from negligent utilization management policies or patient treatment decisions through all available means, including proportionate or comparative liability, depending on state liability rules; (6) Participate proportionately in state high-risk insurance pools that are financed through participation by carriers in that jurisdiction; (7) Be prohibited from indemnifying beneficiaries against actions brought by physicians or other providers to recover charges in excess of the amounts allowed by the plan, in the absence of any provider contractual agreement to accept those amounts as full payment; (8) Inform beneficiaries of any discounted payment arrangements secured by the plan, and base beneficiary coinsurance and deductibles on these discounted amounts when providers have agreed to accept these discounted amounts as full payment; (9) Be subject to breach of contract actions by providers against their administrators; and (10) Adopt coordination of benefits provisions applying to enrollees covered under two or more plans. (CMS Rep. 6, I-96; Reaffirmation A-97; Reaffirmed: Rules and Cred. Cmt., I-97; Reaffirmed by Sub. Res. 202, A-98; Reaffirmation I-98; Reaffirmation A-99; Reaffirmed: Res. 238, A-00; Renumbered: CMS Rep. 7, I-05)

H-285.946 Fair Physician Contracts
Our AMA will develop national (state) standards and model legislation for fair managed care/physician contracts, thereby requiring full disclosure in plain English of important information, including but not limited to: (1) disclosure of reimbursement amounts, conversion factors for the RBRVS system or other formulas if applicable, global follow-up times, multiple procedure reimbursement policies, and all other payment policies; (2) which proprietary "correct coding" CPT bundling program is employed; (3) grievance and appeal mechanisms; (4) conditions under which a contract can be terminated by a physician or health plan; (5) patient confidentiality protections; (6) policies on patient referrals and physician use of consultants; (7) a current listing by name and specialty of the physicians participating in the plan; and (8) a current listing by name of the ancillary service providers participating in the plan. (Res. 727, A-97; Amended by CMS Rep. 3, A-98; Reaffirmed: Res. 814, A-00; Reaffirmation A-06; Reaffirmation A-08; Reaffirmation I-08)
H-285.971 Population Based Practices in Managed Care Systems
The AMA recommends to all managed care plans that they: (1) develop population based programs for prevention, health risk assessments, and health's status improvement; (2) adopt a process to measure clinical quality provided to patients and demonstrate how quality in their system of care is improving; (3) develop programs which assure that communicable and environmentally induced health problems are followed up by physicians within the plan in cooperation with competent health department personnel; and (4) manage these programs in concert with established standards of preventive medicine and public health. (Sub. Resolution 718, I-94; Reaffirmation I-96; Reaffirmed: CMS Rep. 8, A-06)
Advancing a Counterattack on Managed Care Payment Practices:  
Retrospective Audits

STATE STATUTORY ANALYSIS

As insurers seek to better their bottom lines, physicians and their practices need to be aware of the retrospective audit. A retrospective audit occurs when an insurer reviews claims it has already paid out to the provider over a certain set amount of time, in order to determine if an overpayment has occurred. Unless an established state law prohibits this practice, or limits the amount of time allowed for such an audit, or the contract between the insurer and provider otherwise states, an insurer can perform a retrospective audit regarding claims paid over two, three (or more) years ago. Where it is determined that an overpayment has occurred, one of two things can happen: (1) the provider may receive notice of the overpayment and request for direct reimbursement of the amount of the overpayment or (2) the insurer may attempt to “offset” the overpayment by deducting a set amount from future payments until the entire overpayment is paid back.

Because of the seriousness of this problem for physicians, slightly less than half the states’ statutes already address retrospective audits (Alabama, Alaska, Arizona, California, Colorado, District of Columbia, Florida, Georgia, Indiana, Kentucky, Louisiana, Maine, Maryland, Missouri, New Hampshire, New York, North Carolina, Ohio, Tennessee, Texas, Utah, Virginia, Washington and West Virginia). In most instances, these provisions are found within a states’ prompt pay statute. However, not all of these statutory provisions favor the physician. In Alaska, for example, the statute provides that there is no prohibition for a health care insurer from recovering an amount mistakenly paid to a provider or a covered person. There are no limits placed on the amount of time that is allowed to pass before an insurer can no longer collect payment retroactively. Rather, Alaska’s statute is left wide open and therefore, the potential for an insurer performing such an audit two, three (or more) years after the payment has occurred, is a true possibility.

Seven states place a 12 month time limit on an insurer auditing a payment of a claim (Alabama, Arizona, Colorado, Maine, Missouri, Virginia and West Virginia), while three states are very aggressive by providing the insurer with six months or less (after the date of payment) to retroactively deny reimbursement (District of Columbia (6 months), Maryland (6 months) and Texas (6 months)). In Georgia, a payer cannot conduct a post payment audit or impose a retroactive denial of payment more than 12 months after the last day of service. Georgia’s statute goes further, however, at provides that such audit must be completed within 18 months of the last date of service (where the claim was submitted within 90 days of the last day of service) or within the lesser of 18 months after the claimants initial submission of such claim or 24
months after the date of service (where the claim is submitted more than 90 days after the last date of service).

Three states (New Hampshire, Tennessee and Utah) allow for retrospective audits to occur within 18 months of payment, while another six states allow for 24 or more months to pass (Florida (30 months), Indiana (24 months), Kentucky (24 months), New York (24 months), Ohio (24 months) and Washington (24 months)). Louisiana’s statute states that where an insurer limits the period of time that a provider has to submit claims for payment, that insurer is faced with the same limited period of time following payment of a claim to perform any review or audit for purposes of reconsidering the validity of its decision to pay the claim. Finally, North Carolina is the only state that allows the contract between the insurer and the health care provider to govern whether an insurer may recover overpayments made to the health care provider by making demands for refunds and by offsetting further payments.

While many of the statutes require that the insurer provide written notice identifying the overpayment, the reasons therefor and the amount thereof (Alabama, California, District of Columbia, Georgia, Florida, Indiana, Kentucky, Maine, Maryland, New Hampshire, New York, Ohio, Tennessee, Texas, Virginia and Washington), some fail to provide for any such requirements (Louisiana, Missouri, North Carolina, Utah and West Virginia). In Washington, where a provider fails to contest the request in writing to the carrier within 30 days of its receipt, the request is deemed accepted and the refund must be paid.

Finally, there are a few state statutes that penalize the health care provider monetarily for not making reimbursement on an uncontested overpayment within a certain amount of time, e.g. California (“. . .If the provider does not make reimbursement for an uncontested overpayment within 30 working days after receipt, interest shall accrue at the rate of 10 percent per annum beginning with the first calendar day after the 30-working day period. . .”), Florida (“. . .Failure to pay or deny overpayment and claim within 140 days after receipt creates an uncontestable obligation to pay the claim . . .An overdue payment of a claim bears simple interest at the rate of 12 percent per year. Interest on an overdue payment for a claim for an overpayment payment begins to accrue when the claim should have been paid, denied, or contested), Tennessee (the Commissioner of Insurance may impose a penalty of two times the amount of the claim or $750, whichever amount is less). In Ohio, where the provider fails to respond to the notice sent by the insurer regarding an adjustment within a certain time frame, the insurer is allowed to “initiate recovery of the overpayment.” Tennessee also allows the provider to seek injunctive or “other appropriate relief” in the chancery or circuit court, instead of having the Commissioner of Insurance impose a penalty.
How to prepare for a health plan retrospective audit

A retrospective audit is a cost containment mechanism that health plans use to determine whether overpayments on claims have been made to a particular physician practice. Though some attempts to recoup overpayments may be appropriate, such as when honest health plan payment mistakes are made, retrospective audits are burdensome and add to administrative expenses of the physician practice. If a health plan determines, through a retrospective audit, that overpayments have been made because the documentation does not support billed charges, physicians may be asked to make repayments for services and procedures already provided or unwillingly accept automatic reductions in future reimbursements. Because health plans are using retrospective audits to recoup suspected overpayments more frequently and because of the attention retrospective audits and recoupments have garnered in connection with recent litigation, the American Medical Association’s (AMA) Practice Management Center along with the American Academy of Neurology (AAN) have developed this resource to help physicians understand the retrospective audit process, their contractual rights under the law, the options available to them and the necessary resources needed to determine the appropriateness of a retrospective audit finding.

What is a retrospective audit?

In a retrospective audit, health plans review claims that have been paid to a particular physician practice. The review of claims and ensuing request for repayment often dates back several years. The initial stage of the audit is typically conducted without notice to the physician. If the health plan determines, based on its own medical payment policies, that an overpayment was made, the health plan will typically notify the physician in writing. Practice managers, administrators or physicians should be alerted immediately upon receipt of these notices. Such notices from health plans informing physicians of suspected over-payments should not be overlooked.

These notices usually include the reasons for the suspected overpayments, such as lack of medical necessity, patient eligibility or medical record documentation. If the health plan disputes the medical necessity or eligibility for reimbursement of services or procedures, the health plan will usually request additional information, medical records and documentation, which the health plan may feel will assist it in making a determination.

Are retrospective audits like the medical peer review process?

Medical peer review, unlike retrospective audits, generally serves educational or other constructive functions. Its emphasis is on improving patient care. Retrospective audits are conducted to recoup payments that health plans have determined were made inappropriately. Generally, medical peer review sessions that fall within the scope of specific laws are confidential and any records, transcripts or individuals participating in the process are shielded from any subsequent litigation. All aspects of a retrospective audit, however, can be made part of any litigation. Physicians should respond to health plan inquiries very carefully to avoid jeopardizing or eliminating any possible defenses should the matter lead to litigation. Most physicians, in responding to health plan inquiries about retrospective audits, should consider involving legal counsel to ensure their rights are protected. It also may be prudent to alert state and local medical societies.
Why was I selected for a retrospective audit?

Health plans may choose to audit physicians’ claims for the reasons below, among others.

High service volume

Health plans may suspect that high service volumes indicate over-utilization of reimbursable health care services or procedures. Physicians may substantiate high volume or frequency of services by citing the size, specialty, local disease prevalence, patient case-mix and other factors that affect a physician practice’s billing patterns.

Coding issues

Health plans may view repeated use of the same evaluation and management (E/M) Current Procedural Terminology (CPT®) code as inaccurate reporting of E/M services. Because patient encounters vary in complexity, health plans expect that coding for such encounters will also vary. Physicians with high usage patterns of a single level of complexity may be more likely to be audited. It is critical that physicians bill each service case by case rather than employing “generic” billing practices, as well as ensure that either internal billing staff or third-party billing companies report services and procedures in accordance with CPT coding, guidelines and conventions.

Certain physician specialties, like neurology, may be more likely to bill for higher level E/M services because of the potential for increased frequency of complicated cases. Physicians that accept more cases with increased complexity may fall outside the normal range of higher level E/M billing volume as compared to physicians that accept less complex cases. Health plans may suspect that the physician’s elevated frequency of high level E/M billing indicates a pattern of overcoding, leading to a greater likelihood of being selected for a retrospective audit.

Modifiers

The reporting of a high volume of CPT modifiers, such as modifier 25, may prompt a retrospective audit. According to AMA CPT codes, guidelines and conventions, “the CPT modifier 25 is appended to the CPT code to indicate that on the day a procedure or service was performed, the patient’s condition required a significant, separately identifiable E/M service, above and beyond the other service provided or beyond the usual preoperative and postoperative care associated with the procedure that was performed.” A high reporting volume of E/M services with the CPT modifier 25 appended may prompt a retrospective audit so that health plans can determine whether the additionally reported services were, indeed, above and beyond the service performed during the E/M service based on the health plan’s medical payment policies.

Other reasons

Physicians may be selected for retrospective audits for previous nonconformity with health plan coding guidelines. Further, health plans may conduct retrospective audits randomly.

What should I do when I learn that I have been selected for a retrospective audit?

Adequate preparation is key in substantiating claims under a retrospective audit. Part of the preparation involves gathering as much information as possible about the health plan conducting the audit, the process involved and any current industry trends. Inquiries can be made to organizations such as state and county medical associations, national medical specialty societies, the AMA and possibly any government agencies that regulate insurance (e.g., state departments of insurance). These organizations may have valuable information for physicians and may be able to provide referrals to consultants. Such inquiries may also alert these medical associations and government agencies to unfair health plan practices currently affecting physicians. A developing pattern may bring about initiatives to address the issues on a larger scale through advocacy efforts or regulatory oversight.

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** This document contains links to non-AMA Web sites. The AMA is not responsible for the content of other Web sites.

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**Make inquiries**
Physicians should try to determine whether medical associations or government agencies are aware of any “hot button” issues involving the health plan, such as coding complexities, specific services and certain procedures or CPT modifiers. Physicians can also request information about the health plan’s auditing history such as which services and procedures or medical specialties have been recently audited by the same health plan. Further, physicians should try to determine whether the health plan has been compliant with state laws pertaining to insurance transactions and specifically to retrospective audits. A pattern of noncompliance may indicate that legal counsel may be necessary to address the health plan’s noncompliance.

**Review compliance guidance**
Physicians should review any pertinent documents related to billing and coding. This includes items such as a physician practice’s internal compliance program, the CPT coding manual and associated coding resources, any government guidance such as through CMS and any billing guidelines the health plan has provided to the practice. Physicians can compare their billing and coding practices with the requirements of such guidelines. A high rate of compliance can prove very helpful in substantiating claims billed to the health plan.

**Review health plan contract**
The basis for virtually all health plan requests is the underlying contract between the health plan and physician. The contract imposes both rights and obligations but may also provide important substantive or procedural protections for the physician. Physicians should aggressively pursue their rights and understand their limitations under their contracts. Therefore, physicians and/or their legal counsel should review their contracts to determine whether the health plan’s actions are consistent with contract provisions addressing retrospective audits. If retrospective audits are not specifically addressed in the contract, physicians should look to general provisions addressing offsets or adjustments. These types of provisions discuss the health plan’s ability to deduct payments otherwise due to physicians or the health plan’s ability to retrospectively adjust contract payments. Physicians and/or their legal counsel should ensure health plans comply with contract provisions and note any health plan noncompliance.

Physicians and/or their legal counsel should also review contract provisions that address medical necessity. Medical necessity, as defined in the contract, may greatly impact the audit results. If the contract allows for the health plan to have full discretion in determining the medical necessity of a particular service, physicians may face a bigger hurdle compared to a contract that uses the AMA’s “prudent physician” standard in defining medical necessity. The AMA defines medical necessity as:

> “Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.”

Provisions dealing with access to medical records should also be reviewed. These provisions may either protect physicians from inappropriate health plan requests for access to records or give health plans free access to the requested health records. In any event, physicians should be aware of and comply with contract provisions and, with the aid of legal counsel as necessary, ensure that the health plan does as well.

Lastly, some state laws exist that regulate the health plan retrospective audit process. Physicians and/or their legal counsel should check to see if any laws exist in their state that address retrospective audits.
How do I prepare for a retrospective audit?

Physicians can take additional measures to prepare for a retrospective audit. Physicians who have not contacted legal counsel at this point should consider conferring with legal counsel, accountants or coding consultants. These professionals can aid physicians in determining and limiting any potential liability exposures. Additionally, physicians should take careful measures to ensure patient privacy. While the Health Insurance Portability and Accountability Act of 1996 (HIPAA) does not require patients to authorize the release of private health information for purposes of conducting a retrospective audit, both physicians and health plans are responsible for ensuring that only the “minimum necessary” information is made available. Some state laws, however, may impose more stringent requirements.

Contact the health plan

Physicians should review the notice that details the suspected overpayments and contact the health plan for any needed clarification. Inquiries to the health plan at this point should be mostly procedural, since the retrospective audit is still in its initial phase—that is, the health plan may have determined that a billing or payment error has been made, but the extent or breadth of such occurrences may not have yet been determined.

Physicians may also attempt to obtain the health plan’s medical payment policies to determine whether the services and procedures in question were eligible for reimbursement under the health plan’s medical payment policies. Physicians should be aware, however, that many health plans do not release these policies citing legal proprietary rights.

Documentation review

Substantiating charges under a retrospective audit means presenting detailed documentation as evidence that services and procedures were performed as billed and were medically necessary. Physicians should review medical records and gather all available documentation such as referrals from colleague physicians, handwritten notes from patients or patients’ families, notes of phone contacts, template patient questionnaires, and laboratory or radiology reports. Physicians should provide copies of such records to the health plan and retain the originals for their records.

Physicians should prepare a letter to accompany each medical record that the health plan requested. The letter, signed by the attending physician, should expand on any missing or ambiguous information and should also articulate on the appropriateness of the coding methodology used to report the services provided.

What should I expect during the audit process?

Once all requested information is received, the health plan will begin its audit, likely to take place in one of the health plan’s offices. Physicians are generally not required to be present. If given the option, however, physicians should be present to facilitate better communication and allow immediate access to the auditors. Physicians may also consider having the audit conducted in their office, but on-site audits can be intrusive.

Audit findings

If the health plan determines that the physician’s documentation substantiates the billed charges, the health plan may not send notice of this finding. If the submitted records do not substantiate all billed charges, however, the health plan will likely send notice to the physician practice or initiate refund procedures.

Sometimes the health plan will request refund amounts from the overpayments discovered from the audited claims only. However, especially for overpayments resulting from overcoding, some health plans may extrapolate the discovered overpaid amount or percentage to apply across all claims submitted during a specified time period. For example, if 50 percent of the services on the audited claims were determined to be overcoded, the health plan may request repayment for 50 percent of the services performed by a physician over several years.

In cases where overpayments are not promptly refunded, the health plan may elect to deduct amounts otherwise due to physicians from future payments, often without warning. Physicians and/or their legal counsel should review their health plan contracts and state law to determine whether this practice is allowed.

Audit findings may also result in health plans requesting physicians to alter their standard of patient care to meet the health plans’ treatment guidelines. Physicians that health plans deem as over-utilizers or having a pattern of prescribing or providing more costly treatments are typically targets for these types of requests.

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Contesting the audit finding

If the retrospective audit results in an adverse finding, despite presenting sufficient documentation, physicians, with the aid of legal counsel and other consultants as necessary, should investigate the appropriateness of the finding. Since random coding errors may occur, physicians may consider having the same charts (claims) that were reviewed by the health plan reviewed by an independent coding professional to verify and validate the physician practice’s reporting of services and procedures. Retaining an independent coding professional may help to correct the random coding errors that are present in any coding review. This verification will assist physicians in substantiating the physician practice’s otherwise accurate reporting of the services and procedures provided, as well as help to disprove, invalidate, or even mitigate the penalties associated with the health plan audit results. The independent coding professional’s findings can be presented through any internal appeals process that the health plan and/or underlying contract affords physicians.

Note: The AMA has extensive policy regarding retrospective audits and recoupment that physicians may find useful in contesting retrospective audit findings (see additional resources at the end of this document). Additional AMA policy can be found on the PolicyFinder page on the AMA Web site at www.ama-assn.org/go/policyfinder.

Reporting unfair health plan business practices

Physicians should consider contacting their state medical associations and national medical specialty societies to alert them to any unfair health plan practices. Physicians can also file a complaint through the AMA’s Health Plan Complaint Form (HPCF). While the AMA may pursue compliance activities with health plans or payers where a pattern of complaints warrant, the information gathered from the HPCF will be used primarily to further shape AMA advocacy agendas. Physicians visit www.ama-assn.org/go/clickandcomplain to access this form.

Physicians may also want to alert the government agency that regulates insurance in their state. These agencies may provide remedies that benefit physicians. The National Association of Insurance Commissioners’ Web site at www.naic.org provides links to each state’s insurance regulatory agency.

How to avoid another health plan retrospective audit

Education and re-education of physicians and practice staff on the importance of consistently providing clear, accurate and detailed documentation for every patient encounter is essential. Stressing such a basic component of record keeping is necessary because once a physician is notified that a retrospective audit has been initiated, it is usually too late to improve the documentation for the medical records in question.

Internal self-audits conducted periodically allow physicians to identity specific deficiencies in their billing practices before claims are denied or a health plan retrospective audit is initiated. Deficiencies should be corrected and the processes taken to correct the deficiencies should be documented. For more information on internal self-audits, see “How to perform a physician practice internal billing audit,” available on the AAN Web site at http://aan.com/professionals/coding/index.cfm or from the AMA’s Practice Management Center Web site at www.ama-assn.org/go/pmc.

Physicians and/or legal counsel should review their health plan contracts, with specific attention to retrospective audit provisions. Where needed, physicians should attempt to renegotiate their contracts to facilitate a fair retrospective audit process. Physicians can reference the AMA Model Managed Care Contract to address issues regarding retrospective audits generally and to help identify and avoid contract language that unfairly allows health plans to offset payments to physicians. The AMA Model Managed Care Contract can be accessed from www.ama-assn.org/go/psa.
Additional resources

Existing AMA policy on retrospective audits and federal legislation:

- **Reasonable Time Limitations on Post-Payment Audits and Recoupment by Third Party Payors:** This AMA policy allows health plans up to one year after the claim has been submitted or equal to the time physicians are permitted to submit claims, whichever is less, to initiate recoupment efforts. (H-70.926)

- **Physicians’ Experiences with Retrospective Denial of Payment and Downcoding by Managed Care Plan:** This AMA policy requires health plans to issue written notification in a timely manner to both physician and patient of its determination to retrospectively deny payment of claims or downcode claims. The notice shall include the principal reasons for the determination, the clinical rationale and a statement describing the process for appeal. (H-320.948)

- **Postpayment Review and Recoupment Specific to Medicare:** This AMA policy calls on the AMA to seek specific clarification from CMS on the process, procedures, and criteria of physician office postpayment review and recoupment; oppose the concept and application of extrapolation; oppose arbitrary, erratic, or inappropriate components of postpayment review and recoupment; and seek appropriate relief to achieve equitable treatment of physicians in office postpayment review and recoupment situations. (H-335.981)

- **The Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003:** Includes provisions designed to make auditing of physicians more fair. The MMA also requires the Centers for Medicare and Medicaid Services (CMS) to establish auditing standards for physicians within the Medicare program. Physicians should check with MMA and CMS guidelines as they become available to see if health plans are complying with federally mandated requirements. More information is available on the CMS Web site at www.cms.hhs.gov.

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Questions or concerns about practice management issues?

AMA members and their practice staff can e-mail the AMA Practice Management Center at practicemanagementcenter@ama-assn.org for assistance.

For additional information and resources, there are three easy ways to contact the AMA Practice Management Center:

- Call **(800) 621-8335** and ask for the AMA Practice Management Center.

- Fax information to **(312) 464-5541**.

- Visit [www.ama-assn.org/go/pmc](http://www.ama-assn.org/go/pmc) to access the AMA Practice Management Center Web site.

For more information, you may also visit the American Academy of Neurology’s Web site at [www.aan.com](http://www.aan.com).

The AMA Practice Management Center is a resource of the AMA Private Sector Advocacy unit.
Advancing a Counterattack on Managed Care Payment Practices:  
Retrospective Audits

STATE STATUTORY PROVISIONS

ALABAMA

Ala. Code 27-1-17(E)
“An insurer, health service corporation, and health benefit plan shall not retroactively deny, adjust, or seek recoupment or refund of a paid claim for health care expenses submitted by a health care provider for any reason, other than fraud or coordination of benefits or for duplicate payments on claims received from the same insurer, health service corporation, or health benefit plan for the same service, after the expiration of one year from the date that the initial claim was paid or after the expiration of the same period of time that the health care provider is required to submit claims pursuant to a contract between the health care provider and an insurer, health service corporation, or health benefit plan, whichever date occurs first. Retroactive denials, adjustments, recoupments or refunds based on coordination of benefits shall be governed by subsection (F) Notwithstanding any other provision of law or contract to the contrary, if an insurer, health service corporation, or health benefit plan retroactively denies, adjusts, or seeks recoupment or refund of a paid claim, the health care provider shall have an additional period of six months from the date that the notice required by subsection (G) was received within which to file either a revised claim or a request for reconsideration with additional medical records or information . . . (F) An insurer, health service corporation, or health benefit plan shall not retroactively deny, adjust, or seek recoupment or refund of a paid claim submitted by a health care provider for reasons related to coordination of benefits with another insurer or entity responsible for payment of the claim after the expiration of 18 months from the date that the original claim was paid . . . (G) An insurer, health service corporation, or health benefit plan that retroactively denies, adjusts, or seeks recoupment or refund of a paid claim submitted by a health care provider shall give the health care provider notice specifying the reason for the action taken. Any retroactive denials, adjustments, or requests for recoupment or refund of previous payments which are based upon medical necessity determinations, level of service determinations, coding errors, or billing irregularities shall be reconciled to specific claims . . .”

ALASKA

Alaska Stat. § 21.54.020(h)
“This section does not prohibit a health care insurer from recovering an amount mistakenly paid to a provider or a covered person.”

ARIZONA

“Except in cases of fraud, a health care insurer or health care provider shall not adjust or request adjustment of the payment of a claim more than one year after the health care insurer has paid that claim.”

American Medical Association - Advocacy Resource Center
October 2007
CALIFORNIA

Cal. Health & Safety Code § 1371.1
“Whenever a health care service plan, including a specialized health care service plan, determines that in reimbursing a claim for provider services an institutional or professional provider has been overpaid, and then notifies the provider in writing through a separate notice identifying the overpayment and the amount of the overpayment, the provider shall reimburse the health care service plan within 30 working days of receipt by the provider of the notice of overpayment unless the overpayment or portion thereof is contested by the provider in which case the health care service plan shall be notified, in writing, within 30 working days . . . If the provider does not make reimbursement for an uncontested overpayment within 30 working days after receipt, interest shall accrue at the rate of 10 percent per annum beginning with the first calendar day after the 30-working day period.”

COLORADO

Colo. Rev. Stat. § 10-16-106.5(6)
“This section shall not prohibit a carrier from retroactively adjusting payment of a claim if: (a) the policyholder notifies the carrier of a change in eligibility of an individual; and (b) the adjustment is made within thirty days after the carrier’s receipt of such notification.”

DISTRICT OF COLUMBIA

D.C. Code Ann. § 31-3133
“(a) A health insurer may only retroactively deny reimbursement to a health care provider: (1) For services to coordination of benefits with another health insurer during the 18-month period after the date that the health insurer paid the health care provider; or (2) Except as provided in paragraph (1) of this subsection, during the 6-month period after the date that the health insurer paid the health care provider. (b)(1) A health insurer that retroactively denies reimbursement to a health care provider under subsection (a)(1) of this section shall provide the health care provider with a written statement specifying the basis for the retroactive denial . . .”

FLORIDA

Fla. Stat. § 641.3155(5)
“If a health maintenance organization determines that it has made an overpayment to a provider for services rendered to a subscriber, the health maintenance organization must make a claim for such overpayment to the provider’s designated location. A health maintenance organization that makes a claim for overpayment to a provider under this section shall give the provider a written or electronic statement specifying the basis for the retroactive denial or payment adjustment. The health maintenance organization must identify the claim or claims, or overpayment claim portion thereof, for which a claim for overpayment is submitted. (a) If an overpayment determination is the result of retroactive review or audit of coverage decisions or payment levels not related to fraud, a health maintenance organization shall adhere to the following procedures: 1. All claims for overpayment must be submitted to a provider within 30 months after the health maintenance organization’s payment of the claim. A provider must pay, deny, or contest the health maintenance organization’s claim for overpayment within 40 days after the receipt of the claim. All contested claims for overpayment must be paid or denied within 120 days after receipt of the claim. Failure to pay or deny overpayment and claim within 140 days after receipt creates an uncontestable obligation to pay the claim. 2. A provider that denies or contests a health maintenance organization’s claim for overpayment or any portion of a claim shall notify the
organization, in writing, within 35 days after the provider receives the claim that the claim for overpayment is contested or denied. The notice that the claim for overpayment is denied or contested must identify the contested portion of the claim and the specific reason for contesting or denying the claim and, if contested, must include a request for additional information. If the organization submits additional information, the organization must, within 35 days after receipt of the request, mail or electronically transfer the information to the provider. The provider shall pay or deny the claim for overpayment within 45 days after receipt of the information. The notice is considered made on the date the notice is mailed or electronically transferred by the provider. 3. The health maintenance organization may not reduce payment to the provider for other services unless the provider agrees to the reduction in writing or fails to respond to the health maintenance organization’s overpayment claim as required by this paragraph. 4. Payment of an overpayment is considered made on the date the payment was mailed or electronically transferred. An overdue payment of a claim bears simple interest at the rate of 12 percent per year. Interest on an overdue payment for a claim for an overpayment payment begins to accrue when the claim should have been paid, denied, or contested. (b) A claim for overpayment shall not be permitted beyond 30 months after the health maintenance organization’s payment of a claim, except that claims for overpayment may be sought beyond that time from providers convicted of fraud pursuant to s. 817.234.

**Fla. Stat. § 641.3155(10)**
“A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility more than 1 year after the date of payment of the claim.”

**KENTUCKY**

“(a) Except in cases of fraud, an insurer may only retroactively deny reimbursement to a provider during the twenty-four (24) month period after the date that the insurer paid the claim submitted by the provider. (b) An insurer that retroactively denies reimbursement to a provider under this section shall give the provider a written or electronic statement specifying the basis for the retroactive denial. (c) If the retroactive denial of reimbursement results from coordination of benefits, the written statement shall specify the name and address of the entity acknowledging responsibility for payment of the denied claim. (d) If an insurer retroactively denies reimbursement for services as a result of coordination of benefits with another insurer, the provider shall have twelve (12) months from the date that the provider received notice of the denial, unless the insurer that retroactively denied reimbursement permits a longer period, to submit a claim for reimbursement for the service to the insurer, the medical assistance program, or the Medicare program responsible for payment.”

**LOUISIANA**

“Health insurance issuers that limit the period of time a preferred provider or entity under contract for delivery of covered benefits has to submit claims for payment under R.S. 22:250.32 or 250.33 shall have the same limited period of time following payment of such claims to perform any review or audit for purposes of reconsidering the validity of such claims.”
MAINE

“...A carrier offering a health plan in this State may not impose on any provider any retrospective denial of a previously paid claim or any part of that previously paid claim unless:

A. The carrier has provided the reason for the retrospective denial in writing to the provider; and

B. The time that has elapsed since the date of payment of the previously paid claim does not exceed 12 months. The retrospective denial of a previously paid claim may be permitted beyond 12 months from the date of payment only for the following reasons:

(1) The claim was submitted fraudulently;
(2) The claim payment was incorrect because the provider or the insured was already paid for the health care services identified in the claim;
(3) The health care services identified in the claim were not delivered by the provider;
(4) The claim payment was for services covered by Title XVIII, Title XIX or Title XXI of the Social Security Act;
(5) The claim payment is the subject of adjustment with another insurer, administrator or payor; or
(6) The claim payment is the subject of legal action.”

MARYLAND

Md. Code Ann., Ins. § 15-1008
“... (c) In general - (1) If a carrier retroactively denies reimbursement to a health care provider, the carrier: (i) may only retroactively deny reimbursement for services subject to coordination of benefits with another carrier, the Maryland Medical Assistance Program, or the Medicare Program during the 18-month period after the date that the carrier paid the claim submitted by the health care provider; and (ii) except as provided in item (i) of this paragraph, may only retroactively deny reimbursement during the 6-month period after the date that the carrier paid the claim submitted by the health care provider. (2)(i) A carrier that retroactively denies reimbursement to a health care provider under paragraph (1) of this subsection shall provide the health care provider with a written statement specifying the basis for the retroactive denial. (ii) If the retroactive denial of reimbursement results from coordination of benefits, the written statement shall provide the name and address of the entity acknowledging responsibility for payment of the denied claim . . .”

MISSOURI

Mo. Rev. Stat. § 376.384
“1. All health carriers shall . . . (3) Not request a refund or offset against a claim more than twelve months after a health carrier has paid a claim except in cases of fraud or misrepresentation by the health care provider.”

NEW HAMPSHIRE

“II. No insurer shall impose on any health care provider any retroactive denial of a previously paid claim or any part thereof unless: (a) The insurer has provided the reason for the retroactive
denial in writing to the health care provider; and (b) The time which has elapsed since the date of payment of the challenged claim does not exceed 18 months. The retroactive denial of a previously paid claim may be permitted beyond 18 months from the date of payment only for the following reasons: (1) The claim was submitted fraudulently; (2) The claim payment was incorrect because the health care provider or the insured was already paid for the health care services identified in the claim; (3) The health care services identified in the claim were not delivered by the health care provider; (4) The claim payment was for services covered by Title XVIII, Title XIX, or Title XXI of the Social Security Act; (5) The claim payment is the subject of adjustment with another insurer, administrator, or payor; or (6) The claim payment is the subject of legal action. III. An insurer shall notify a health care provider at least 15 days in advance of the imposition of any retroactive denials of previously paid claims. The health care provider shall have 6 months from the date of notification under this paragraph to determine whether the insured has other appropriate insurance, which was in effect on the date of service. Notwithstanding the contractual terms between the insurer and provider, the insurer shall allow for the submission of a claim that was previously denied by another insurer due to the insured’s transfer or termination of coverage.”

NORTH CAROLINA

N.C. Gen. Stat. § 58-3-225(h)
“To the extent permitted by the contract between the insurer and the health care provider or health care facility, the insurer may recover overpayments made to the health care provider or health care facility by making demands for refunds and by offsetting future payments. Any such recoveries may also include related interest payments that were made under the requirements of this section. Recoveries by the insurer must be accompanied by the specific reason and adequate information to identify the specific claim. To the extent permitted by the contract between the insurer and the health care provider or health care facility, the health care provider or the health care facility may recover underpayments or nonpayments by the insurer by making demands for refunds. Any such recoveries by the health care provider or health care facility of underpayments or nonpayment by the insurer may include applicable interest under this section. The period for which such recoveries may be made may be specified in the contract between the insurer and health care provider or health care facility.”

OHIO

Ohio Rev. Code Ann. § 3901.388
“(A) A payment made by a third-party payer to a provider in accordance with [state law] shall be considered final two years after payment is made. After that date, the amount of the payment is not subject to adjustment, except in the case of fraud by the provider. (B) A third-party payer may recover the amount of any part of a payment that the third-party payer determines to be an overpayment if the recovery process is initiated not later than two years after the payment was made to the provider. The third-party payer shall inform the provider of its determination of overpayment by providing notice….The third-party payer shall give the provider an opportunity to appeal the determination. If the provider fails to respond to the notice sooner than thirty days after the notice is made, elects not to appeal the determination, or appeals the determination but the appeal is not upheld, the third-party payer may initiate recovery of the overpayment . . .”

TENNESSEE

(a) As used in this part:
(1) "Covered person" means a person on whose behalf a health insurance entity offering health insurance coverage is obligated to pay benefits or provide services;
(2) "Health care provider" means any person or entity performing services regulated pursuant to title 63 or title 68, chapter 11;
(3) "Health insurance coverage" has the same meaning as in § 56-7-109;
(4) "Health insurance entity" has the same meaning as in § 56-7-109;
(5) "Recoupment" means the action by a health insurance entity to recover amounts previously paid to a health care provider by withholding or setting off such amounts against current payments to the health care provider; and
(6) "Retroactive denial of a previously paid claim" or "retroactive denial of payment" means any attempt by a health insurance entity retroactively to collect payments already made to a health care provider with respect to a claim by reducing other payments currently owed to the health care provider, by withholding or setting off against future payments, by demanding payment back from a health care provider for a claim already paid or in any other manner reducing or affecting the future claim payments to the health care provider.

(b) A health insurance entity shall not be required to correct a payment error to a health care provider if the provider's request for a payment correction is filed more than eighteen (18) months after the date that the health care provider received payment for the claim from the health insurance entity.

(c) Except in cases of fraud committed by the health care provider, a health insurance entity may only retroactively deny reimbursements to the provider during the eighteen (18) month period after the date that the health insurance entity paid the claim submitted by the health care provider.

(d) A health insurance entity that retroactively denies reimbursement to a health care provider under this section shall give the health care provider a written or electronic statement specifying the basis for the retroactive denial and the statement shall contain, at a minimum, the information required by subsection (g).

(e) If a health insurance entity determines that payment was made for services not covered under the covered person's health insurance coverage, the health insurance entity shall give written notice to the health care provider of its intent to retroactively deny a previously paid claim and may:
   (1) Request a refund from the health care provider; or
   (2) Make a recoupment of the payment from the health care provider in accordance with subsection (g).

   The notice required by this subsection (e) may be included in the results of an audit submitted to the health care provider.

(f) Notwithstanding subsection (c), if a health insurance entity or an agent contracted to provide eligibility verification, verifies that an individual is a covered person and if the health care provider provides services to the individual in reliance on such verification, the health insurance entity may not thereafter retroactively deny a claim on the basis that the individual is not a covered person unless such retroactive denial occurs within six (6) months of the date that the health insurance entity paid the claim; otherwise the health insurance entity is barred from making such recoupment unless there was fraud by the health care provider.

(g) If a health insurance entity chooses to recoup from a health care provider amounts previously paid under a retroactively denied claim pursuant to subsection (c) or (e), the health insurance entity shall provide the health care provider written documentation that specifies:
   (1) The amount of the recoupment;
   (2) The covered person's name to whom the recoupment applies;
   (3) Patient identification number;
   (4) Date or dates of service;
   (5) The service or services on which the recoupment is based; and
   (6) The pending claims being recouped or that future claims will be recouped.
(h) (1) If the commissioner of commerce and insurance finds a health insurance entity has failed to comply with the provisions of this section, the commissioner may impose a penalty of two (2) times the amount of the claim or seven hundred fifty dollars ($750) whichever amount is less.

(2) In the alternative, the health care provider may seek injunctive or other appropriate relief in the chancery or circuit court in the county where the provider resides or practices.

(i) The commissioner shall adopt rules and regulations to ensure compliance with this section by January 1, 2005. All such rules shall be adopted in accordance with the provisions of title 4 chapter 5 and may be promulgated by public necessity rulemaking.

(j) The provisions of this section shall not be waived, voided or nullified by contract.

(k) (1) The provisions of this section shall not interfere or otherwise repeal the following:

(A) The prompt payment appeals process described in § 56-32-226;

(B) The authority of a receiver appointed by the commissioner of commerce and insurance pursuant to provisions of chapter 9 of this title to audit or collect overpayment made to providers more than eighteen (18) months from the date that the managed care organization (MCO) paid the claim;

(C) The authority of the TennCare bureau to collect overpayments made to providers more than eighteen (18) months from the date that the MCO paid the claim if discovered and verified by the bureau pursuant to an audit of an MCO; or

(D) The subrogation rights or authority of the TennCare bureau.

(2) Health insurance entities that contract directly with the TennCare bureau in the provision of services for TennCare recipients are specifically excluded from the provisions of this section only for the products and services made by such health insurance entities on behalf of the TennCare bureau.

TEXAS

Tex. Ins. Code Ann. § 3.70-3C, Sec. 3D
“(a) An insurer may recover an overpayment to a physician or provider if: (1) Not later than the 180th day after the date the physician or provider receives the payment, the insurer provides written notice of the overpayment to the physician or provider that includes the basis and specific reasons for the request for recovery of funds; and (2) The physician or provider does not make arrangements for repayment of the requested funds on or before the 45th day after the date the physician or provider receives notice. (b) If a physician or provider disagrees with a request for recovery of an overpayment, the insurer shall provide the physician or provider with an opportunity to appeal, and the insurer may not attempt to recover the overpayment until all appeal rights are exhausted.”

UTAH

Utah Code Ann. § 31A-26-301.6(15)
“Nothing in this section may be construed as limiting the ability of an insurer to: (a) recover any amount improperly paid to a provider: (i) in accordance with Section 31A-31-103 [insurance fraud provision] or any other provision of state or federal law; (ii) within 36 months for a coordination of benefits error; or (iii) within 18 months for any other reason not identified in Subsection (15)(a)(i) or (ii); (b) take any action against a provider that is permitted under the terms of the provider contract and not prohibited by this section; (c) report the provider to a state or federal agency with regulatory authority over the provider for unprofessional, unlawful, or fraudulent conduct; or (d) enter into a mutual agreement with a provider to resolve alleged violations of this section through mediation or binding arbitration.”

VIRGINIA

American Medical Association - Advocacy Resource Center
October 2007
**Va. Code Ann. § 38.2-3407.15(B)(7)**

“Notwithstanding subdivision B6, with respect to provider contracts entered into, amended, extended, or renewed on or after July 1, 2004, no carrier shall impose any retroactive denial of payment or in any other way seek recovery or refund of a previously paid claim unless the carrier specifies in writing the specific claim or claims for which the retroactive denial is to be imposed or the recovery or refund is sought. The written communication shall also contain an explanation of why the claim is being retroactively adjusted.”


“No carrier may impose any retroactive denial of a previously paid claim unless the carrier has provided the reason for the retroactive denial and (i) the original claim was submitted fraudulently, (ii) the original claim payment was incorrect because the provider was already paid for the health care services identified on the claim or the health care services identified on the claim were not delivered by the provider, or (iii) the time which has elapsed since the date of the payment of the original challenged claim does not exceed the lesser of (a) twelve months or (b) the number of days within which the carrier requires under its provider contract that a claim be submitted by the provider following the date on which a health care service is provided. Effective July 1, 2000, a carrier shall notify a provider at least thirty days in advance of any retroactive denial of a claim.”

**WEST VIRGINIA**


“A previously paid claim may be retroactively denied only in accordance with this subdivision. (A) No insurance company may retroactively deny a previously paid claim unless: (i) The claim was submitted fraudulently; (ii) The claim contained material misrepresentations; (iii) The claim payment was incorrect because the provider was already paid for the health care services identified on the claim or the health care services were not delivered by the provider; (iv) The provider was not entitled to reimbursement; (v) The service provided was not covered by the health benefit plan; or (vi) The insured was not eligible for reimbursement. (B) A provider to whom a previously paid claim has been denied by a health plan in accordance with this section shall, upon receipt of notice of retroactive denial by the plan, notify the health plan within forty days of the provider’s intent to pay or demand written explanation of the reasons for the denial. (i) Upon receipt of explanation for retroactive denial, the provider shall reimburse the plan within thirty days for allowing an offset against future payments or provide written notice of dispute. (ii) Disputes shall be resolved between the parties within thirty days of receipt of notice of dispute. The parties may agree to a process to resolve the disputes in a provider contract. (iii) Upon resolution of dispute, the provider shall pay any amount due or provide written authorization for an offset against future payments. (C) A health plan may retroactively deny a claim only for the reasons set forth in subparagraphs (iii), (iv), (v) and (vi), paragraph (A) of this subdivision (7) for a period of one year from the date the claim was originally paid. There shall be no time limitations for retroactively denying a claim for the reasons set forth in subparagraphs (i) and (ii) above.”
Advancing a Counterattack on Managed Care Payment Practices: 
Retrospective Audits

MODEL STATE LEGISLATIVE TALKING POINTS 
IN SUPPORT OF S.B. __/H.B. __ 
STATE OF _____________

Background on the issue of retrospective audits and why this legislation is critical:

- Over the past 20 years, the health care market has evolved from one dominated by traditional insurers, paying on a fee-for-service basis, to a competitive and complex market. Today’s health care market includes various types of managed care products, each with different provider networks, each having separate, lengthy provider agreements and negotiated discounts.

- A retrospective audit is one method used by insurers to determine whether a physician has received an overpayment for service rendered. In such an audit, an insurer reviews claims paid to a health care provider over a certain amount of time – sometimes several years past. If the insurer determines that an overpayment has been made, it will seek repayment from the provider either by seeking a full sum reimbursement or by “offsetting” future payments (decreasing future reimbursements).

- As insurers seek to better their financial bottom line, there need to be clear rules for when and how a retrospective audit can occur. The reality is that unless an established state law or regulation prohibits this practice, or limits the amount of time allowed for such an audit, or the contract between the insurer and health care provider otherwise states, an insurer can perform a retrospective audit on claims paid two, three (or more) years ago.

- S.B. __/H.B. __ is a common sense measure that establishes a level playing field between insurers and health care providers.

- The following provides briefing notes outlining the need for this legislation and clarifies the impact on insurers and providers.

Why the state legislature should pass S.B. __/H.B. __:

- [Insert general overview of state legislation.] E.g. S.B. __/H.B. __ establishes the following:
  - Creates a time limit on the health plan to initiate a retrospective audit after initially making payment to a provider for medical services rendered;
  - Places the burden on the insurer to provide documentation providing the health care provider with the reasons for the audit and the identity of the specific claims being audited; and
Forbids the insurer from recovering the amount of the overpayment by withholding or reducing other payments owed to the provider (“offsets”).

This legislation is needed to accomplish the following:

Stop this fundamentally unfair business practice where insurers come back years after paying a claim, assert that an overpayment has occurred and demand a refund.

- In a time where insurers are constantly looking for ways to better their financial bottom line, it is not uncommon for them to audit claims already paid to a health care provider, determine that an overpayment has occurred and demand a refund for the overpayment.

- Providers should be able to determine if an insurer will pay for a service before they perform the service.

- Creating uncertainty as to whether a payment is “final” is fundamentally unfair to both the provider and the patient.
  - Many insurers require pre-admission or pre-procedure review before a patient is admitted into an inpatient facility or prior to the delivery of certain health care procedures.
  - A provider is usually required to provide a medical justification for such admission or procedure and approval is obtained prior to the admission or procedure.
  - It is therefore wrong for the insurer to issue a conflicting retrospective audit if the documentation provided by the physician prior to the admission or procedure supports the case as originally presented, and where approval was originally obtained.

Level the playing field between insurers and providers.

- Providers are at a distinct disadvantage compared to an insurer once notice of a retrospective audit has occurred. Insurers have more advanced and sophisticated information databases to perform these audits. Not only do physician offices not have databases that are as advanced as those of the insurers, but many times, they do not have valuable information, e.g. terms of the beneficiary’s contract, available to them (information that insurers are in sole possession of).

- Moreover, if a retrospective audit occurs many years after the payment is made and the insurer requests supporting documentation, it is unreasonable to expect that a physician practice will maintain this supporting documentation indefinitely. It is especially unreasonable given that most times, insurers send letters regarding the implementation of a retrospective audit without attaching supporting documentation as to why such an audit is taking place. Placing the burden solely on the physician is unreasonable.
Stop a payment practice that may be against existing state law.

- Whether or not an insurer has the right to initiate a retrospective audit depends on either the terms of the managed care agreement, or existing state law (if the law states that it trumps contrary contract language).

- 48 states now have prompt payment statutes that address timely payment of claims. (Name of State) has a prompt payment statute that provides a specific timeline and deadlines regarding payment of claims. Specifically, [insert provisions of state prompt payment statute].

- Where a managed care agreement allows the insurer to “offset” future payments in order to recoup the amount of the alleged overpayment, the contract arguably violates (name of state)’s prompt payment statute, which requires an insurer to pay [insert provisions of state prompt payment statute].

- Where the contract is silent and does not specifically allow for an “offset,” general contract law governs. In most cases, under these types of contracts, the health care provider has a duty to perform services and the insurer is obligated to pay the provider once the physician has provided these services. Requiring a reimbursement of funds long after the claim has been paid arguably violates the terms of the contract.

For all of these reasons, we urge support for S.B. __/H.B. __.
IN THE GENERAL ASSEMBLY
STATE OF ______________

An Act to Prevent Retrospective Denial of Payment
For Any Previously Authorized or Paid Claim

Be it enacted by the People of the State of ______________, represented in the General Assembly:

Section 1. Title. This Act shall be known and may be cited as the "Act to Prevent Retrospective Denial of Payment For Any Previously Authorized or Paid Claim."

Section 2. Purpose. The Legislature hereby finds and declares that:

(a) Physicians should be able to determine if a third party payor will pay for a service before it is performed.

(b) Before admission to inpatient facilities and/or prior to delivery of certain health care procedures, many insurers and other third party payors of health benefits claims require pre-admission or pre-procedure review, for which the physician is required to state the medical justification for the admission or procedure and obtain approval in order to proceed; and

(c) Where the claim for medical services is then authorized by a third party payor, it is fundamentally unfair for a third party payor to issue conflicting retrospective review for the same claim if the documentation supports the case as originally presented.
(d) Where the claim for medical services is paid by a third party payor, it is fundamentally unfair for a third party payor to retroactively deny reimbursement for the paid claim.

Section 3. Prohibition of Retrospective Denial of Payment for Previously Authorized Claim.

(a) No third party payor shall issue a retrospective denial of payment for any claim for medical services for which a physician has previously obtained authorization, if the documentation for the claim supports the case as originally presented.

(b) Where an individual is covered by two or more health insurance plans, no secondary payor shall deny payment of any claim for which a physician has previously obtained authorization from a primary payor.

(c) Where an individual is covered by two or more health insurance plans, if the primary payor does not require prior authorization for medical services, no secondary payor may condition coverage on pre-authorization of such services.

Section 4. Prohibition of Retrospective Denial of Payment for Previously Paid Claim.

(a) No third party payor may retroactively deny reimbursement to a health care provider after the 6-month period from the date that the third party payor paid the claim submitted by the health care provider.
(b) A third party payor that retroactively denies reimbursement to a health care provider under this section must provide the health care provider with a written statement specifying the basis for the retroactive denial.

(c) If the retroactive denial of reimbursement results from coordination of benefits, the written statement shall provide the name and address of the entity acknowledging responsibility for payment of the denied claim.

(d) Effect of noncompliance. Except as provided in subsection (e) of this section, a third party payor that does not comply with the provisions of this section may not engage in the following practices:

(i) retroactively deny reimbursement, or

(ii) attempt in any manner to retroactively collect reimbursement already paid to the health care provider by reducing reimbursements currently owed to the health care provider, withholding future reimbursement, or in any other manner affecting the future reimbursement to the health care provider.

(e) Fraudulent or improperly coded information. The provisions of this section do not apply if the third party payor retroactively denies reimbursement to a health care provider because the information submitted to the third party payor was fraudulent or improperly coded.

Section 5. Effective Date. This Act shall become effective immediately upon being enacted into law.
Section 6. Severability. If any provision of this Act is held by a court to be invalid, such invalidity shall not affect the remaining provisions of this Act, and to this end the provisions of this Act are hereby declared severable.
Introduction by: Pennsylvania Delegation

Subject: Open Source Code Electronic Medical Records

Referred to: Reference Committee B
(Monica C. Wehby, MD, Chair)

Whereas, The medical record is intended primarily as a record of care and treatment rendered to the patient; and

Whereas, The electronic medical record (EMR) can enhance the medical record by integrating electronic prescribing, decision support, medical images, privacy protections, and other features; and

Whereas, The EMR holds the potential to vastly improve the efficiency, safety, cost, and quality of medical care, as well as the protection of personal health information; and

Whereas, There is substantial dissatisfaction among physicians as to the potential costs, level of usability, efficiency, interoperability, protection from obsolescence, and protections of personal health information in the EMR as it exists today; and

Whereas, Such dissatisfaction exists in large part, because patients and the physicians who actually treat them have inadequate input and control as to how virtually all proprietary EMR systems are designed; and

Whereas, Such dissatisfaction represents a major barrier to widespread adoption of EMR by physicians; and

Whereas, The facilitation of input from physicians and their patients into the design and structure of EMR systems would substantially alleviate such dissatisfaction; and

Whereas, The single most effective way in which such facilitation can be achieved is by the free distribution to providers, of an EMR system based on open source code, supported and governed by a public-private consortium, as, for example, set out in H.R. 6898 introduced into the 110th Congress in September, 2008; therefore be it

RESOLVED, That our American Medical Association support law and public policy that would make available to providers at nominal cost, an EMR system based on open source code, that would meet the certification and “meaningful use” requirements of the American Recovery and Reinvestment Act of 2009 (P.L. 111-5), with technical support and upgrade governance by a public-private consortium that meaningfully represents and implements the interests of physicians and their patients. (New HOD Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09
**H-478.995 National Health Information Technology**
Our AMA supports the development, adoption, and implementation of national health information technology standards through collaboration with public and private interests, and consistent with current efforts to set health information technology standards for use by the federal government. (Res. 730, I-04; Reaffirmed in lieu of Res. 726, A-08)

**D-478.994 Health Information Technology**
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; and (3) support initiatives to ensure interoperability among all HIT systems. (Res. 723, A-05; Reaffirmation A-07; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed: Res. 726, A-08; Reaffirmation I-08)

**D-478.992 Health Information Technology Purchasing Guidance**
Our AMA will help educate physicians via the AMA web site and appropriate AMA publications about issues to consider when purchasing health information technology (HIT) systems, including ensuring the availability of adequate technical support. (Sub. Res. 712, A-07; Reaffirmation I-08)
The Honorable Max S. Baucus  
Chairman  
Senate Committee on Finance  
219 Dirksen Senate Office Building  
Washington, DC  20510

The Honorable Charles E. Grassley  
Ranking Member  
Senate Committee on Finance  
135 Hart Senate Office Building  
Washington, DC  20510

Re: The Profession of Medicine’s Commitment to and Vision for Improving Patient Outcomes and the Efficiency of Health Care Delivery

Dear Chairman Baucus and Senator Grassley:

As leaders in the profession of medicine, we share with the Administration, Congress, and other stakeholders a sense of urgency and responsibility to meet the challenges that we face in creating a sustainable 21st century healthcare system. We are committed to creating a cultural transformation that better supports delivery of the highest quality care for individual patients and communities and which, among other strategies, will allow for a more appropriate allocation of finite resources. These two elements are extremely important, and we hold ourselves accountable to achieve them.

We speak here with one collective voice to share with you our vision for achieving significant, sustainable progress in improving the quality and delivery of healthcare. This vision builds upon the groundwork laid by the profession of medicine and many others with whom the profession have collaborated, including other healthcare professionals, consumer groups, public and private payers, quality organizations, and employers. We seek to advance policy decisions by broadening discussions to include a framework for creating a “patient-centered culture” throughout the health care system, which we believe is integral to achieving both high quality care and high efficiency of healthcare delivery. Recognizing the complexity of the health care challenges we face, and our professional obligations to help our nation meet them, we stand together and are committed to demonstrating progress from our profession and to engaging constructively with you to create the high-performing healthcare system that our patients and our country deserve.

A Vision for Sustainable Quality Improvement and Effective Use of Resources

Within the health care system, sustainable quality improvement and efficient use of resources must be achieved in the context of a “patient-centered culture.” Achieving the desired outcomes will require broadening policy discussions beyond measurement and public reporting; these components are necessary but insufficient to the task at hand which requires a transformation of the delivery system. To promote such a transformation, we propose moving from a focus of strictly data aggregation and reporting at the national level to a focus that includes “real time” data availability for decision making, timely review of measurement results to identify leverage points, best practices to improve the quality of care, and incorporation of a broader set of evaluation tools.

*We define this new culture as having 10 critical components. We seek to collaborate with the new Administration and Congress and other organizations to develop and carry out action plans to achieve them.*
10 Critical Components of a Patient-Centered Culture

1. **Shared Decision Making**—each patient and caregiver and the accountable team of healthcare professionals—physicians and all healthcare professionals—providing care to the patient have a shared understanding of the options for treatment, selected treatment plans, and desired outcomes

2. **Shared Understanding of Quality**—each member of the team understands the core facets of high quality care and has the competencies to practice in a 21st century system, as envisioned by the Institute of Medicine’s Crossing the Quality Chasm report

In support of efficiently implementing the plan and achieving good outcomes for the patient, the team of healthcare professionals:

3. *has timely access to patient records*, including all relevant tests results to avoid redundancy and risk to the patient

4. *has access to comparative-effectiveness research* information to assist in value-based decision-making at the point of care

5. *is implementing a set of performance measures*—based on clinical evidence and supported by their profession and other stakeholders—and these measures encompass processes, outcomes, and appropriateness of care

6. *enters patient data into an interoperable electronic health record system (EHRS)* once; the EHRS provides decision support; performance measurement results; and the ability to export data to other entities overseeing professional accountability, data aggregation, and public reporting

7. *reviews performance reports* routinely to identify areas for improvement; these reports track variations in care, particularly across patient co-morbidities as well as patient race, ethnicity, primary language and other relevant demographic characteristics

8. *implements best practices* from participation in a Quality Improvement (QI) collaborative—partnership among local and state entities that provide resources, tools, technical assistance, and training on quality improvement techniques

*With input from other stakeholders, the profession of medicine in this new culture:*

9. *comes together consistently to set targets; evaluates its progress on improving patient outcomes and effectively managing resources; determines which improvement methodologies have the greatest impact in practice; and monitors unintended consequences*

10. *practices transparency and accountability by reporting findings broadly*

Building on Foundation Pillars of the Profession and Other Key Stakeholders
The foundation for this cultural transformation exists today. Through volunteer hours of practicing physicians and the leadership of professional organizations, and via collaborations with other stakeholders, several pillars are moving into place. That said, there remains tremendous work to do on each of these fronts. We request your support and assistance as we seek to link these pillars, which include:
• Clinical guidelines developed by medical specialty societies that translate the evidence (including experience from practice) into recommendations, with regular updates. More evidence-based guidelines are under development and are beginning to include appropriateness criteria.

• Sets of clinical performance measures developed by the AMA-convened Physician Consortium for Performance Improvement (PCPI) that will now include not only process measures—including measures of overuse—but also measures of outcomes and measures for teams of health care professionals.

• Training for medical students and residents that is starting to include quality and safety strategies and requirements to demonstrate competence in these areas.

• Maintenance of board certification requirements that include self-evaluation of practice using measurements for quality and efficiency as well as a broader set of evaluation tools that assess patient experience and physician characteristics critical at the point of care such as diagnostic acumen, clinical judgment and medical knowledge.

• A discrete number of condition-specific data registries for timely feedback to physicians and external reporting, with plans to build an array of such registries going forward.

• Best practices in integrating performance measures into EHRS, using the data at the point of care, and exporting data from EHRS to a data warehouse for external analysis.

• A coding methodology for tracking variation in care and a schema for providing measure specifications to EHRS vendors.

• Best practices that work in complex practice environments and are beginning to move toward a more high-performing health care system.

**Medical Professionalism, Quality Improvement, and Management of Finite Resources**

The 10 critical components of a patient-centered culture and the pillars in place toward that culture stem from our medical professionalism. A core, historic principle of the medical profession is that physicians place the interests of patients first, underscroing altruism, competence and advocacy on behalf of patients; this principle is the foundation of our social contract and central to trusting patient-physician relationships. Moreover, every physician should respect patient autonomy and foster informed patient choice; shepherd the fair and equitable distribution of health care resources; and eliminate discrimination in health care.

Achieving these obligations in today’s challenging environment as described in the Quality Chasm report—with a proliferation of scientific discoveries, technological innovations, increasing complexity of patient needs, and variable delivery systems—requires that we further delineate and clearly articulate our professional responsibilities. In empowering our patients to make informed choices, we must not only consider treatment options but also what constitutes inappropriate and ineffective care. To shepherd the fair distribution of resources, we must engage patients and the broader community of stakeholders to facilitate value-based decision-making—weighing risk, benefit and cost. To maintain public trust, our self-regulation must be transparent and put continuous quality improvement first. Fulfilling these obligations requires physician action day in, day out, with each patient, at the point of care.
Opportunity for Collaboration
As a profession, our challenge is to work collaboratively with others dedicated to improving quality to expand and link these efforts in support of a new culture. We are positioned to do so and to demonstrate results. For example, the PCPI is inviting additional health care professionals to join in measure development for teams of professionals and has established a purchaser/consumer advisory panel. A number of the certifying boards have aligned their efforts with those of the private plans and CMS focused on facilitating physician collection and reporting of standardized performance measures. The certifying boards—with educational tools from specialty societies and elsewhere—then support physicians in developing and implementing action steps to address identified practice weaknesses. In addition, the medical profession is best positioned to assess which improvement methodologies have the greatest impact on improving quality in practice.

Physicians are committed to the principles of medical professionalism and dedicated to providing the best care possible to each and every patient. To that end, physicians remain committed to delivering high quality care for patients while increasing efficiencies in health care. We are in a unique position to advance a patient-centered culture and therefore must be an integral partner in all national efforts to transform our health care system. We will provide to you in the near future a specific list of our planned action steps and associated deliverables. We look forward to working with Congress, the Administration and other stakeholders to develop the necessary linkages to promote a health care system focused on quality.

From:
Christine Cassel MD, President and CEO, American Board of Internal Medicine
John Crosby JD, Executive Director, American Osteopathic Association
Douglas Henley MD, Executive Vice-president, American Academy of Family Physicians
Norman Kahn MD, Executive Vice-president and CEO, Council of Medical Specialty Societies
Frank Lewis, Executive Director, American Board of Surgery
Nancy Nielsen MD, President, American Medical Association
James Puffer MD, President and CEO, American Board of Family Medicine
Bernard Rosof MD, Chair, Physicians Consortium for Performance Improvement
Thomas Russell MD, Executive Director, American College of Surgeons
John Tooker MD, Executive Vice-president and CEO, American College of Physicians


Identical letters sent to:
President Barack Obama
The Honorable Joe Barton
The Honorable David L. Camp
The Honorable Nathan Deal
The Honorable Michael B. Enzi
The Honorable Walter W. Herger, Jr.
The Honorable Edward M. Kennedy
The Honorable Frank J. Pallone
The Honorable Charles D. Rangel
The Honorable Fortney H. Stark, Jr.
The Honorable Henry A. Waxman
January 23, 2009

The Honorable Nancy Pelosi  
Speaker  
U.S. House of Representatives  
H-232 Capitol Building  
Washington, DC 20515

Dear Speaker Pelosi:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to applaud the Energy and Commerce and Ways & Means Committees for adopting the American Recovery Investment Act’s provisions ensuring that millions of Americans are able to maintain health insurance coverage during this time of economic crisis.

The current economic downturn has hit Medicaid hard. Rising unemployment has increased the number of people who need Medicaid coverage while falling state revenues have made it increasingly difficult for states to finance their share of Medicaid costs. At least 43 states have faced or are facing budget deficits. Several states have enacted or are considering enrollment and eligibility limitations, benefit cuts, and/or reductions in provider reimbursement. The bill’s additional resources for state Medicaid programs will ensure that millions of Americans will be able to maintain their coverage or gain coverage when they otherwise would have been uninsured.

By extending COBRA benefits, the bill will also ensure that the loss of one’s job does not automatically mean that health insurance coverage will be interrupted or unaffordable. Millions will be able to maintain the private health insurance coverage they currently have for themselves and their families.

These temporary extensions of health care benefits during this time of economic turmoil, however, must only be a first step. We must continue to work together to ensure that all Americans have access to quality, affordable health care insurance.

Michael D. Maves, MD, MBA, Executive Vice President, CEO
We further applaud actions by the committees to pave the way for the widespread adoption of health information technology (HIT). The AMA supports accelerating the transition to a connected, nationwide HIT infrastructure and the use of HIT as a means to improve patient safety, advance care coordination, and increase administrative efficiency. We believe that the federal government has a crucial role in assisting the health care industry to accelerate the adoption and implementation of HIT systems and tools. When implemented properly in a connected environment, widespread HIT adoption will transform the practice of medicine and provide physicians with a powerful tool by putting real-time, clinically relevant patient information and up-to-date clinical decision support tools in practitioners’ hands at the point of care.

Two of the largest barriers to the adoption of HIT by physicians have proven to be the lack of interoperability standards and the paucity of resources available to help them purchase HIT systems. This legislation makes major strides in addressing both of these barriers through the adoption of standards and a significant commitment of resources. We are pleased to support your efforts in this regard. We look forward to working with you, other members of Congress, and the new Administration to ensure that these provisions are implemented in a timely manner that benefits patients and is achievable for the physicians who care for them.

It goes without saying that the health care system as a whole, and Medicare in particular, face many challenges. The need to address pending Medicare physician reimbursement cuts of more than 20 percent next year must remain a top priority. We must continue work closely together to ensure that affordable, high-quality care is available to every American.

Sincerely,

Michael D. Maves, MD, MBA
Whereas, Health insurance companies and self-insured plans, through their third-party administrators, are offering fixed-fee schedules or “take it or leave it” fee schedules to physicians, with no chance of negotiations; and

Whereas, More and more physicians are choosing to go out of network; and

Whereas, The Attorney General (AG) of New York (NY) investigated and settled with UnitedHealth Group and its for-profit subsidiary Ingenix, which sells out-of-network rates to health insurance companies; and

Whereas, The NY AG's investigation showed that the Ingenix information was on average 28 percent lower than usual, customary, and reasonable charges throughout different regions of the United States and agreed to stop this service to insurance companies; and

Whereas, Many health insurance companies use Ingenix data for out-of-network pricing which is costing Texas patients more money out of pocket; and

Whereas, Our American Medical Association (AMA) has joined a class-action lawsuit with other state associations against CIGNA, Aetna and WellPoint for using flawed Ingenix information; and

Whereas, Patient responsibility for out-of-network services is not clearly transparent in the benefit communication to patients from the health insurance company; therefore be it

RESOLVED, That our American Medical Association support state and federal legislation and regulation mandating clear and transparent health insurance company language so that prudent lay persons know their financial responsibility when receiving care out of network (Directive to Take Action); and be it further

RESOLVED, That our AMA seek legislation and regulation necessary to assure clear and transparent language describing patient financial responsibility for patients covered by self-funded ERISA plans subjecting such plans to stricter regulation by the US Department of Labor, Internal Revenue Service (IRS), and US Attorney General. (Directive to Take Action).

Fiscal Note: Implement accordingly at estimated staff cost of $18,688.

Received: 05/06/09
RELEVANT AMA POLICY

D-180.985 Health Plan and Insurer Transparency
Our AMA will: (1) continue to closely monitor any new "transparency" programs unveiled by health plans to determine the impact on physicians; (2) communicate to health plans, employers and patients our concerns about current "transparency" programs, and educate them about "true transparency"; and (3) continue to educate physicians about the complexities of claims adjudication and payment processes to enable them to more efficiently manage their practices. (BOT Rep. 19, A-06; Reaffirmation A-07)
H-165.846 Adequacy of Health Insurance Coverage Options
Our AMA supports the following principles to guide in the evaluation of the adequacy of health insurance coverage options: 1. Any insurance pool or similar structure designed to enable access to age-appropriate health insurance coverage must include a wide variety of coverage options from which to choose. 2. Existing federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations) should be used as a reference when considering if a given plan would provide meaningful coverage. 3. Provisions must be made to assist individuals with low-incomes or unusually high medical costs in obtaining health insurance coverage and meeting cost-sharing obligations. 4. Mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services. (CMS Rep. 7, A-07; Reaffirmation I-07)

D-180.985 Health Plan and Insurer Transparency
Our AMA will: (1) continue to closely monitor any new "transparency" programs unveiled by health plans to determine the impact on physicians; (2) communicate to health plans, employers and patients our concerns about current "transparency" programs, and educate them about "true transparency"; and (3) continue to educate physicians about the complexities of claims adjudication and payment processes to enable them to more efficiently manage their practices. (BOT Rep. 19, A-06; Reaffirmation A-07)
A Bill to assure that Health Benefit Plans disclose information to enrollees and prospective enrollees to allow informed decisions on plan selection and continuation in a health benefit plan.

**SHORT TITLE** -- This Act may be cited as the "Health Benefit Plan Disclosure Act".

Sec. 1. Notice. -- Health benefit plans must provide a Notice, in a clear and concise format and in bold type on the front page of all marketing materials and policies, that explicitly details any limitations in choice of primary care physicians and access to specialists and also describes the method(s) of physician payment.

Sec. 2. Disclosure Requirements. -- Health benefit plans must provide to all prospective enrollees prior to enrollment and to all current enrollees at least 30 days prior to annual renewal of the plan, written information describing the terms and conditions of the plan to enable enrollees to make informed decisions regarding their choice of a system of health care delivery. Where the plan is described orally to enrollees, easily understood, truthful, objective, and consumer-tested terms must be used. The written plan description must be provided at the same time as any oral description of the plan. All written plan descriptions must be in a readable, easily understood, and, objective, consumer-tested format, consistent with standards developed for supplemental insurance coverage under Title XVIII of the Social Security Act. The format must be standardized so that customers can compare the attributes of the plans. The following specific information must be communicated:
(A) coverage provisions, benefits, and any exclusions by category of service, provider or physician, and if applicable, by specific service;

(B) any and all authorization or other review requirements, including, but not limited to, preauthorization review, concurrent review, post-service review, post-payment review and any procedures that may lead the patient to be denied coverage for or not be provided a particular service;

(C) financial arrangements, incentives or contractual provisions with hospitals, review companies, physicians or any other provider of health care services that could limit or induce the limitation of the services offered, restrict referral or treatment options, or negatively affect a physician's fiduciary responsibility to his or her patients, including but not limited to capitation, discounted fee-for-service, salary arrangements and any other method that could serve to restrict the provision of medical or other services;

(D) explanation of how plan makes determinations of whether a service or item is covered including policy regarding new and emerging technology;

(E) explanation of limitations impact enrollees, including restrictions limiting coverage to certain physicians, providers or facilities and information on
enrollee financial responsibility for payment for coinsurance or other costs associated with non-covered or out-of-plan services;

(F) description of grievance and appeal procedures available under the plan and any requirements for further appeals authorized by law and the percentage of appeals where the plan's initial determination has been reversed;

(E) medical benefit/loss ratio of the plan and an explanation that such ratio reflects the percentage of premiums expended for health services as compared to total premiums; and

(F) annual enrollee and provider satisfaction statistics (including, but not limited to, percent re-enrollment statistics and reasons for leaving the plan).

(G) Health benefit plans must publish or make available upon request to physicians and current and prospective beneficiaries the following information:

(i) Payment policies, including, but not limited to payment rates, use of payment modifiers, coding rules, bundling rules, global surgical policies, and the methodologies used in developing these payment policies;
(ii) Payment schedules and fee schedules; and

(iii) Utilization review criteria, including the screening criteria, weighting elements and computer algorithms utilized in the review process and their method of development.

Sec. 3. Definitions.

(A) Health Benefit Plan. -- For purposes of this Act, the term "health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, except such term does not include any of the following -

(i) coverage only for accident, dental, vision, disability income, or long-term care insurance, or any combination thereof,

(ii) medicare supplemental health insurance,

(iii) coverage issued as a supplement to liability insurance,

(iv) worker’s compensation or similar insurance, or
(v) automobile medical payment insurance, or any combination thereof.

(B) Health Carrier - The term `health carrier' means an entity subject to the insurance laws and regulations of this state that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan or health insurance, health benefits or health services.
A bill to assure that Health Benefit Plans provide access to medically necessary services to their enrollees.

SHORT TITLE -- This Act may be cited as the "Patient Access to Needed Health Care Act".

Sec. 1. Access to physicians and facilities -- Health Benefit Plans must demonstrate reasonable access to physicians and other providers within the geographic area covered by the plan, and ensure that all covered health care services are provided in a timely fashion, by establishing standards, such as physician/patient ratios, to ensure enrollees reasonable access to primary care physicians, specialty and subspecialty care, routine, urgent, and emergency care, and needed services of other providers. This requirement cannot be waived and must be met in all areas, including rural or underserved areas, where the plan has enrollees. Plans must assure access to necessary specialist, subspecialties and facilities with special expertise in dealing with chronic and other special medical conditions.

Sec. 2. Non-Discrimination -- Health Benefit Plans shall not discriminate against enrollees with expensive, long-term, or chronic medical conditions by excluding practitioners with practices containing a substantial number of such patients;
Sec. 3. Medical Gag Clause Prohibition -- (a) No Health Benefit Plan, independent practice association, other entity contracting with a health benefit plan for the provision of medical professional services, or any other entity, shall prohibit or restrict any medical provider from disclosing to any subscriber, enrollee or member any medically appropriate health care information that such medical provider deems appropriate regarding the nature of treatment, risks or alternatives thereto, the availability of alternate therapies, consultation, or test, the decision of any plan to authorize or deny services, or the process the plan or any person contracting with the plan uses, or proposes to use, to authorize or deny health care services or benefits. Any such prohibition or restriction contained in contract with a medical provider is contrary to public policy and shall be void and unenforceable.

(b) Prohibition against discrimination or retaliation for providing appropriate health care information or advocating medically appropriate health care. Upon the application and rendering by any person of a decision to terminate an employment or other contractual relationship with or otherwise penalize a physician, surgeon or medical provider, that person shall be prohibited from denying such an application or terminating that relationship principally for advocating medically appropriate health that is consistent with that degree of learning and skill ordinarily possessed by reputable physicians, surgeons and medical providers practicing according to the applicable legal standard of care.

(c) This section shall not be construed to prohibit a health benefit plan from making a determination not to pay for a particular medical treatment or service, or to prohibit a
medical group, independent practice association, preferred provider organization, foundation, hospital medical staff, hospital governing body, or payer from enforcing reasonable peer review or utilization review protocols or determining whether a physician, surgeon or medical provider has complied with those protocols.

(d) For purpose of this section "to advocate medically appropriate health care" shall mean to appeal a payor's decision to deny payment for a service pursuant to the reasonable grievance or appeal procedure established by a medical group, independent practice association, preferred provider organization, foundation, hospital medical staff and governing body, or payor, or to protest a decision policy, or practice that the physician, consistent with that degree of learning and skill ordinarily possessed by reputable physicians practicing according to the applicable legal standard of care, reasonably believes impairs the physician's ability to provide medically appropriate health care to his or her patients.

Sec. 4. Financial Incentives -- (a) Any plan that operates a physician incentive plan must meet the following requirements:

(i) no specific payment may be offered directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to an individual patient;
(ii) if the plan places a physician or physician group at financial risk for services not provided by the physician or physician group, the plan shall provide stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary of Health and Human Services, that take into account the number of physicians placed at such financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or physician group.

(b) Physician Incentive Plan. -- For purposes of this Act, "physician incentive plan" means any compensation arrangement between the plan and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to an individual or individuals enrolled in the plan.

Sec. 5. Choice Requirements for Point of Service Plans --

(a) Each sponsor of a health benefit plan that offers a plan that restricts access to providers or controls utilization, including plans provided, offered, or made available by insurance companies to individuals and plans offered by group health purchasing entities, employers, and self-insurers, shall offer to all eligible enrollees the opportunity to obtain from the plan or some other source, coverage for out-of-network services through a "point of service" plan, as defined by subsection (b), at the time of enrollment and at least for a continuous one-month period annually thereafter.
(b) For purposes of this Act, an "out-of-network" or "point of service" plan means a plan that provides additional coverage and/or access to care to non-network providers to an eligible enrollee of a health plan that restricts access to items and services provided by a health care provider who is not a member of the plan's provider network (as defined in subsection (c)), or, that may cover any other services the enrollee seeks, whether such services are provided in or outside of the enrollee's plan.

(c) A "provider network" means, with respect to a health benefit plan that restricts access or controls utilization, those providers who have entered into a contract or agreement with the plan under which such providers are obligated to provide items and services to eligible individuals enrolled in the plan, or have an agreement to provide services on a fee-for-service basis.

(d) A plan may charge an enrollee who opts to obtain point of service coverage an alternative premium that reflects no more than the actuarial value of such coverage.

(e) A point of service plan may require payment of coinsurance for an out-of-network item or service with the applicable coinsurance percentage not to be greater than 20 percent of payment for items and services.

Sec. 6. Emergency Services -- Health Benefit plans may not require prior authorization for emergency service, including a medical screening exam and stabilizing treatment as
defined in Section 1867 of the Social Security Act. Any prior authorization requirement for medically necessary services arising from such screening exam or stabilizing treatment shall be deemed to be approved unless a required request is denied within 45 minutes. Other patient or physician requests for prior authorization of a non-emergency service must be answered within two business days, and qualified personnel must be available for same-day telephone responses to inquiries about medical necessity, including qualification of continued length of stay;

For purposes of this Section, "emergency services" means those health care items or services that are provided in an emergency facility to the extent that they are required to treat an emergency medical condition.

For purposes of this section "emergency medical condition" means a medical condition, the sudden onset of which is sudden, that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in:

(1) placing the patient's health in serious jeopardy;

(2) serious impairment to bodily functions; or

(3) serious dysfunction of any bodily organ or part.
Sec. 7. Continuity of Care -- (a) A Health Benefit Plan shall develop a policy to provide for the continuity of care for its enrollees.

(b) Enrollees who are receiving a course of treatment or who have selected a physician or provider who participated in the plan or whose services were covered by the plan or whose name was contained in a list of participating physicians and providers at the time the enrollee selected the physician or provider shall receive notice, no less than 30 days prior to the termination of participation of the physician or provider, individual provider within a medical group or an individual practice association.

(c) The written policy required by subsection (a) shall describe how the health plan shall facilitate the continuity of care for new enrollees receiving services during a current episode of care for an acute condition from a nonparticipating physician or provider and current enrollees when the participation of a physician or provider described in subsection (b) is terminated. The policy shall also describe procedures to be used by the enrollee to request to continue services. In determining whether to continue services, the policy shall ensure that reasonable consideration is given to the potential clinical effect that a change of physician or provider would have on the enrollee's treatment for the acute condition.

(d) A health benefit plan may require a nonparticipating physician or provider whose services are covered by the continuity of care policy to agree to meet the same contractual conditions and requirements as participating physicians and providers.
(e) Nothing in this section shall require a health benefit plan to cover services or provide benefits that are not otherwise covered under the terms and provisions of the plan.

(f) This section shall not apply to an enrollee who is offered an out-of-network option or for new enrollees, had the option to continue with his/her previous health plan or provider and chose to change health benefit plans voluntarily.

Sec. 8. Post-Partum Care -- (a) A Health Benefit Plan that provides maternity benefits, including benefits for child birth, shall provide coverage for the inpatient care of a mother and her newborn which is determined to be medically necessary by the attending physician following a vaginal delivery or a cesarean section.

(b) A Health Benefit Plan that provides maternity benefits, including benefits for child birth, is prohibited from offering or providing monetary incentives to new mothers to leave the inpatient care setting before the time period determined by the attending physician to be medically necessary.

(c) A Health Benefit Plan that provides maternity benefits, including benefits for child birth, is prohibited from deselecting, terminating the services of, requiring additional utilization review, reducing payments or otherwise providing financial disincentives to
any attending physician who orders inpatient care for a mother or her newborn which in his or her judgment is medically necessary.

(d) A Health Benefit Plan shall provide notice to each covered person under such plan regarding the coverage required by this section. Such notice shall be in writing and prominently positioned in any literature or correspondence made available or distributed by the health carrier and shall be transmitted: in the next mailing made by the health carrier to the covered person, as part of the yearly informational packet sent to the covered person, or not later than 1 year, whichever is earlier.

(e) For purposes of this Section, the term "Attending Physician" means the obstetrician-gynecologist, pediatrician or other physician attending the mother or newborn child.

Sec. 9. Coverage of Post-Mastectomy Breast Reconstruction. -- (a) Every Health Benefit Plan which provides for the surgical procedure known as a mastectomy shall include coverage for prosthetic devices and reconstructive surgery, including surgery on the operated breast and the contralateral breast, to restore and achieve symmetry for the patient incident to the mastectomy.

(b) Coverage for prosthetic devices and reconstructive surgery shall be subject to the deductible and coinsurance conditions applied to the mastectomy and all other terms and conditions applicable to other benefits.
(c) For purposes of this section the term "mastectomy" means the removal of all or part of the breast for medically necessary reasons, as determined by a licensed physician and surgeon.

Sec. 10. Definitions.

(A) Health Benefit Plan. -- For purposes of this Act, the term "health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, except such term does not include any of the following -

(i) coverage only for accident, dental, vision, disability income, or long-term care insurance, or any combination thereof,

(ii) medicare supplemental health insurance,

(iii) coverage issued as a supplement to liability insurance,

(iv) worker`s compensation or similar insurance, or

(v) automobile medical payment insurance, or any combination thereof.

(B) Health Carrier - The term `health carrier` means an entity subject to the insurance laws and regulations of this state that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for or
reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan or health insurance, health benefits or health services.
A bill to assure fairness in health benefit plans.

SHORT TITLE -- This Act may be cited as the "Fairness in Health Care Act".

Sec. 1. Grievance and Appeal Procedures -- Health Benefit Plans shall establish grievance and appeal procedures for enrollees and providers within the plan. Such procedures shall provide for initial review and attempt to address any problem, grievance or denial within the plan. If a final determination within the plan is against the position of the enrollee, the plan shall provide for a review of its decision by an entity or individual independent of the plan.

Sec. 2. The plan shall establish mechanisms for soliciting and acting upon applications for physician, other practitioners, providers and facilities seeking participation in the plan in a fair and systematic manner, initially upon formation of the plan and thereafter on an annual basis, consistent with the plan's business needs, capacity, and objectives. These mechanisms shall include, but not be limited to:

(a) making available to applicants the objective standards that will be used in determining participation in the plan, including education, training, background, experience, professional disposition, demonstrated competence, and demonstrated quality. When graduate medical education is a consideration in physician credentialing, equal recognition will be given to training programs
accredited by the Accrediting Council on Graduate Medical Education and by the American Osteopathic Association. Other relevant factors may be considered, including, but not limited to, membership and clinical privileges at a particular hospital, membership in a particular medical group, professional liability insurance requirements, the number of physicians in a given specialty needed by the plan, and the economics or capacity of a physician's practice;

(b) a mechanism for ensuring review of applications;

(c) when the economics and capacity of a physician's practice are used as a credentialing factor, the applicable criteria must be documented, and made available to the applying physician. Any economic or capacity profiling of a physician must be adjusted to recognize case mix, severity of illness, age of patients and other features of a physician's practice that may account for higher than or lower than expected costs or utilization of services;

Sec. 2. Health Benefit Plans shall not base physician participation decisions on gender, race, creed, national origin, or any other factor prohibited by law.

Sec. 3. The same credentialing considerations that apply to the granting or initial participation status shall apply to renewals.
Sec. 4. Plans shall establish mechanisms to assure basic fairness in processing applications for initial participation and in making decisions that adversely affect participation status. These mechanisms shall include:

(a) provisions to receive a written statement of reasons, and to have an opportunity to respond, either in writing or at a meeting, before a final decision is made by the governing body to deny an application for initial participation or renewal. If the action that is under consideration by the governing body is of a type that must be reported to the National Practitioner Data Bank or to a state medical board under federal or state law, the physician's procedural rights, at a minimum, must meet the standards of fairness contemplated by the federal Health Care Quality Improvement Act of 1986, 42 U.S.C. § 11101-11152;

(b) provisions to ensure that prior to initiation of termination, or denial or restriction of participation in the plan based on utilization of services or economic criteria, the physician shall receive a written statement of reasons, which must take into consideration and recognize the physician's case mix, severity of illness, age of patients, and other features of the physician's practice that may account for higher or lower than expected costs. The physician shall have the opportunity to respond either in writing or at a meeting.

Sec. 5. Definitions.

(A) Health Benefit Plan. -- For purposes of this Act, the term "health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a
health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of
health care services, except such term does not include any of the following -

(i) coverage only for accident, dental, vision, disability income, or
long-term care insurance, or any combination thereof,

(ii) medicare supplemental health insurance,

(iii) coverage issued as a supplement to liability insurance,

(iv) worker’s compensation or similar insurance, or

(v) automobile medical payment insurance, or any combination thereof.

(B) Health Carrier - The term ‘health carrier’ means an entity subject to the insurance
laws and regulations of this state that contracts or offers to contract, or
enters into an agreement to provide, deliver, arrange for, pay for or
reimburse any of the costs of health care services, including a sickness
and accident insurance company, a health maintenance organization, a
nonprofit hospital and health service corporation, or any other entity
providing a plan or health insurance, health benefits or health services.
A bill to assure that Health Benefit Plans maintain appropriate procedures to insure quality of care.

**SHORT TITLE** -- This Act may be cited as the "Quality Review in Health Benefit Plans Act".

Sec. 1. (a) All Health Benefit Plans that have a utilization review program must have a physician (MD or DO) medical director responsible for all clinical decisions by the plan based on recommendations made by reviewers meeting the criteria established under (c) and provide assurances that the medical review or utilization practices they use, and the medical review or utilization practices of payers or reviewers with whom they contract meet the requirements established under (b) through (g).

(b) Screening criteria, weighting elements, and computer algorithms utilized in the review process and their method of development, must be based on sound scientific principles and developed in cooperation with practicing physicians and other affected health care providers. Such criteria must be released upon request to enrollees, physicians, other practitioners and facilities. Plans can require that those receiving proprietary information enter into confidentiality agreements.
(c) Any person who recommends denial of coverage or payment, or determines that a service should not be provided, based on medical necessity standards, must be of the same medical branch (allopathic/osteopathic medicine for physicians) and related specialty (specialties as recognized by the American Board of Medical Specialties, the American Osteopathic Association or such other recognized equivalent) as the practitioner who provided the service;

(d) Each claimant and physician or other provider (upon assignment of a claimant) who has had a claim denied as not medically necessary or appropriate must be provided a written statement of reasons for the decision, which must be clearly documented in the permanent case record, whether such record is automated or manual. The written determination letter shall include a general description of the reason the service was denied, an explanation of both the claimant's and physician's appeal rights, and instructions for both the claimant and physician to appeal to the plan's utilization review director, medical director, physician peer review committee, or other appropriate person or entity designated by the plan.

(e) The final determination of a plan's denial of services or benefits based on lack of medical necessity or appropriateness must be made or reviewed by a physician fully licensed to practice medicine with such review provided in accordance with relevant laws or regulations of the jurisdiction in which the claim arose. Physicians and claimants have the right to have reviewed any final denial of services or benefits based on lack of medical necessity or appropriateness, as determined by the physician, where
possible by a physician independent of the health plan, who is of the same specialty as that relevant to the denied service or benefit, and has appropriate experience and expertise in the field;

(f) Upon request, physicians will be provided the names and credentials of all individuals conducting medical necessity or appropriateness review, subject to reasonable safeguards and standards;

(g) Health Benefit plans may not require prior authorization for emergency services, including a medical screening exam and stabilizing treatment as defined in Section 1867 of the Social Security Act. Any prior authorization requirement for medically necessary services arising from such screening exam or stabilizing treatment shall be deemed to be approved unless a required request is denied within 45 minutes. Other patient or physician requests for prior authorization of a non-emergency service must be answered within two business days, and qualified personnel must be available for same-day telephone responses to inquiries about medical necessity, including qualification of continued length of stay;

For purposes of this Act, "emergency services" means those health care items or services that are provided in an emergency facility to the extent that they are required to treat an emergency medical condition.
For purposes of this Act "emergency medical condition" means a medical condition, the sudden onset of which is sudden, that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in:

(1) placing the patient's health in serious jeopardy;

(2) serious impairment to bodily functions; or

(3) serious dysfunction of any bodily organ or part.

(h) When prior approval for a service or other covered item is obtained, it shall be considered approval for all purposes, and the service shall be considered to be covered unless there was fraud or incorrect information provided at the time such prior approval was obtained.

(i) For purposes of this Act, the term "utilization review program" means a system of review, using guidelines, of the medical necessity, appropriateness, or quality of health care services and supplies provided under a health benefit plan. Such a system includes, but is not limited to, preadmission certification, the application of practice guidelines, continued stay review, discharge planning, preauthorization of ambulatory procedures, and prospective, concurrent, and retrospective review.
Sec. 2. Definitions.

(A) Health Benefit Plan. -- For purposes of this Act, the term "health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, except such term does not include any of the following -

(i) coverage only for accident, dental, vision, disability income, or long-term care insurance, or any combination thereof,

(ii) medicare supplemental health insurance,

(iii) coverage issued as a supplement to liability insurance,

(iv) worker’s compensation or similar insurance, or

(v) automobile medical payment insurance, or any combination thereof.

(B) Health Carrier - The term `health carrier' means an entity subject to the insurance laws and regulations of this state that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a
nonprofit hospital and health service corporation, or any other entity providing a plan or health insurance, health benefits or health services.
A bill to assure that there is adequate involvement of physicians and other health care professionals in the medical determinations of health benefit plans.

SHORT TITLE -- This Act may be cited as the "Physician involvement in Health Benefit Plan Act".

Sec. 1. All health benefit plans shall be required to establish a mechanism, with defined rights, under which physicians and other health care practitioners participating in the plan provide input into the plan's medical policy (including coverage of new technology and procedures), utilization review criteria, referral practices and procedures (including the selection of both facilities and practitioners that enrollees may be referred to for covered services), quality and credentialing criteria, and medical management procedures.

Sec. 2. All health benefit plans must have a physician (MD or DO) medical director responsible for all clinical decisions by the plan using procedures and protocols based upon input from the physicians and other health care practitioners in the plan.

Sec. 3. Any person who recommends denial of coverage or payment, or determines that a service should not be provided, based on medical necessity standards, must be
of the same medical branch (allopathic/osteopathic medicine for physicians) and related specialty (specialties as recognized by the American Board of Medical Specialties, the American Osteopathic Association or such other recognized equivalent) as the practitioner who provided the service.

Sec. 4. The final determination of a plan's denial of services or benefits based on lack of medical necessity or appropriateness must be made or reviewed by a physician fully licensed to practice medicine with such review provided in accordance with relevant laws or regulations of the jurisdiction in which the claim arose.

Sec. 5. Enrollees and physicians and other practitioners have the right to have reviewed any final denial of services or benefits based on lack of medical necessity or appropriateness, as determined by the physician, where possible by a physician independent of the health plan, who is of the same specialty as that relevant to the denied service or benefit, and has appropriate experience and expertise in the field.

Sec. 6. To comply with the requirements of Section 1, health benefit plans may establish a Physician Executive Committee of no less than 5 members, comprised entirely of participating physicians (MDs, DOs). Such Physician Executive Committees shall meet the following requirements:

(i) Membership and leadership shall be determined initially by the governing body of the plan for a period not to exceed ninety days.
Thereafter, the membership and leadership, and rules governing the operation of the Physician Executive Committee, shall be determined solely in accordance with rules to be adopted by the Physician Executive Committee, whose members shall be elected by and come from the physicians participating in the plan.

(ii) The responsibilities of the Physician Executive Committee shall be to provide input into the plan's medical policies (including the range of services and the use of new technologies and procedures for providing care to enrollees), to provide input into the plan's utilization review program and quality assurance program, to conduct credentialing and peer review activities and make recommendations to the governing body regarding initial and ongoing physician participation, and to serve as a liaison between the governing body and participating physicians regarding matters of mutual interest and concern.

(iii) The Physician Executive Committee shall have reasonable discretion in discharging its responsibilities, including the authority to appoint standing and ad hoc committees, which where appropriate will include a panel of enrollees, and to adopt rules, policies, and procedures. Approval by the governing body of rules, policies and procedures recommended by the Physician Executive Committee in carrying out its responsibilities shall not be unreasonably withheld.
Sec. 7. Definitions.

(A) Health Benefit Plan. -- For purposes of this Act, the term "health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, except such term does not include any of the following:

(i) coverage only for accident, dental, vision, disability income, or long-term care insurance, or any combination thereof,

(ii) medicare supplemental health insurance,

(iii) coverage issued as a supplement to liability insurance,

(iv) worker`s compensation or similar insurance, or

(v) automobile medical payment insurance, or any combination thereof.

(B) Health Carrier - The term `health carrier` means an entity subject to the insurance laws and regulations of this state that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a
nonprofit hospital and health service corporation, or any other entity providing a plan or health insurance, health benefits or health services.
A bill to assure that Americans have choice in the selection of health benefit plans and physicians and other health care providers.

SHORT TITLE -- This Act may be cited as the "Patient Choice in Health Care Plans Act".

Sec. 1. Nothing in this Act or any other State law shall be construed as prohibiting an individual from purchasing any health care services with that individual's own funds, whether such services are covered under the individual's health benefit plan or any other health care provider or plan.

Sec. 2. (a) In the individual health insurance market, each health carrier that offers, available such benefit plan must provide a choice of health plans among available plans.

(b) Offering of Plans by plan sponsors. Each voluntary health insurance purchasing entity or health carrier shall include among its health plan offerings at least one of each of the following types of health benefit plans, where available:

(A) A health maintenance organization or preferred provider organization;

(B) A traditional insurance plan (as defined in paragraph (c));

(C) A benefit payment schedule plan (as defined in paragraph (d)); and

(D) A medical savings account.
(c) Traditional insurance plan defined. For purposes of this act, the term "traditional insurance plan" is defined to include those plans that pay for medical services on a fee-for-service basis using a usual, customary or reasonable payment methodology or a resource based relative value schedule, usually linked to an annual deductible and/or coinsurance payment on each allowed amount.

(d) Benefit payment schedule plan defined.

   (1) In general. For purposes of this Act, the term "benefit payment schedule plan" means a health plan that--

   (i) provides coverage for all items and services included in the benefit package that are furnished by any lawful health care provider of the enrollee's choice (within the scope of state licensure);

   (ii) makes payment for the services of a provider on a fee-for-service basis without regard to whether or not there is a contractual arrangement between the plan and the provider;

   (iii) provides a benefit payment schedule that identifies covered services and the payment for each service covered by the plan. No co-payments or coinsurance shall be applied. The plan shall reimburse the enrollee the payment unless the individual authorizes direct payment to the provider.

Sec. 3. Nondiscrimination Based on Price of Coverage Selected.

(a) If an employer provides a financial contribution to the cost of a health benefit plan, the employer may not vary the dollar amount of any employer contribution, within
a class of family coverage, with respect to such coverage for an individual employee, solely on the basis of the total premium price of the coverage selected by the employee.

(b) For the purposes of subsection (a) the "total premium price" shall include, in the case of a medical saving account, amounts paid by an employer for any high deductible health insurance coverage and amounts paid into a medical savings account.

(c) Nothing in this section is to be construed as requiring an employer to make any contribution to the cost of health coverage.

Sec. 4. Health Plan Purchasing Cooperatives.

(a) Health Plan Purchasing Cooperatives may be established to facilitate the availability of health benefit plans. Each purchasing cooperative shall be charted under State law and operate as a not-for-profit entity. Each cooperative shall establish its own membership, but must accept small employers, their eligible employees and individuals who request membership in the cooperative.

(b) Each purchasing cooperative shall: enter into agreements with health benefit plans regarding the offering of such plans; provide information to its members regarding the benefits and costs of such plans; enroll members with plans being offered; and collect premiums from members to be forwarded to plans.

(c) A health benefit plan may not form, underwrite or possess a majority vote of the purchasing cooperative nor may a cooperative assume financial risk in relation to any health benefit plan.
(d) This section is not to be construed as requiring the establishment of health plan purchasing cooperatives nor shall this section be construed to limit the number of cooperatives in any area.

Sec. 5. Definitions.

(A) Health Benefit Plan. -- For purposes of this Act, the term "health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, except such term does not include any of the following -

(i) coverage only for accident, dental, vision, disability income, or long-term care insurance, or any combination thereof,

(ii) medicare supplemental health insurance,

(iii) coverage issued as a supplement to liability insurance,

(iv) worker`s compensation or similar insurance, or

(v) automobile medical payment insurance, or any combination thereof.

(B) Health Carrier - The term `health carrier' means an entity subject to the insurance laws and regulations of this state that contracts or offers to contract, or enters into an agreement to provide, deliver, arrange for, pay for or
reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan or health insurance, health benefits or health services.
of the
American Medical Association
to the
Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives

Re: Price Transparency in the Health Care Sector

July 18, 2006

Division of Legislative Counsel
202 789-7426
The American Medical Association (AMA) is pleased to offer the perspective of our practicing physician members on the issue of price transparency in the health care sector. We have long supported efforts to promote transparency and consumer driven health care. We believe that empowering patients with understandable price information and incentives to make prudent choices will strengthen the health care market. To that end, we believe that all methods of physician payment should incorporate mechanisms to foster increased cost-awareness by both providers and recipients of service. Disclosure of price information, however, can only be meaningful if, in addition to disclosure of physician fees, there is disclosure of insurance claims processing and payment practices. Without transparency on the part of health plans and insurers, both patients and physicians suffer.

TRANSPARENCY FOR PATIENTS

In order to facilitate cost-conscious, informed market-based decision-making in health care, physicians, hospitals, pharmacies, durable medical equipment suppliers, and other health care providers should make information readily available to consumers on fees/prices charged for frequently provided services, procedures, and products prior to the provision of such services, procedures, and products. Any requirement for providing price information, however, must extend to health plans and insurers, such that they will make available to enrollees and prospective enrollees information, in a standard format, on the amount of payment provided toward each type of service identified as a covered benefit.

Because much of the public discussion over transparency reflects a misunderstanding of the relevant common terms and the way in which physician claims are adjudicated and paid, the discussion often focuses on physicians disclosing their “fees” while failing to confront the serious problem of lack of transparency with the claims and payment processes. Drawing inferences about physician fees based upon submitted charge data, however, is misleading and inappropriate because actual payment from Medicare and private insurers is substantially lower than physician submitted charges. Thus, it is essential that any discussion of
transparency confront the various misunderstandings related to relevant physician claims adjudication and payment terms.

The distinction between various terms related to physician payment is critical as they are often mistakenly used interchangeably, leading to fundamental misconceptions about the costs of health care. Physician billed charges, or the “physician fee schedule,” for example, are the physician’s actual charges for a service or procedure. They reflect the physician’s costs of providing the services and procedures, which includes the value the physician assigns to his or her work, as well as the substantial overhead costs of running a practice. The physician billed charges, however, is not the amount the physician is paid. After a physician submits a claim with the physician billed charges, the health plan or insurer’s adjudication system determines patient eligibility, matching, and coverage of the services. The plan or insurer then reduces the physician’s billed charge on a claim in two ways. First, it determines and applies the health plan fee schedule under the contract. Second, it applies automatic payment and payer-specific proprietary edits, which reduce the health plan fee schedule. This becomes the “allowed amount.” The health plan allowed amount is the total amount of payment the physician will receive from the health plan or insurer and the patient. This amount is distinct from the “health plan amount paid,” which is the amount the physician receives just from the health plan or insurer—the allowed amount minus any co-payment, deductible, or coinsurance that the physician should receive from the patient.

Given the complex procedures related to claims adjudication and payment and the many similar but distinct terms associated with these procedures, it is easy to see how patients could be easily confused and misled if they only get pieces of the health care claims processing and payment puzzle. For example, health plans and insurers often publish physician charges as part of publishing “allowable payment.” This practice could easily lead patients to misconstrue the difference in allowable payment and a physician’s actual charge as an attempt by the physician to overcharge the patient. Misunderstanding could also occur with publication of “physician fee schedules,” as they overstate the amount physicians actually receive as payment from the health plan or insurer for services and procedures.

Given this enormous potential for confusion, misunderstanding, and dissimulation, we believe that true and accurate transparency can only be achieved if health plan’s and insurer’s medical payment policies, claim edits, and benefit plan provisions are embedded in their fee schedules or “negotiated rates,” and are made available to patients. Failure to provide such information is specious and misleading, and rather than making the system more transparent, simply perpetuates its current opacity.

**TRANSPARENCY FOR PHYSICIANS**

The AMA believes that disclosure of information on pricing must extend to all components of the health care system. Patients are not the only ones kept in the dark regarding physician payments. Physicians, themselves, often have no idea what payment they will receive from a health plan or insurer, making it impossible for them to provide patients with price transparency at the point of service. This is because of a pervasive refusal by payers to disclose information regarding what they pay and how they pay it. This deliberate and
systematic effort to conceal payment information means physicians are frequently unaware of what they will be paid for any given service, and they have no way to get the information that would enable them to challenge health plan or insurer payment decisions.

Physician reimbursement is based on a complex array of factors, most of which are outside a physician’s control or knowledge. In recent years, physicians have faced increasingly aggressive strategies by payers to contain costs through systemic reductions in reimbursement. This means that payers pay what they want, often as little as 30 cents on the dollar. The other 70 cents typically is consumed by authorized and unauthorized discounts and various code-editing practices. These practices range from relatively straightforward methods to extremely complicated transactions that involve several layers of entities. In fact, in many instances, there are intermediaries that are completely unknown to the physician that take a slice of his or her reimbursement.

Some of the relatively straightforward reduction practices employed by health plan payers include unfair bundling and downcoding policies. The terms “downcoding” and “bundling” refer to unilateral changes payers apply to Current Procedural Terminology (CPT)® codes. Bundling occurs when a provider submits a claim listing multiple codes and the insurer or health plan combines two or more of the codes, effectively reimbursing the provider for fewer procedures than the physician has performed and listed on the claim. Similarly, downcoding takes place when a payer changes CPT codes submitted by a provider from codes describing higher levels of service to codes describing lower levels of service. Often, there is no consistent or logical application of these selective payer code edits. Payers simply randomly turn edits “on” and “off”—leading physicians to be paid, in some cases, 10 or more different rates for the same service without any explanation as to how or why.

More complex reduction practices result from the secondary discount market, a market that is entirely unregulated. This market consists of entities that develop health care provider panels (groups of physicians) and lease them, along with their associated provider discounts, to various health plan payers. These entities are known as “rental network PPOs” or “lease network PPOs.” Also part of the unregulated secondary discount market are entities referred to as “repricers,” whose sole purpose is to find and apply the lowest discounted rate for its client-payers, often without authorization from the physician. Together these entities manipulate the market and make it virtually impossible for physicians to predict payments, trace claims, and/or challenge payer determinations.

A rental network PPO typically works by contracting with a physician for a discounted rate based on its contractual arrangement with one or more large health plans or insurers. Then, unbeknownst to the physician, the rental network PPO rents or leases the physician’s discount information to downstream entities for a profit. This allows the payer to shop for the physician’s lowest payment rate, at which point the payer can load all of the physician’s available discounts into its claims system and pay the physician his or her lowest agreed upon rate—even if that rate is completely unrelated to the prevailing contract between the payer and the physician. Thus, the lowest discount the physician has agreed to in any single PPO agreement becomes the ceiling for payment, rendering the underlying contract meaningless and eviscerating the physician’s right to freely contract.
These wholly unregulated secondary discount entities provide no value whatsoever to the health care system. They exist solely to traffic in provider discounts and they thrive in a health care market that lacks transparency. They significantly disadvantage physician practices and undermine attempts to promote a consumer driven health care system. Indeed, the problems with this surreptitious process are even more pronounced when patients have consumer directed health plans (CDHP), such as Health Savings Accounts. CDHPs feature high deductibles, and thus patients often pay physicians directly at the point of service. This is difficult, however, when entities apply discounts under a cloak of secrecy, and there is no way for the patient or physician to determine the payer’s allowed amount. Shining a light on this unscrupulous behavior is the only way to ensure that patients have accurate, current information at their disposal to make critical well-informed decisions about the spending of their health care dollars.

The routine refusal of payers to disclose information regarding discounts, edits, and final payment amounts is unacceptable and such actions would never be tolerated in other business transactions. Moreover, there is no legitimate policy rationale behind health plan payers’ refusal to provide this information to physicians and patients. It serves only as a means to increase profits at the expense of employers, patients, and physicians.

Thus, the AMA believes that all health plan and insurance payers, as well as all intermediary organizations involved in the claims paying process, should be required to disclose fee schedule information and payment policies, including any coding methodologies used in the reimbursement process. Providing this information to physicians will not only help them to adjust and sustain their practices, it will allow them to pass essential pricing information on to patients at the point of service—furthering the worthy goal of providing patients with the tools they need to be informed, competent consumers of health care.

**CONCLUSION**

Clarifying and illuminating health care claims payment and adjudication is the only way to ensure that patients will have accurate, current information at their disposal. Such information will enable them to make informed decisions about the most priceless thing in life—their health. Moreover, bringing health care pricing information out of the dark will allow physicians to regain some control over their practices and focus on what they were trained for—treating and healing their patients.
Memo to:  Roger Brown  
From:   Andrea Garcia  
Date:   May 26, 2009  
Subject:  Resolutions for Reaffirmation, A-09 – Reference Committee D

I have reviewed the resolutions assigned to Reference Committee D for A-2009, and believe that the following resolutions are covered by existing policy. Copies of the resolutions are attached along with the existing policies recommended for reaffirmation.

**Resolution 403 – Oppose Sale of Tobacco in Pharmacies**

Resolution 403 asks that our AMA “support prohibitions on the sale of tobacco products in any store that contains a pharmacy.” AMA policy **H-495.986** covers this request. It states that our AMA …(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; (9) supports that the sale of tobacco products be restricted to tobacco specialty stores. Also, **H-495.977** supports efforts to ban the sale of tobacco products and/or tobacco by-products in retail outlets housing store-based health clinics. The AMA has communicated with various stakeholder groups on this issue, including the Campaign for Tobacco-Free Kids, American Heart Association, American Lung Association, and American Cancer Society. Since current policy and AMA activities under such policy cover the request of Resolutions 403, it has been placed on the Reaffirmation Calendar.

**H-495.986 should be reaffirmed**

**Resolution 405 – Raising the Age of Alcohol Consumption in the Territory of Guam**

Resolution 405 asks the AMA to “endorse raising the age of legal alcohol consumption to 21 years on Guam to mirror the local federal military standard and to help reduce any future adverse social impact of the impending military build up by 8,000 Marines and 22,000 support staff relocating to the small Island of Guam.” Current AMA policy **H-30.986** states that our AMA supports 21 as the legal drinking age and **H-30.989** encourages each state medical society to seek and support legislation to maintain at 21 the minimum legal drinking age. Furthermore, **D-30.996** states that our AMA will encourage Guam’s 28th legislature and the Governor of Guam to support 21 as the legal drinking age. Existing AMA policy could be utilized to address the request of Resolution 405. Therefore, it has been placed on the Reaffirmation Calendar.

**H-30.986 and D-30.996 should be reaffirmed.**
Resolution 408 - The Physicians Obligation to Identify and Treat Prenatal and Perinatal Addiction

Resolution 408 asks the AMA to do the following: (1) through its communication vehicles, encourage all physicians to increase their knowledge regarding the effects of drug and alcohol abuse during pregnancy and to communicate that information to women of reproductive age pre-conception; (2) encourage physicians to routinely inquire about alcohol, tobacco and drug use during the course of providing prenatal care; (3) encourage physicians to identify alcohol, tobacco, and drug use in their pregnant patients and provide them with treatment options best suited to their needs; and (4) collaborate with health partners across the country to study the prevalence and benefits of implementing a simple screening process. Current AMA policy addresses these requests. Under policy H-420.962, the AMA: support[s] …establishing and making broadly available specialized treatment programs for drug-addicted pregnant women wherever possible and through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol abuse during pregnancy and to routinely inquire about alcohol and drug use in the course of providing prenatal care. The AMA also reaffirms the following statement: pregnant substance abusers should be provided with rehabilitative treatment appropriate to their specific physiological and psychological needs. Policy H-95.976 states that the AMA: 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; 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; and 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. Existing AMA policy addresses the request of Resolution 408. Therefore, it has been placed on the Reaffirmation Calendar.

H-420.962 and H-95.976 should be reaffirmed.

Resolution 411 – Reduction or Elimination of Gun Violence in the Mass Media

Resolution 411 asks the AMA to “ask the Council on Science and Public Health to evaluate the feasibility and value of pursuing a multi-media campaign with the AMA Alliance and AMA Foundation to promote the reduction, and/or elimination, of gratuitous gun violence in the media as well as portraying the devastating consequences of gratuitous gun violence in films, and undertake an initiative calling for the popular media to portray responsible gun ownership and advertise this initiative in theaters, and portray leading characters demonstrating this behavior.” Current policy H-515.974 states that our AMA will speak out against the excessive portrayal of violence in the news and entertainment media, including newscasts, movies, videos, computer games, music and print outlets, and encourage the depiction of the medical, social and legal consequences of violence by the media and H-485.995 states that the AMA reaffirms its vigorous opposition to television violence. The AMA has been outspoken on this issue. In 1996, the AMA launched the Campaign to Reduce Media Violence. As a part of this campaign, the AMA published the Physician Guide to Media Violence, a 21-page booklet offering suggestions for taking a patient’s “media history” as well as tips on how to monitor media viewing. In July of 2000, the AMA partnered with the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, the American Psychological Association, the American Psychiatric Association, and the American Academy of Family Physicians to host a Congressional Public Health Summit. At this summit, the organizations released the following consensus statement: “The conclusion of the public health community, based on over 30 years of research, is that viewing entertainment violence can lead to increases in aggressive attitudes, values and behavior, particularly in children.” Existing policy and AMA activities address the request in this resolution. Therefore, it has been placed on the Reaffirmation Calendar.

H-515.974 and H-485.995 should be reaffirmed.
Please let me know if you have any questions. I can be reached at extension 4065.

Thanks,
Andrea Garcia
Whereas, San Francisco recently approved a ban on sale of any tobacco products at pharmacies doing business in the city and county, a new policy slated to take effect in October 2008 and supported by a broad range of elected officials, medical and public health authorities and organizations; and

Whereas, Philip Morris tobacco corporation and Walgreens corporation in September filed suit to stop this ban, and hearings on the lawsuits are pending this fall; and

Whereas, Tobacco remains the leading preventable contributor to morbidity and mortality in the United States and beyond, with the most effective means of preventing this harm being preventing people from starting the use of tobacco and helping those who are users to quit, with social perception of smoking an important component of clinical and public health efforts to prevent and decrease tobacco use; and

Whereas, Pharmacies are rightly seen as vendors of health-promoting products, and it is contradictory and inconsistent with good health for them to also be marketing a lethal product with no positive use; and

Whereas, The Philip Morris suit challenging the San Francisco policy argues and admits that their contracts with some pharmacies include prominent placement of advertising for tobacco and that they have found this practice to be particularly valuable in marketing to smokers; and

Whereas, Many pharmacists have joined medical and public health officials and experts in opposing sales of tobacco in pharmacies, with the CMA, California Pharmacists Association, American Pharmacists Association, and others calling for voluntary removal of tobacco from pharmacies, which has been successful in reducing the number of independent pharmacies selling tobacco, but has not decreased the number of chain pharmacies doing so; and

Whereas, Contrary to some claims, there is no evidence to date that removing tobacco from pharmacies places an economic burden upon these businesses, will pose only an inconvenience for committed/addicted smokers, and San Francisco’s new policy includes exemptions for some supermarkets and ‘big box’ chains which are not solely pharmacy retailers; and

Whereas, San Francisco’s new policy has already attracted much attention and planned emulation with other municipalities around the nation expressing interest in similar health-promoting policies; therefore be it

RESOLVED, That our American Medical Association support prohibitions on the sale of tobacco products in any store that contains a pharmacy. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/01/09
H-495.986 Tobacco Product Sales and Distribution
Our AMA: (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)
Whereas, We as physicians encourage individual responsibility rather than statute as a general rule of conduct; and

Whereas, Underage alcohol use on Guam creates both negative health and social issues; therefore be it

RESOLVED, That our American Medical Association endorse raising the age of legal alcohol consumption to 21 years on Guam to mirror the local federal military standard and to help reduce any future adverse social impact of the impending military build up by 8,000 Marines and 22,000 support staff relocating to the small Island of Guam. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09
**D-30.996 Uniform Drinking Age Standards**
Our AMA will encourage Guam’s 28th legislature and the Governor of Guam to support 21 as the legal drinking age, support 0.04 percent blood-alcohol level as per se illegal for driving, and urge incorporation of that provision in drunk driving laws in all US states and territories in accordance with AMA Policies H-30.986 and H-30.989. (Res. 404, A-05)

**H-30.986 Alcohol and the Driver**
Our AMA (1) favors public information and education against any drinking by drivers; (2) supports 0.04 percent blood-alcohol level as per se illegal for driving, and urges incorporation of that provision in all state drunk driving laws; (3) **supports 21 as the legal drinking age**, supports strong penalties for providing alcohol to persons younger than 21, and stronger penalties for providing alcohol to drivers younger than 21; (4) urges adoption by all states of legislation calling for administrative suspension or revocation of driver licenses after conviction for driving under the influence, and mandatory revocation after a specified number of repeat offenses; and (5) encourages industry efforts to develop a safety module that thwarts operation of a car by an intoxicated person. (CSA Rep. A, A-85; Reaffirmed by CLRPD Rep. 2, I-95; Modified: Sub. Res. 401, I-97; Reaffirmed: BOT Rep. 17, A-01)

**H-30.989 Nationwide Legal Drinking Age of 21 Years**
The AMA (1) encourages each state medical society to seek and support legislation to maintain at 21 the minimum legal drinking age; and (2) urges all physicians to educate their patients about the dangers of alcohol abuse and operating a motor vehicle while under the influence of alcohol. (Sub. Res. 95, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed and Modified: CSA Rep. 8, A-05)
Whereas, Prenatal alcohol exposure is associated with significant maternal and fetal health risks including spontaneous abortion, prenatal and postnatal growth restriction, birth defects, and neurodevelopmental deficits, including fetal alcohol syndrome—the most common cause of mental retardation1; and

Whereas, Smoking during pregnancy increases the likelihood of placenta previa, abruptio, premature rupture of membranes, preterm delivery, fetal growth restriction, low birth weight, as well as increasing the incidence of orofacial cleft defects and sudden infant death syndrome after birth2; and

Whereas, Illicit drug use during pregnancy, especially cocaine use, has been linked to increased risk of low birth weight, prematurity, perinatal death, abruptio placenta, and small-for-gestational-age births3; and

Whereas, The 2006 National Survey on Drug Use and Health found that 11.8 percent of women reported current alcohol use and 2.9 percent reported binge drinking (greater than five drinks on the same occasion) during pregnancy, 16.5 percent of women reported tobacco use during pregnancy, and four percent of women reported using illicit drugs during pregnancy4; and

Whereas, A variety of screening tools have been introduced to properly screen and identify pregnant women using alcohol, tobacco, and illicit drugs, including the five A’s of tobacco, TACE for alcohol, and FRAMES for other drug use5; and

Whereas, The American College of Obstetricians and Gynecologists endorses universal screening as an ethical obligation6; and

Whereas, One study shows that by merely identifying the pregnant substance user and the particular substance(s) used, 54% of women cleaned up after brief physician advice and a urine drug screen at each prenatal visit7; and

Whereas, In one treatment facility from 2002-2008, detection and simple intervention resulted in 274/323 (84.8%) substance-free births, with a pre-term rate of 22.2% (pre-term delivery rate for all patients in this hospital is 19.6%)8; and

Whereas, In that same facility, of the patients who were identified as positive with a urine drug screen who did not return for prenatal care but who did show up for delivery, 26/49 (53%) were substance-free births, indicating that the process of detection is, in fact, an intervention in and of itself9; and

Whereas, The medical profession has historically expressed concern for a healthy intrauterine environment for the prenatal period; and

Whereas, The medical profession has historically supported initiatives to help those who are addicted to drugs and ask for help, and supports government initiatives to implement substance abuse programs that are appropriately designed and monitored for quality, cost effectiveness, and reduced recidivism; therefore be it
RESOLVED, That our American Medical Association, through its communication vehicles, encourage all physicians to increase their knowledge regarding the effects of drug and alcohol abuse during pregnancy and to communicate that information to women of reproductive age pre-conception (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage physicians to routinely inquire about alcohol, tobacco and drug use during the course of providing prenatal care (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage physicians to identify alcohol, tobacco, and drug use in their pregnant patients and provide them with treatment options best suited to their needs (Directive to Take Action); and be it further

RESOLVED, That our AMA collaborate with health partners across the country to study the prevalence and benefits of implementing a simple screening process. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated cost of $10,721 which includes staff time and costs for approximately 2 meetings of appropriate stakeholders to survey current screening procedures, evaluate the benefits of implementing standard screening, and make recommendations.

2 Id.
3 Id.
8 James. J. Nocon, M.D., J.D., Director Prenatal Substance Use Clinic, Wishard Memorial Hospital, 1001 West 10th Street, F5102, Indianapolis, IN 46202
9 Id.
**H-420.962 Perinatal Addiction - Issues in Care and Prevention**
The AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to
criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of
funds allocated to drug treatment, prevention, and education within the context of its "War on Drugs." In
particular, support is crucial for establishing and making broadly available specialized treatment programs
for drug-addicted pregnant women wherever possible; (3) urges the federal government to fund additional
research to further knowledge about and effective treatment programs for drug-addicted pregnant women,
encourages also the support of research that provides long-term follow-up data on the developmental
consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention
with perinatally exposed children; (4) reaffirms the following statement: Pregnant substance abusers
should be provided with rehabilitative treatment appropriate to their specific physiological and
psychological needs; (5) through its communication vehicles, encourages all physicians to increase their
knowledge regarding the effects of drug and alcohol abuse during pregnancy and to routinely inquire
about alcohol and drug use in the course of providing prenatal care; and (6) will address the special needs
of pregnant drug abusers within the context of its ongoing Health Access America programs. (CSA Rep.
G, A-92; Reaffirmation A-99)

**H-95.976 Drug Abuse in the United States - the Next Generation**
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. (BOT Rep. Y, I-89;
Reaffirmed: Sunset Report, A-00)
Whereas, Our AMA has conducted a very successful media campaign for several years to minimize, or eliminate, tobacco use in films because tobacco has been recognized as a public health problem; and

Whereas, Gratuitous gun violence is a public health problem and has become a staple of certain film genres, e.g., Die Hard, Terminator, Indiana Jones, and James Bond films among others; and

Whereas, These films are often pitched to teenage and young adult male audiences and have the power to influence their behavior; and

Whereas, As an example, on 4/16/2007 a senior at Virginia Tech University shot and killed 32 people and wounded 17 others and took video images of himself before the assault brandishing guns in both hands in a manner similar to many scenes from such movies and video games; and

Whereas, Gun violence among members of this specific group has increased in recent years with devastating effect on their peers and society at large; and

Whereas, A recent study shows 39% of US households have a firearm on the premises, 20% of households that include adolescents have at least one firearm in the home, nearly a third of those firearms are stored unlocked, a fifth are stored loaded and a twelfth are stored unlocked and loaded; and

Whereas, “Typically in households where there are both firearms and children, parents are not aware of the extent to which their children are knowledgeable about the location of the guns and ammunition...(and) fully one-third of children and adolescents reported handling a firearm within the household (and) 5% of adolescents who have handled guns report unsupervised use and ...half have actually fired the gun without supervision”;

Whereas, Guns are the weapons used in most homicides in the US as well as in the majority of completed suicides; and

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2 McNamara NK Findling RL: Guns adolescents and mental illness. Am. J. Psychiat. 165:2 2008 190-194
Whereas, A sixteen year old Maryland boy on 2/2/2008 left a party where he was playing video games with his friends, went home and took one of the many guns lying around the house unsecured, and shot and killed his father (an attorney), his mother (a former PTA President), and two young brothers as they slept, and then returned to the party and continued to play the games as though nothing had happened eventually confessing to the crime; and

Whereas, There is very little in the media that shows responsible gun ownership and use; therefore be it

RESOLVED, That our American Medical Association ask the Council on Science and Public Health to evaluate the feasibility and value of pursuing a multi-media campaign with the AMA Alliance and AMA Foundation to promote the reduction, and/or elimination, of gratuitous gun violence in the media as well as portraying the devastating consequences of gratuitous gun violence in films, and undertake an initiative calling for the popular media to portray responsible gun ownership and advertise this initiative in theaters, and portray leading characters demonstrating this behavior. (Directive to Take Action)

Fiscal Note:

Received: 05/06/09

H-515.974 Mass Media Violence and Film Ratings
Redressing Shortcomings in the Current System: The AMA: (1) will speak out against the excessive portrayal of violence in the news and entertainment media, including newscasts, movies, videos, computer games, music and print outlets, and encourage the depiction of the medical, social and legal consequences of violence by the media; (2) advises physicians to counsel parents about the known effects of media violence on children's behavior and encouraging them to reduce the amount of violent programming viewed by their children; (3) monitors changes in the current ratings system and working through state medical societies to inform physicians and their patients about these changes; and (4) supports all other appropriate measures to address and reduce television, cable television, and motion picture violence. (BOT Rep. 18, A-94; Modified: Res. 417, I-95; Appended: Sub. Res. 419, A-98; Modified and Reaffirmed: CSAPH Rep. 2, A-08)

H-485.995 TV Violence
The AMA reaffirms its vigorous opposition to television violence and its support for efforts designed to increase the awareness of physicians and patients that television violence is a risk factor threatening the health of young people. (Res. 19, I-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03)
Memo to: Roger Brown
From: Katie Johansen
Date: May 27, 2009
Subject: Reaffirmation Resolutions, A-2009 – Reference Committee E

I have reviewed the resolutions assigned to Reference Committee E for A-2009, and believe that the following resolutions are covered by existing policy. Copies of the resolutions are attached, along with the existing policies recommended for reaffirmation and relevant Board and Council reports.

**Resolution 508 – State Vaccine Registry Interfaces**
The intent of resolution 508 is to increase collaboration and cooperation on the development of vaccine registries to ensure maximum interoperability. The AMA supports the collaborative development and communication of vaccine registry systems. Two existing AMA policies specifically support vaccine registry development. **H-440.899** encourages physicians to participate in the development of immunization registries in their communities and use them in their practices, and policy **D-440.961** directs the AMA to work with the Centers for Disease Control and Prevention, the Department of Health and Human Services, the Public Health Service and other interested organizations to develop a network of state-based immunization registries that meet a set of minimum standards and allow for access at a national level, while ensuring the protection of the patient-physician relationship. Furthermore, **H-480.971** states that the AMA act as a source of physician input to the revolutionary developments in computer-based medical information applications, and provide leadership on these absolutely critical and rapidly accelerating issues and activities. These policies support the intent of Resolution 508; this resolution has therefore been placed on the Reaffirmation Calendar.

**H-440.899, D-440.961, and H-480.971 should be reaffirmed.**

**Resolution 511 – Reducing Medication Waste From Extended Care Facilities**
Resolution 511 asks that our American Medical Association work with appropriate stakeholders to develop plans to recover safe, unused, unopened, and unexpired medications. The AMA has supportive policies on medication recycling and for stewardship of the environment. AMA policy **H-280.959** supports the return and reuse of medications to the dispensing pharmacy to reduce waste associated with unused medications in long-term care facilities (LTCFs) and to offer substantial savings to the health care system. In addition, policy **H-135.939** supports responsible waste management policies, including the promotion of appropriate recycling and waste reduction; and community-wide adoption of “green” initiatives and activities by organizations, businesses, homes, schools, and government and health care entities. Since these existing polices cover the intent of Resolution 511, it has been placed on the Reaffirmation Calendar.

**H-280.959 and H-135.939 should be reaffirmed.**
Resolution 513 – Novel Antibiotics and Antimicrobial Resistance

The intent of Resolution 513 is to encourage the AMA to monitor the spread of antibiotic resistance and to support mechanisms for the timely development of novel antibiotics. Existing AMA policy as well as AMA activities cover these requests. The AMA became involved in the problem of antibiotic resistance nearly 15 years ago, and in 1995, submitted a proposed statement to the WMA on "Resistance to Antimicrobial Drugs." The seven AMA proposals to address the problem of antimicrobial resistance worldwide ranged from international surveillance, to more research for vaccines and new antimicrobials, to better education of physicians and the public. This statement (as revised) was adopted by the WMA in 1996. The AMA has continued to monitor the issue of antibiotic resistance, as directed by a number of policies. D-100.998 directs our AMA to continue to collaborate with the appropriate federal agencies, other medical specialty societies, and other appropriate public health organizations to address the urgent problem of increasing antimicrobial resistance and its impact on public health; D-100.995 directs our AMA to work with other organizations to establish a national program to counter antibiotic resistance in clinical practice ...; and D-440.991 directs our AMA to urge that increased surveillance of antimicrobial use and resistance be funded and instituted as recommended by the Institute of Medicine and American Society of Microbiology. Under D-100.998, the AMA has supported mechanisms for the development of novel antibiotics. The AMA has publicly supported the Infectious Diseases Society of America’s “Bad Bugs, No Drugs” program, which works to spur new antibiotic development, and along with many other medical and public health organizations, has publicly endorsed the STAAR (Strategies to Address Antimicrobial Resistance) Act, legislation which would provide incentives for new drug development and ensure better stewardship of existing life saving crucial antibiotics. Existing policies that have directed AMA involvement in the issue of antibiotic resistance covers the Resolve in Resolution 513. It has been placed on the Reaffirmation Calendar.

D-100.998, D-100.995, and D-440.991 should be reaffirmed.

Resolution 518 – Generic Drugs from Foreign Manufacturers Sold in the US

The intent of Resolution 518 is to investigate the substitution of foreign-made generic medications in US pharmacies, express concerns about the possible risks to patients from foreign-made generic medications to the FDA, and educate physicians about the prevalence and legality of generic drug substitution. Several AMA policies and reports cover the resolution’s requests regarding foreign-made drugs and substitution of generics. H-100.969 recommends inspection of all foreign manufacturers of pharmaceutical chemicals and products which are exported to the United States to assure compliance with U.S. standards, and timely follow-up inspection of all foreign manufacturers that have been identified as having serious manufacturing deficiencies. D-100.983, policy stemming from a comprehensive report on prescription drug importation and patient safety (BOT Rep 3, A-04), directs our AMA to support the import of prescription drug products as long as the products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; that same policy also directs our AMA to educate its members regarding the risks and benefits associated with drug importation and reimportation efforts. The AMA completed a comprehensive report on the subject of generic substitution. CSA Rep 6 (A-02) analyzed the status of generic drug use and cost, the regulatory framework for the approval and clinical use of generic drugs, and issues relevant to the bioequivalence and therapeutic equivalence. H-125.984, policy stemming from that report, acknowledges the physician’s right to choose either generic or brand name drugs for their patients, and supports exploration of ways to more effectively inform physicians about the bioequivalence of generic drugs.

H-100.969, D-100.983, and H-125.984 should be reaffirmed.

Resolution 525 – Research Visa Waiver for Physician Scientists

The intent of Resolution 525 is to improve the shortage of physician scientists in the US. It asks the AMA to urge Congress to create a Visa waiver program for physicians who choose to pursue a research
career in medicine. The AMA has been strongly supportive of physician scientists, with extensive policy attesting to such. **H-460.995** supports policies and legislation designed to increase the number of physician-investigators. **H-460.994** supports joining with other public and private bodies in encouraging multiple approaches at local, state and national levels in support of the development of physician-investigators, and **D-255.991** directs the AMA to work with the Educational Commission for Foreign Medical Graduates to minimize delays in the visa process for International Medical Graduates applying for visas and to promote regular communication and discussion of existing and evolving issues related to the immigration and registration process required for International Medical Graduates. Since these policies cover the request in Resolution 525, it has been placed on the Reaffirmation Calendar.

**H-460.995, H-460.994, and D-255.991 should be reaffirmed.**

Please let me know if you have any questions. I can be reached at extension 4964.

Thanks,
Katie Johansen
Whereas, The State of California has divided its state vaccine registry functions into regions; and

Whereas, Regional vaccine registries play a vital role in state and local efforts to improve vaccination rates; and

Whereas, The number of physicians using an electronic health record (EHR) system or population management system is increasing rapidly; and

Whereas, Most of the Regional Immunization Registries in California have been resistant to developing interfaces with EHR systems; and

Whereas, The San Diego Regional Immunization Registry in California and other state vaccine registries have demonstrated that cooperation with developing interfaces with EHR systems is possible; and

Whereas, The interchange of data on vaccination between EHR systems and regional registries will improve efficiency of provider offices, save money and reduce errors; therefore be it

RESOLVED, That our American Medical Association encourage collaboration between national, state and local governments and electronic health record vendors to develop standard contract language, including a hold harmless clause, for vaccine registries that assure interoperability (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage all states to build the electronic link which will connect all regional vaccine registries as originally planned when the regional vaccine registries were established. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/01/09

RELEVANT AMA POLICY

H-480.971 The Computer-Based Patient Record
The following steps will allow the AMA to act as a source of physician input to the revolutionary developments in computer-based medical information applications, as a coordinator, and as an educational resource for physicians. The AMA will: (1) Provide leadership on these absolutely critical and rapidly accelerating issues and activities. (2) Work, in cooperation with state and specialty associations, to bring computer education and information to physicians. (3) Work to define the characteristics of an optimal medical record system; the goal being to define the content, format and functionality of medical record systems, and aid physicians in evaluating systems for office practice computerization. (4) Focus on the CPR aspect of human-computer interaction (the physician data input
step) and work with software vendors on the design of facile interfaces. (5) Provide guidance on the use of computer diagnosis and therapeutic support systems. (6) Continue to be involved in national forums on issues of electronic medical data control, access, security, and confidentiality. (7) Continue to work to ensure that issues of patient confidentiality and security of data are continually addressed with implementation resolved prior to the implementation and use of a computer-based patient record. (BOT Rep. 29, A-96; Reaffirmation A-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation I-08)

**H-440.901 Achieving National Adolescent Immunization Goals**
Our AMA: (1) endorses the National Adolescent Vaccine Coverage Goals; and (2) endorses the collaboration of physicians, public health officials and legislators in each state to carry out strategies that ensure the National Adolescent Vaccine Coverage Goals are met. (Res. 411, I-98; Modified and Reaffirmed: CSAPH Rep. 2, A-08)

**H-440.899 Immunization Registries**
Our AMA encourages physicians to participate in the development of immunization registries in their communities and use them in their practices. (Res. 415, A-99; Reaffirmed: 415, A-01)

**D-440.961 Establishment of a Network of State Immunization Registries**
Our AMA will work with the Centers for Disease Control and Prevention, the Department of Health and Human Services, the Public Health Service and other interested organizations to develop a network of state-based immunization registries that meet a set of minimum standards and allow for access at a national level, while ensuring the protection of the patient-physician relationship. (Sub. Res. 709, I-05)
Existing Policy Recommended for Reaffirmation (Res 508, A-09):

H-440.899 Immunization Registries
Our AMA encourages physicians to participate in the development of immunization registries in their communities and use them in their practices. (Res. 415, A-99; Reaffirmed: 415, A-01)

D-440.961 Establishment of a Network of State Immunization Registries
Our AMA will work with the Centers for Disease Control and Prevention, the Department of Health and Human Services, the Public Health Service and other interested organizations to develop a network of state-based immunization registries that meet a set of minimum standards and allow for access at a national level, while ensuring the protection of the patient-physician relationship. (Sub. Res. 709, I-05)

H-480.971 The Computer-Based Patient Record
The following steps will allow the AMA to act as a source of physician input to the revolutionary developments in computer-based medical information applications, as a coordinator, and as an educational resource for physicians. The AMA will: (1) Provide leadership on these absolutely critical and rapidly accelerating issues and activities. (2) Work, in cooperation with state and specialty associations, to bring computer education and information to physicians. (3) Work to define the characteristics of an optimal medical record system; the goal being to define the content, format and functionality of medical record systems, and aid physicians in evaluating systems for office practice computerization. (4) Focus on the CPR aspect of human-computer interaction (the physician data input step) and work with software vendors on the design of facile interfaces. (5) Provide guidance on the use of computer diagnosis and therapeutic support systems. (6) Continue to be involved in national forums on issues of electronic medical data control, access, security, and confidentiality. (7) Continue to work to ensure that issues of patient confidentiality and security of data are continually addressed with implementation resolved prior to the implementation and use of a computer-based patient record. (BOT Rep. 29, A-96; Reaffirmation A-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation I-08)
Whereas, Costs of prescription medications continue to escalate; and
Whereas, Many people, especially those on fixed incomes, the less fortunate, and seniors, have to choose between medications and food; and
Whereas, In some states and jurisdictions it may be illegal to return and reuse or resell prescription medications; and
Whereas, The systems by which certain medications—particularly those used for cancer treatments—can be implemented or improved, making it easier for patients in need to receive them; and
Whereas, Since it is overly onerous to do otherwise, extended care facilities discard all unused medications of expired patients, regardless of whether the medications are in sealed, unopened blister packs or have not reached their expiration dates; and
Whereas, Studies have demonstrated levels of prescription medications in ground water due to their presence in household waste, landfills and waste water; and
Whereas, Not discarding safe, unopened, unexpired medications would have multiple benefits, including cost savings, assisting the less fortunate, and decreasing the environmental impact; therefore be it
RESOLVED, That our American Medical Association work with appropriate agencies and professional associations to develop plans to recover safe, unused, unopened, and unexpired medications. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $3,633.

Received: 05/06/09
Existing Policy Recommended for Reaffirmation (Res 511, A-09):

H-280.959 Recycling of Nursing Home Drugs
Our AMA supports the return and reuse of medications to the dispensing pharmacy to reduce waste associated with unused medications in long-term care facilities (LTCFs) and to offer substantial savings to the health care system, provided the following conditions are satisfied: (1) The returned medications are not controlled substances. (2) The medications are dispensed in tamper-evident packaging and returned with packaging intact (e.g., unit dose, unused injectable vials and ampules). (3) In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity. (4) Policies and procedures are followed for the appropriate storage and handling of medications at the LTCF and for the transfer, receipt, and security of medications returned to the dispensing pharmacy. (5) A system is in place to track re-stocking and reuse to allow medications to be recalled if required. (6) A mechanism (reasonable for both the payer and the dispensing LTC pharmacy) is in place for billing only the number of doses used or crediting the number of doses returned, regardless of payer source. (CSA Rep. 2, I-97; Reaffirmed: BOT Rep. 33, A-07; Modified and Reaffirmed: CSAPH Rep. 3, A-07)

H-135.939 Green Initiatives and the Health Care Community
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)
Whereas, According to the US Food and Drug Administration (FDA), approximately 70 percent of bacteria that cause infections in hospitals are resistant to at least one of the drugs most commonly used to treat infections; and

Whereas, Although the vast majority of bacterial infections can be treated with existing antibiotics, bacterial resistance to all known antimicrobials has been reported; and

Whereas, Between 1983 and 1997, novel antibiotics were approved by the FDA at an average rate of nearly three new drugs per year; and

Whereas, Despite alarming recent increases in resistance to existing antibiotics, since 1998 novel antibiotics have been approved by the FDA at a rate of barely one new drug per year; and

Whereas, A number of factors, including increasing costs and complexity of clinical trials, increasing length of time-to-market, and minimal demand for “one-time-use” drugs such as antibiotics, contribute to decreased market incentive to develop novel antibiotics; and

Whereas, A combination of push incentives, wherein the government subsidizes research it believes to be valuable (e.g. grants, tax credits), and pull incentives, wherein the government rewards successful innovators by paying high prices (e.g. purchase commitments, patent extensions), would prompt pharmaceutical manufacturers to develop and bring to market novel antibiotics; and

Whereas, The effectiveness of push and pull market incentives is evident in the success of the Orphan Drug Act in prompting pharmaceutical manufacturers to develop drugs that would have otherwise been relatively unprofitable; and

Whereas, Our AMA already supports “a system of grants that will encourage through appropriate funding a few research efforts investigating those drugs for which there may be no mass market” (AMA Policy H-100.993) and supports “extensions of marketing exclusivity” for drugs that treat orphan diseases (H-120.988); and

Whereas, The development of novel antibiotics alone will not solve the problem of antimicrobial resistance if physicians and patients are not properly educated about the appropriate prescribing and use of existing antibiotics; and

Whereas, Our AMA is already committed to combating antimicrobial resistance through education (H-100.973); therefore be it
RESOLVED, That our American Medical Association continue to monitor the spread of antibiotic resistance and, if deemed necessary, support mechanisms that would result in the timely development of novel antibiotics. Mechanisms should include a combination of push and pull incentives with legislation modeled after the Orphan Drug Act in conjunction with intensive educational efforts targeting physicians and patients. (Directive to Take Action

Fiscal note: Implement accordingly at estimated staff cost of $3,042.

Received: 04/30/09

RELEVANT AMA POLICY

H-100.993 Recommendations on Drug Development and Drug Regulation
(1) The FDA must be given the funds and quality personnel to perform its tasks effectively and efficiently. Career opportunities must be made more attractive in terms both of salary and scientific career opportunities. (2) The FDA should be encouraged to make use of foreign data generated by reputable foreign scientists. This would reduce the reduplicative efforts now required and avoid the questionable ethics of demanding clinical trials for strictly regulatory purposes. (3) The FDA should be encouraged to confer with industry and clinical investigators during the IND phase of drug application. Sponsors should design their protocols and report forms in collaboration with the FDA and the involved clinical investigators. Thus, the pharmaceutical company sponsor may be secure in the knowledge that the early clinical trials so constructed will provide the FDA with information necessary to its new drug application. (4) The FDA should develop a system of grants that will encourage through appropriate funding a few research efforts investigating those drugs for which there may be no mass market, but which promise to fill an important need in rare but serious diseases. (5) The AMA supports the funding of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively. (CSA Rep. B, Parts 1, 2, 4, 5, I-78; Reaffirmed: CLRPD Rep. C, A-89; BOT Rep. 32, I-94; Reaffirmed and Modified: CSA Rep. 6, A-04)

H-100.973 Combating Antimicrobial Resistance through Education
Our AMA: (1) encourages the federal government, the World Health Organization, the World Medical Association, and the International Federation of Pharmacists to promote more effective education concerning the appropriate use of antibiotics; (2) strongly urges physicians to educate their patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance; (3) will continue to educate physicians and physicians-in-training about the appropriate prescribing of antimicrobial agents; (4) encourages the use of antibiotic resistance management programs; these education-based programs should be multidisciplinary and cooperative (i.e., including infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists); and (5) encourages continued scientific research on the issue of antibiotic resistance. (Sub. Res. 521, A-94; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmation I-98; Modified: CSA Rep. 3, A-00; Reaffirmation I-07)
Existing Policy Recommended for Reaffirmation (Res 513, A-09):

**D-100.998 Combating Antibiotic Resistance Via Physician Action and Education: AMA Activities**
Our AMA will continue to collaborate with the appropriate federal agencies, other medical specialty societies, and other appropriate public health organizations to address the urgent problem of increasing antimicrobial resistance and its impact on public health. (CMS Rep. 3, A-00; Reaffirmation I-07)

**D-100.995 Antimicrobial Use and Resistance**
Our AMA will work with other organizations to establish a national program to counter antibiotic resistance in clinical practice similar to the California Medical Association Foundation AWARE program. (Res. 508, A-01; Reaffirmation I-07)

**D-440.991 Antimicrobial Use and Resistance**
Our AMA will urge that increased surveillance of antimicrobial use and resistance be funded and instituted as recommended by the Institute of Medicine and American Society of Microbiology. (Res. 508, A-01)
Whereas, The US drug market is becoming increasingly globalized, with Indian and Chinese pharmaceutical companies manufacturing generic versions of medications not necessarily licensed and inspected by the FDA; and

Whereas, US drug consumers and physicians may be unaware of the supplier of their medications; and

Whereas, Quality control problems have arisen with foreign drug manufacturers, such as the recent deaths due to supra-therapeutic Chinese Heparin; therefore be it

RESOLVED, That our American Medical Association investigate the substitution of foreign-made generic medications by US pharmacies, take our concerns about possible risks to our patients from foreign-made generic medications to the US Food and Drug Administration, and educate physicians about the prevalence and legality of generic drug substitution by US pharmacies so that we may appropriately counsel our patients. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $3,406.

Received: 05/06/09
Existing Policy Recommended for Reaffirmation (Res 518, A-09):

**H-100.969 Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals**
Our AMA supports: (1) the inspection of all foreign manufacturers of pharmaceutical chemicals and products which are exported to the United States to assure compliance with U.S. standards; and (2) periodic surveillance inspections of all foreign pharmaceutical manufacturers with timely follow-up inspection of all foreign manufacturers that have been identified as having serious manufacturing deficiencies. (Res. 512, A-99; Reaffirmation I-06; Reaffirmation A-08; Reaffirmed: Res. 508, A-08)

**D-100.983 Prescription Drug Importation and Patient Safety**
Our AMA will: (1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported; (2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured; (3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation; and (4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts. (BOT Rep. 3, I-04)

**H-125.984 Generic Drugs**
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)
EXECUTIVE SUMMARY

Objectives: To analyze several issues relevant to the approval and clinical use of generic drugs since passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act) and to create a resource document for any legislative or regulatory efforts deemed advisable by our American Medical Association (AMA) that may be related to the availability and/or interchangeability of multisource drug products.

Methods: Literature searches were conducted in the MEDLINE database for English-language articles published between 1992 and February 2002 using the search terms “drugs, generic” in combination with “therapeutic equivalency,” “human,” “drug approval,” “health care costs,” “drug monitoring,” and “pharmacokinetics.” Searches were also conducted for articles published between 1984 and February 2002 using the terms “generic substitution” or “therapeutic equivalency,” excluding the terms “drug utilization,” “pharmacy and therapeutic committee,” “decision making,” “formularies,” “hospital,” and “dose-response relationship.” A total of 783 articles were retrieved for analysis. Articles on therapeutic alternates, patents or other legal issues, or involving generic drugs not approved for marketing in the United States were excluded, leaving 253 articles that were reviewed for information pertinent to this report. Additional references were culled from the bibliographies of these references.

Results: The process for generic drug approval has evolved along with changes in federal drug law and regulations. Passage of the Hatch-Waxman Act both encouraged the development of new innovator drugs by extending patent rights and established procedures facilitating the approval of low-cost generic drugs. Concerns about implementation of the Act were raised by the generic drug scandal of 1989, after which the Food and Drug Administration (FDA) reorganized its generic drug operations division. Generic drugs accounted for approximately 42% of all prescriptions at the retail level in the year 2000, but consumed only 8% of the $141 billion spent on prescription drugs. Currently, the FDA uses an average bioequivalence approach to assure interchangeability. A recent guidance offered by the agency allows a sponsor the option of using another criterion, such as individual bioequivalence. Products that are designated as therapeutically equivalent are designated with an “A” rating in the FDA’s publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”). Although numerous case reports have noted problems temporally related to generic switches for an “A”-rated product, the FDA has been unable to document therapeutic failures attributable to such switches. Nevertheless, physicians remain concerned about therapeutic equivalence, especially for drugs with a narrow therapeutic index.

Conclusions: The approval of generic drug products was greatly facilitated by passage of the Hatch-Waxman Act. However, the criteria used by the FDA to ensure bioequivalence among multisource products are widely misunderstood. In practice the mean difference in pharmacokinetic parameters for most generic products is in the range of 3% to 4%. While case reports continue to appear questioning the therapeutic equivalence of selected generic products, a large volume of data supports the safety of generic substitution. The FDA continues to take steps designed to improve the process of bioequivalence testing, including consideration of measures of intrasubject variability that may allow for a better understanding of the general applicability of bioequivalence testing results.
Introduction

Resolution 222, introduced by the California Delegation and referred to the Board of Trustees at the 2001 Annual Meeting, asks:

That our American Medical Association (AMA) support legislation to increase the availability of generic drugs, and specifically support legislation to prohibit anti-competitive agreements that delay market entry for generic drugs.

Testimony provided at the Reference Committee focused on questions about the current regulatory framework governing the approval of generic drugs by the Food and Drug Administration (FDA), the safety and effectiveness of these drugs compared with brand-name innovator products, and potential harms to patients associated with generic substitution. This report analyzes several issues relevant to the approval and clinical use of orally administered generic drugs since passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act).

It is intended to serve as a primer for physician members of the AMA’s House of Delegates and as a resource document for any legislative or regulatory efforts deemed advisable by our AMA that may be related to the availability and/or interchangeability of multisource drug products. This report does not address patent term restoration or patent extension issues, or economic/legal strategies that have been employed by manufacturers to retain market exclusivity for innovator products.

Methods

Literature searches were conducted in the MEDLINE database for English-language articles published between 1992 and February 2002 using the search terms “drugs, generic” in combination with “therapeutic equivalency,” “human,” “drug approval,” “health care costs,” “drug monitoring,” and “pharmacokinetics.” Searches were also conducted for articles published between 1984 and February 2002 using the terms “generic substitution” or “therapeutic equivalency,” excluding the terms “drug utilization,” “pharmacy and therapeutic committee,” “decision making,” “formularies,” “hospital,” and “dose-response relationship.” A total of 783 articles were retrieved for analysis. Articles on therapeutic alternates, patents or other legal issues, or involving generic drugs not approved for marketing in the United States were excluded, leaving 253 articles that were reviewed for information pertinent to this report. Additional references were culled from the bibliographies of these references.

Background

Current Status of Generic Drug Use and Costs. The rationale for the development and clinical use of generic drugs is to reduce drug-related health care costs. Generic drugs accounted for approximately 42% of all prescriptions at the retail level in the year 2000, but consumed only 8% of the $141 billion spent on

prescription drugs. The average price of a generic prescription was $19.33 in 2000, while the average price of a prescription dispensed with a brand-name drug was $65.29. A recent study conducted by the Managed Care Institute of Samford University and released by the Generic Pharmaceutical Association estimated that $1.16 billion could be saved for every percentage-point increase in the use of generic medications. Another report estimated that beneficiaries of a Medicare prescription drug program could save more than $350 per person annually in 2003 with the use of generic incentives, for total savings of $14 billion.

The relative proportion of generic prescriptions began increasing in the early 1990s but has since stabilized. The proportion of total pharmaceutical sales represented by generic drugs has decreased, reflecting the stable percentage of generic prescriptions coupled with increases in total pharmaceutical sales attributed to the successful marketing of higher priced, brand-name (innovator) products.

AMA Policy. Our AMA has extensive policy on issues related to generic drugs. These policies: (1) support the ability of physicians to use either generic or brand-name drugs; (2) encourage physicians to consider relative cost when making their decision; (3) recognize that only “A”-rated generic drugs are suitable for substitution; and (4) suggest several steps that can be taken by physicians and pharmacists to avoid confusion among patients when generic substitution or switching among generic products occurs. The relevant policies are listed in Appendix I.

Various specialty societies also have taken formal positions on the issue of generic substitution; these statements or policies are summarized in Appendix II. Of note, every state has a mechanism in place by which physicians can prevent substitution.

Generic Drug Scandal and FDA Reaction. In 1989 federal investigators implicated several generic industry officials in the conduct of fraud, obstruction of justice, and noncompliance with various manufacturing procedures. The investigations also revealed that several FDA employees had accepted illegal gratuities or other compensation in exchange for information and assistance that gave certain firms an advantage in the approval process. Investigators also discovered that 10 or more generic companies had submitted fraudulent data related to bioequivalency, stability testing, and manufacturing protocols for some of their products.

The FDA reacted to these findings by reorganizing its generic drug operations and conducting comprehensive inspections. FDA investigators reevaluated data from hundreds of generic drug applications. More than 2,550 samples of the top 30 prescribed generic drugs—or about 30% of all generic drugs on the market—were collected and laboratory-tested, and the agency conducted intensive inspections of 36 of the largest generic drug firms and 12 contract laboratories. The agency determined that only 27 samples, or approximately 1% of those tested, did not comply with standards of potency, dissolution, content uniformity, product identification, moisture determination, or purity.

The FDA also tested 429 samples representing at least three different batches of so-called narrow-therapeutic-range drugs that were currently marketed. These 24 drugs, made by 73 brand-name and generic drug manufacturers, were selected because of their potential for adverse reactions or therapeutic failure if they lacked bioequivalency. Only five of the samples (all aminophylline tablets) failed to meet United States Pharmacopoeia standards. None of the defects in the generic drugs were judged to pose a public health hazard.

Based on these results and the fact that brand-name products demonstrated similar failure rates, the agency recommended that doctors continue to consider prescribing generic drugs when appropriate in order to offer products at lower cost to consumers. However, as a result of the negative publicity and fraud associated with these events, the feeling was reinforced among many physicians that generic drugs were inferior and potentially harmful.
Generic Drug Approval Process

Pre-1984. The process for generic drug approval has evolved along with changes in federal drug law and regulations. Before enactment of the Food, Drug, and Cosmetic Act (FDCA) in 1938, significant regulatory barriers to generic competition in the market did not exist.9 Manufacturers of such products (eg, codeine sulfate, phenobarbital) could formulate, manufacture, and sell their products without submitting bioequivalence or efficacy data to the FDA. The 1938 Act established a “new drug” category, requiring manufacturers to document the safety of a product to the FDA and established a 60-day delay before marketing could proceed, absent FDA objection.9 Until 1962, generic versions of post-1938 drugs were marketed based on a “general recognition” of safety. Typically, this designation was based on a history of safe use of the innovator product. Such generic products were designated as “not new drugs.”9

Amendments to the FDCA in 1962 added requirements for “substantial evidence of both safety and efficacy, obtained in adequate and well-controlled studies,” and affirmative FDA approval of the New Drug Application (NDA); these criteria also applied to generic drugs. These amendments also contained a provision for retroactive evaluations of pre-1962 drugs that had been recognized as safe. The Drug Efficacy Study Implementation (DESI) Review established expert panels to review data on all drugs marketed between 1938 and 1962 and to make recommendations on their efficacy. Drugs found to be ineffective were to be withdrawn by the FDA. The agency also was to notify potential generic manufacturers of requirements for developing generic versions of these approved drugs. The result was the Abbreviated New Drug Application (ANDA), for which approval was based on active ingredients and bioequivalence, rather than on safety and efficacy data (see below).

The original ANDA procedure did not apply to products that were chemically equivalent to drugs first marketed after 1962. As patents on post-1962 drugs began to expire in the 1970s, the FDA created a paper NDA policy that permitted generic versions of new drugs to be approved based on submission of safety and efficacy information obtained from the published medical literature rather than new clinical data.10 This approach did not establish a viable generic drug approval process and ultimately the Drug Price Competition and Patent Term Restoration Act was enacted in 1984, under which generic drugs are approved today.

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). The dual purposes of the Hatch-Waxman Act were to encourage the development of new innovator drugs by extending patent rights and to establish procedures facilitating the approval of low-cost generic drugs.11 These amendments to the FDCA codified in statute an abbreviated process (ANDA) for post-1962 drugs whereby a generic company could gain approval of its version of a drug without repeating the expensive and lengthy clinical trials used to establish safety and efficacy of the innovator drug. Under certain circumstances relating to patent challenges, the first generic version of a brand-name innovator medication receives a 180-day period of market exclusivity.

Products approved under an ANDA must be pharmaceutical equivalents (ie, have the same active ingredient(s), route of administration, dosage form, and strength) as the reference drug. They must also be bioequivalent and the manufacturer must supply other basic technical information related to manufacturing of the product that is normally required of an NDA.12 Generic drugs are pharmaceutical equivalents only with respect to their active ingredients. The binders, diluents, and excipients (filler) in the formulation, as well as the method of manufacture, may vary.

In contrast to FDA regulations for NDAs, which require submission of each study and a description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product, the regulations for ANDAs only require that the submission include information that shows that the drug product is bioequivalent to the reference listed drug upon which the applicant relies. The FDA’s policy of not requiring failed bioequivalence studies to be submitted in ANDAs along with the passing study may lead to an incomplete evaluation of the data. This policy applies to both innovator and
generic firms submitting an ANDA. In a recent example involving cyclosporine, the revelation of a failed bioequivalence study resulted in a Class II recall of SangCya™ Oral Solution. The company subsequently discontinued this product.

The FDA considers drug products to be therapeutic equivalents if they are pharmaceutical equivalents and are bioequivalent.

The publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”), identifies drug products approved by the FDA on the basis of safety and effectiveness and includes therapeutic equivalence evaluations for approved multisource prescription drug products. Products on the list are identified by the names of the holder of approved applications (applicants) who may not necessarily be the manufacturer of the product. This publication satisfies the requirements of the Hatch-Waxman Act that the FDA make publicly available a list of approved drug products that is updated monthly.

For every multiple-source product, the Orange Book cites a letter code that indicates the FDA’s evaluation regarding the therapeutic equivalence of the product relative to the reference innovator or brand-name product. These drugs are placed in one of two categories as follows: “A”-rated products are considered to be therapeutically equivalent to other pharmaceutically equivalent products; “B”-rated products are considered not to be therapeutically equivalent to other pharmaceutically equivalent products. Class AB is a subset of “A” and includes DESI drug products and post-1962 drug products for which actual or potential bioequivalence problems have been resolved and that the FDA now considers to be therapeutically equivalent. Most new generic products are defined as having “potential” problems until data is submitted to establish their bioequivalence.

Requirements for Establishing the Bioequivalence of Generic Products. The primary substantive requirement for approval of an ANDA is that the manufacturer seeking approval to market a generic drug product must submit data demonstrating that the drug product is bioequivalent to the innovator brand-name drug product. A major premise underlying the 1984 law is that bioequivalent drug products are therapeutically equivalent and, therefore, interchangeable.

Bioequivalent drug products must display comparable bioavailability when studied under similar experimental conditions. Bioavailability refers to the “rate and extent to which the active ingredient or active moiety is absorbed from a drug product and becomes available at the site of action.” The bioequivalence requirement means that an ANDA must contain either results of human studies showing bioequivalence, or other “information” enabling the FDA to conclude that the ANDA product will be bioequivalent to its reference listed drug. For example, bioequivalence for certain highly soluble, rapidly dissolving oral dosage forms may be inferred by using an in vitro dissolution standard when such an in vitro test has been correlated with human in vivo bioavailability data. Alternate study methods, using clinical or pharmacodynamic endpoints, are used for drug products when plasma concentrations are not useful, such as with oral inhalers, nasal sprays, and topical products applied to the skin. This report does not address such products.

Determination of Bioequivalence. Originally, bioequivalence was based on a demonstration that simple mean bioavailability parameters differed by less than 20% from the brand-name product. In 1977 this was modified to include a “power” approach that tested the null hypothesis that the rate and extent of bioavailability of the generic product was similar to the innovator product, and the power of the study was sufficient to detect at least a 20% difference. In 1986, the FDA adopted the currently used average bioequivalence approach, which involves a comparison of means.

For immediate-release oral dosage forms, the standard average bioequivalence determination employs a single-dose crossover study, typically conducted in a limited number of healthy volunteers (usually 24 to 36 adults). For drugs with long half-lives, parallel design studies may be used. Both the rate and extent
of absorption are evaluated. The former includes the maximum plasma concentration (C_{max}) and the time required to achieve this value (T_{max}). The extent of absorption is measured by the area under the plasma concentration-time curve (AUC).

Results are analyzed according to whether the generic product (test), when substituted for the brand-name product (reference), is significantly less bioavailable, and alternatively, whether the brand-name product, when substituted for a generic product, is significantly less bioavailable (the two 1-sided tests).\textsuperscript{16} The core of the bioequivalence concept is an “absence of a significant difference.” A difference of >20\% is viewed by the FDA as significant. By convention, all data are expressed as a ratio of the average response (AUC and C_{max}) for test/reference, so the limit expressed in the second analysis is 125\% (reciprocal of 80\%).

Tests are carried out using an analysis of variance and calculating a 90\% confidence interval (CI) for the average of each pharmacokinetic parameter, which must be entirely within the 80\% to 125\% boundaries.\textsuperscript{16} The width of the CI reflects, in part, the within-subject variability of the test and reference products. A common misconception is that the average values between the reference and test product can vary by -20/+25\%, which could lead to large differences between multisource products. In fact, when applying these statistical criteria to studies involving 20 to 40 subjects, generic products whose mean arithmetic bioavailability parameters differ by more than 5\% to 10\% from the reference product begin failing the CI requirement. The FDA’s Office of Generic Drugs has conducted two large surveys to quantify the differences between generic and brand-name products. The first, conducted on 224 bioequivalence studies submitted in approved applications during 1985 and 1986, found an average difference in AUC measures between reference and generic products of 3.5\%.\textsuperscript{19} The second, involving 127 bioequivalence studies submitted in 1997 found average differences of 3.47\% for AUC and 4.29\% for C_{max}.\textsuperscript{20}

Current FDA Guidance. After careful consideration of all the recommendations from an expert panel as well as public comments, the FDA in 2000 issued a final guidance for industry entitled \textit{Bioavailability and Bioequivalence Studies for Orally Administered Drug Products – General Considerations}.\textsuperscript{21} In this guidance, the agency recommends non-replicated bioequivalence study designs for most orally administered immediate-release drug products and replicated bioequivalence study designs for modified-release dosage forms. The guidance maintains the average bioequivalence criterion but allows the option for a sponsor to provide rationale \textit{a priori} for using another criterion to declare bioequivalence, such as the individual bioequivalence criterion (see following section) for highly variable drug products. An additional concern with bioequivalence testing is that, with certain drugs, it is the peak effect and not AUC that is important for the therapeutic response or ADRs. This guidance recommends use of the partial AUC as an early exposure measure instead of T_{max} to address these concerns.

Individual Bioequivalence. Concerns have been raised about use of the average bioequivalence approach to assure interchangeability for multisource products. It has been suggested that this approach may not be adequate for all drugs and that modified procedures and additional data may be necessary.\textsuperscript{22-24} Measures of average bioequivalence lack any measure of intrasubject variability, and no such information is provided to physicians in the package inserts. An \textit{individual bioequivalence} approach has been advocated as a more appropriate measure to ensure “interchangeability.”\textsuperscript{25,26} Because of the within-subject focus, individual bioequivalence assessments are usually based on a replicate study design in which each subject receives both the test and reference products on at least two occasions. This approach requires a criterion and statistical analysis of within-individual variance for both test and reference products, and also estimates if two pharmaceutically equivalent products exhibit a \textit{subject-by-formulation interaction}. Presence of a subject-by-formulation interaction means that the difference between formulations is not the same from subject to subject.

There is a paucity of data to verify that subject-by-formulation interactions are clinically important. However, FDA post-hoc analysis of data sets from replicate design studies in NDAs and ANDAs (involving predominantly healthy male subjects) found some evidence of subject-by-formulation
interactions involving $C_{\text{max}}$ and AUC.\textsuperscript{27} Additionally, two studies of generic verapamil have been published showing subject-by-formulation interactions in elderly subjects and in the presence of food.\textsuperscript{28,29} In both cases the generic product was better absorbed than the reference product.

There is disagreement as to whether these data are adequate to validate individual bioequivalence as a necessary approach for the approval of generic drug products, and whether the additional expense is justified. However, one consequence of the individual bioequivalence discussion has been more focus on the appropriate subjects for bioequivalence trials. The 2000 FDA guidance on bioavailability and bioequivalence recommends inclusion of women, and, for products intended for use primarily in geriatric patients, inclusion of elderly subjects as well. If this guidance is followed, it may allow for a better understanding of the general applicability of bioequivalence results and the potential value of individual bioequivalence because studies involving subjects more representative of the general population would likely use a replicate study design. Additionally, bioequivalence testing has not been well-validated in pediatric populations and this deficiency should be addressed.

\textit{Does Average Bioequivalence Equal Therapeutic Equivalence?}

The critical question is whether assessment of bioequivalence assures therapeutic equivalence. Pharmacokinetic bioequivalence studies are a surrogate for clinical outcomes. Clinical studies comparing pioneer and generic drugs are rarely performed, and studies comparing one generic product with another are almost never performed. However, in the 1970s it was recognized that differences in the formulation of products containing the same amount of active ingredient could result in significant differences in bioavailability, and several cases of therapeutic inequivalence involving generic products were reported.\textsuperscript{30,31} These involved products that were never judged by the FDA to be bioequivalent, leading to development of the clinical and statistical approaches noted above to establish bioequivalence among pharmaceutically equivalent products. Similarly, several more recent reports involving clinical differences or serious bioequivalence problems with generic products have involved "B"-rated products.\textsuperscript{32-40} These types of reports fueled perceptions that generic products were not equivalent when in fact these products were never rated as equivalent.

However, numerous case reports have also noted problems temporally related to generic switches for a number of “A”-rated products.\textsuperscript{41-52} In response to such reports of possible therapeutic inequivalence, the FDA established the Therapeutic Inequivalence Action Coordinating Committee (TIACC) housed within the FDA Center for Drug Evaluation and Research. This Committee was to identify, evaluate, and when appropriate, investigate reports of apparent therapeutic inequivalence and take appropriate corrective action.

Since the formation of the TIACC in 1988, the FDA has investigated more than 60 reports of potential generic product inequivalence. The agency has been unable to document a single example of therapeutic failure when an FDA-designated therapeutically equivalent generic product, which was manufactured to meet its approved specifications, was substituted for the corresponding brand-name drug listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations.\textsuperscript{53} However, when reports reveal other problems (eg, regarding quality) that are substantiated through investigation, appropriate actions are taken; these may include recommendations for product recall, withdrawal, or reclassification of its therapeutic equivalence code.

Even though other independent studies have confirmed the bioequivalence and/or therapeutic equivalence of many other “A”-rated generic products,\textsuperscript{54-71} the perception persists that the current bioequivalence approach for approving generic products does not adequately account for intraindividual variation in drug disposition. Some investigators believe that the extrapolation of results from single dose studies to steady-state conditions can be problematic, particularly when active metabolites are involved. Also, because bioequivalence tests have been typically carried out in young, healthy male volunteers, some clinicians doubt that this approach assures bioequivalence in the actual target population in which drugs...
are administered, such as the elderly; individuals with gastrointestinal tract, kidney, or liver disease; and
in those taking other medications.

However, few physicians appreciate that a similar situation exists for the majority of innovator new drug
products on the market. That is, the formulation that is finally approved is often not the one used in
clinical efficacy studies that supported the NDA. For example, a survey of new molecular entities
approved from 1981 to 1990, found that nearly 60% of the final marketed formulations were different
from those used in the clinical trial.\textsuperscript{22} Bioequivalence standards, although primarily used for the
evaluation of generic products, are also employed to evaluate innovator products when they are
reformulated or when other significant manufacturing changes are made. Therefore, imposing tighter
controls has implications for both the generic and innovator drug industries.

Narrow Therapeutic Index Drugs. The process of generic substitution or switching among multisource
products requires an act of faith by the prescriber or pharmacist that each product will be therapeutically
equivalent. As mentioned, certain segments of the medical community have emphasized their concern
about the therapeutic equivalence of generic drugs, especially for drugs with a narrow therapeutic index
(NTI). Currently, the NTI designation is not formally recognized by the FDA, although an internal
working list was developed in the 1980s. Additionally, there are state-to-state variations in how these
drugs are defined. Previously, drugs characterized by a narrow therapeutic ratio were defined as
follows:\textsuperscript{72}

- There is less than a twofold difference in median lethal does (LD50) and the median effective dose
  (ED50) values; or
- There is less than a twofold difference in the minimum toxic concentrations and minimum effective
  concentrations in the blood; and
- Safe and effective use of the drug products requires careful titration and patient monitoring.

An updated definition was provided in the 2000 guidance, which defined narrow therapeutic range drug
products as those “containing certain drug substances that are subject to therapeutic drug concentration or
pharmacodynamic monitoring, and/or where product labeling indicates a narrow
therapeutic range designation.”\textsuperscript{21} Examples include digoxin, lithium, phenytoin, theophylline, and
warfarin. Recent surveys and guidelines confirm that many physicians remain concerned about the
potential therapeutic inequivalence of generic NTI products including antiepileptic drugs,
antiarrrhythmics, warfarin, and cyclosporine.\textsuperscript{50,73-77}

Antiepileptic Drugs. The effects of therapeutic nonequivalence can be catastrophic in a previously well-
controlled patient with epilepsy. The presence of low water solubility, nonlinear pharmacokinetics, and
narrow therapeutic ranges for certain antiepileptic drugs exacerbates theoretical concerns. Expert panels
have established practice guidelines opposing generic substitution except when medically necessary,
especially for phenytoin and carbamazepine.\textsuperscript{76}

The occurrence of breakthrough seizures or toxicity has been attributed in case reports to generic
primidone, carbamazepine, and valproic acid.\textsuperscript{44-49} Recalls of generic phenytoin and carbamazepine in
1988 were prompted by such reports; these products had different dissolution profiles than the
formulation used in bioequivalence studies, and yielded lower serum values.\textsuperscript{78,79} Subsequently, several
double-blind, crossover trials in patients with epilepsy (including children) found no bioinequivalence or
therapeutic differences for carbamazepine between “A”-rated generics and the innovator brand-name
product in either pharmacokinetic parameters or seizure frequency.\textsuperscript{54,67} Switching to generic valproic acid
in mentally retarded individuals with seizures also resulted in comparable blood levels and seizure
control.\textsuperscript{80} Of note, studies have also demonstrated clinical sequelae from changes in the formulation of
brand-name compounds.\textsuperscript{51} Additionally, in the last 10 years, FDA Class II recalls of carbamazepine and
phenytoin for failed dissolution or stability testing have more often involved innovator products.\textsuperscript{82}
For phenytoin, a randomized, double-blind crossover study showed a generic product to be associated with higher blood levels of phenytoin. Controlled studies of different phenytoin lots found no significant subject-by-formulation interaction, although women had 30% lower AUCs than men. The effects of food on extended phenytoin preparations may involve some subject-by-formulation interactions.

For the most part, controlled studies based on average bioequivalence measures, as well as therapeutic measures, support the contention that “A”-rated generics for carbamazepine, phenytoin, and valproate are equivalent to their brand-name counterparts. However, many neurologists remain unconvinced by average bioequivalence studies, and hold to the view that interchangeability of products in previously stabilized individual patients can be problematic.

Antiarrhythmic Drugs. Similar to the situation with antiepileptic drugs, many cardiologists believe that generic substitution of antiarrhythmic drugs poses an additional hazard to patients with arrhythmias, and is a risk factor for recurrence of arrhythmias and/or proarrhythmic events. Lack of clinical efficacy data on generic products has been emphasized. One widely quoted case report involving generic procainamide was subsequently retracted. Another involving controlled-release quinidine involved non-“A”-rated products. Several randomized trials in the 1980s supported the therapeutic equivalence of both immediate- and controlled-release generic formulations of procainamide and immediate-release quinidine, but found a lack of bioequivalence for sustained-release preparations of the latter. Many of these products were discontinued, so the relevance of these studies to contemporary preparations is questionable. More recently, generic substitution of amiodarone has been associated with altered metabolite profiles, and at least 3 cases involving suspected therapeutic inequivalence for generic amiodarone have been forwarded to the FDA for review.

As with antiepileptic drugs, therapeutic failure with an antiarrhythmic drug can be catastrophic, and many physicians are reluctant to endorse product interchange for stabilized patients.

Warfarin. Few would disagree that warfarin is an NTI drug requiring special skill to use appropriately. Effective clinical use must deal with the many vagaries of this drug, including nonlinear pharmacokinetics, intra- and interpatient variability, possible drug interactions, vitamin K and ethanol intake, effects of various comorbidities on coagulation profiles, patient age and compliance. Specialized anticoagulation therapy management services have been developed to improve patient care through optimal warfarin dosing, patient education, and follow-up monitoring. Optimal patterns of clinical use have lagged because some physicians are reluctant to use the drug due to concerns, perceived or real, that the potential for major bleeding outweighs the risk of stroke prevention. Concern about the equivalence of generic products adds another element of uncertainty.

Three generic warfarin equivalents are currently on the market; the first was approved in 1997. Some articles purporting to highlight the dangers of generic substitution have relied on studies done in the 1970s and 1980s with products never judged bioequivalent by the FDA. Three case reports suggesting therapeutic inequivalence of “A”-rated generic products have been published.

Studies submitted by one generic manufacturer demonstrated bioequivalence in single-dose studies in healthy volunteers. Generic warfarin also was compared with Coumadin in a clinical setting in which clotting time was measured in a blinded, replicate-design, crossover study. Results showed average therapeutic equivalence with smaller intrasubject variability for the generic product, although individual data were not supplied. Equivalence was also demonstrated in other randomized, crossover studies. Recently, an observational study using a parallel cohort of 210 patients in a managed care organization showed that use of generic warfarin in patients previously stabilized on Coumadin did not change coagulation profiles more than continued use of Coumadin in another group of patients. Confusion surrounding generic warfarin stems from the fact that the tablet itself is not a variable product but that the...
pharmacodynamic (receptor variation) and pharmacokinetic (metabolic enzyme variants) responses are variable.

**Cyclosporine.** The immunosuppressant cyclosporine is generally considered an NTI drug. The availability of generic products raised concern in the transplant community about the relevance to transplant recipients of studies done in healthy volunteers. The validity of standard FDA criteria to establish bioequivalence between cyclosporine formulations has also been challenged. Recommendations have included establishing individual bioequivalence rather than average bioequivalence, establishing bioequivalence in transplant patients and in subgroups known to be poor absorbers, and requiring long-term safety and efficacy studies in transplant patients.

However, at present individual bioequivalence is a theoretical concept, the practical benefits of which have not been statistically proven. The common practice of blood-concentration-guided dosing of cyclosporine has sufficiently compensated for interindividual and intraindividual variability in response, and previously allowed for the safe switching of cyclosporine formulations that were not bioequivalent. Published studies comparing the first generic cyclosporine oral solution formulation with the innovator product, evaluating individual bioequivalence, evaluating bioequivalence in transplant patients, and monitoring of long-term safety after switching appeared to confirm the validity of the standard average bioequivalence criteria for generic cyclosporine, even though this product (as described above) was later withdrawn from the US market.

**Summary and Conclusion**

The approval of generic drug products was greatly facilitated by passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). The main assumption inherent in this Act is that average bioequivalence data obtained in healthy adults are an effective surrogate for safety and efficacy in the target patient population.

A sequence of events over the last 30 years has tended to undermine physician confidence in generic drugs. Several case reports appeared in the 1970s and 1980s suggesting problems with the therapeutic equivalence of generic products. Many of these products had never been judged to be bioequivalent by the FDA, and the criteria used to define bioequivalence were, at that time, not sufficient. At a time when the potential benefits of the Hatch-Waxman Act were being beginning to be realized, a series of criminal events involving both the generic industry and the FDA reinforced concerns about the quality of these products. The availability of generic versions of several NTI drugs has added another layer of concern and enhanced the scrutiny of generic products.

The criteria used by the FDA to ensure bioequivalence among multisource products are widely misunderstood. These criteria do not allow for -20% to +25% difference in bioavailability between products. Rather, these parameters represent the statistical universe in which measures of variance must reside. In practice, the mean differences in pharmacokinetic parameters for most orally administered generic products are closer to 3% or 4%. Additionally, the same criteria for bioequivalence are applied to brand name products when they undergo formulation changes, which often occurs prior to marketing. These re-formulated brand name products also are never tested in a clinical population.

While case reports continue to surface questioning the therapeutic equivalence of selected generic products, the FDA firmly believes that any differences that could exist are no greater than would be expected if one lot of the innovator’s product was substituted for another. Nevertheless, some investigators believe that different approaches may be needed to ensure “switchability” among multisource products, such as testing NTI drugs under clinical conditions in the target population or narrowing the confidence interval allowed for average bioequivalence, or by applying individual bioequivalence criteria. Tighter acceptance criteria or narrower confidence intervals have been proposed for NTIs and are required by some drug regulatory agencies (eg, Canada). However, the FDA believes
that the present requirements to prove bioequivalence are rigorous enough to prevent the possibility that
dosage forms meeting regulatory criteria could lead to therapeutic problems, even for NTI drugs.

Another approach would be to develop individual guidances that are drug-specific, in which acceptance
limits would be based on potency, dose-response relationships, and the intrasubject variability of the drug
product. Presently, no evidence exists that the latter would result in safer products, but it would certainly
be more costly for product development. However, use of an individual bioequivalence approach may be
required for the clinician and patient to be confident with the interchange of different formulations, and
the FDA is open to sponsors requesting this approach.

Theoretical assumptions of the possibility of inequivalence are not a sufficient basis for presuming its
presence and acting on that assumption. Anecdotal reports are similarly unhelpful, since one is often
unable to distinguish product failure from a natural change in disease process or patient response. The
FDA continues to seek evidence of unequal therapeutic effects between “A”-rated generics and brand-
name products. The agency is reluctant to modify its procedures without scientific evidence.
Nevertheless, little is known about the effects on bioequivalence of lot-to-lot variability during the
manufacturing process. All bioequivalence data for a given drug are based on a single point in time, as
there is no requirement for repeated bioequivalence testing to ensure that production batches of
subsequent lots of both brand-name and generic products remain bioequivalent. However, in the relative
absence of data to verify that a problem exists with the interchange of multisource products, little is to be
gained from this approach.

Steps taken recently by the FDA reveal a willingness to enhance what appears to be a sound approach to
generic drug approval. Physicians are encouraged to be alert for the possible occurrence of therapeutic
inequivalence resulting from the substitution of multisource drug products in order to provide the
scientific evidence that may be required to further enhance this process.

RECOMMENDATIONS

The Council on Scientific Affairs recommends that the following recommendations be adopted and the
remainder of this report be filed.

The 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. (New HOD Policy)

2. It should be recognized that generic drugs frequently can be less costly alternatives to brand-name
products. (New HOD Policy)

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. (New HOD Policy)

4. That Policy H-115.974 be reaffirmed. This policy states, in part, that when a physician desires to
prescribe a brand name drug, he or she do so by designating the brand name drug product and the
phrase "Do Not Substitute" (or comparable phrase or designation, as required by state law or
regulation) on the prescription. Every state has a mechanism by which the physician can prevent
generic substitution. (Reaffirm HOD Policy)
5. 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. (New HOD Policy)

6. 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. (New HOD Policy)

7. 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). (New HOD Policy)

8. The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process. (New HOD Policy)

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Appendix I. AMA Policies on Generic Drugs (AMA Policy Database)

**H-110.997 Cost of Prescription Drugs**
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)

**H-115.974 Prescription Labeling**
Our AMA recommends (1) That when a physician desires to prescribe a brand name drug product, he or she do so by designating the brand name drug product and the phrase "Do Not Substitute" (or comparable phrase or designation, as required by state law or regulation) on the prescription; and when a physician desires to prescribe a generic drug product, he or she do so by designating the USAN-assigned generic name of the drug on the prescription. (2) That, except where the prescribing physician has indicated otherwise, the pharmacist should include the following information on the label affixed to the container in which a prescription drug is dispensed: in the absence of product substitution, (a) the brand and generic name of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; and (d) the name of the manufacturer or distributor. (3) When generic substitution occurs: (a) the generic name (or, when applicable, the brand name of the generic substitute ["branded" generic name]) of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; (d) the manufacturer or distributor; and (e) either the phrase "generic for [brand name prescribed]" or the phrase "substituted for [brand name prescribed]". (4) When a prescription for a generic drug product is refilled (e.g., for a patient with a chronic disease), changing the manufacturer or distributor should be discouraged to avoid confusion for the patient; when this is not possible, the dispensing pharmacist should satisfy the following conditions: (a) orally explain to the patient that the generic drug product being dispensed is from a different manufacturer or distributor and, if possible (e.g., for solid oral dosage forms), visually show the product being dispensed to the patient; (b) replace the name of the prior generic drug manufacturer or distributor on the label affixed to the prescription drug container with the name of the new generic drug manufacturer or distributor and, show this to the patient; (c) affix to the primary label an auxiliary (sticker) label that states, "This is the same medication you have been getting. Color, size, or shape may appear different:" and (d) place a notation on the prescription record that contains the name of the new generic drug manufacturer or distributor and the date the product was dispensed. (BOT Rep. 1, A-95; Amended: CSA Rep. 2, I-99; Modified Res. 512, I-00)
**H-115.984 Product Identification of Generic Drugs**
The AMA supports working with the appropriate organizations to: (1) develop a coding system for the identification of all solid medication forms; (2) encourage imprinting, when feasible, each tablet, capsule, or other solid dosage form of generic prescription drug with its unique code and the name or other distinctive mark identifying the manufacturer; and (3) encourage compilation of this coding system into a reference and disseminate it to physicians, pharmacists and law enforcement agencies in an appropriate manner. (Res. 44, A-87; Reaffirmed: Sunset Report, I-97)

**H-115.986 Drug Labeling Regulation**
The AMA favors exploring ways in which information on the bioavailability and bioequivalence of generic drugs could be more readily available to physicians. (BOT Rep. UU, A-85; BOT Rep. 1, A-95)

**H-120.974 Prohibition of Dispensing FDA B-Rated Generic Drugs**
The AMA will petition HCFA, through drug utilization review boards established in each state under Medicaid, to prohibit the dispensing of FDA B-rated generic drug products which are not therapeutically equivalent inasmuch as their use cannot assure consistency in clinical results and outcomes. (Res. 521, I-92; Reaffirmed: BOT Rep. 53-A-94)

**H-120.998 Prescribing and Dispensing of Drugs**
The AMA believes that physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and encourages physicians to supplement medical judgments with cost considerations in making this choice. (Res. 37, A-67; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98)

**H-125.987 Prepaid Prescription Plans Medication Substitution**
Policy of the AMA states that when managed care organizations or prepaid prescription plans attempt to substitute for a physician's prescription, this substitution may only be accomplished after either another physician or a registered pharmacist calls to obtain approval from the prescribing physician. (Res. 727, A-96)

**H-125.988 Substitution of A-Rated Generic Drugs**
Our AMA encourages the National Association of Boards of Pharmacy to: (1) establish appropriate national policy for pharmacists and pharmacies concerning the undesirability of generic substitution with non-A-rated generic drugs, and (2) develop model state legislation to implement that policy. (Sub. Res. 508, I-95)

**H-125.992 Generic Substitution**
(1) The AMA reaffirms its previous policy that all physicians be urged to supplement medical considerations with cost considerations when selecting the drug of choice for an individual patient and to become well-informed about the quality of prescription drug products available from multiple sources. (2) Until the methodology for approval of bioequivalence and therapeutic equivalence of all drug products is resolved, the AMA reaffirms its previous policies: (a) That the dose of any medication continue to be titrated for optimum efficacy and safety, especially in patients with chronic disorders who require prolonged therapy or patients in special population groups not expected to respond to a drug in the normal manner. (b) When multiple refills of a drug product for chronic diseases are anticipated, the physician avoid substitution unless the products have been proven to be bioequivalent. (c) When serious or unusual problems develop that may be related to drug substitution, the findings should be documented. A short FDA reporting form is available on the last page of the FDA Drug Bulletin, which is sent quarterly to all practicing physicians. Physicians are urged to include the manufacturer and lot number of the drug product in the 1639 form. (3) It is the policy of the AMA that the physician and pharmacist should take necessary steps to eliminate confusion to the patient when labels are changed as a result of any drug substitution, particularly when the color, shape, and taste of drug substitutes vary from the originally prescribed product. (4) It is the policy of the AMA that the physician insist that the pharmacist must not
substitute any generic drug product that has a B bioequivalency rating (i.e., potential or documented bioinequivalent problem). All B rated drug products should be required to demonstrate bioequivalence, or their application should be withdrawn by FDA. (5) The AMA reaffirms its previous policy that physicians should become familiar with specific laws governing generic drug substitution in their state, and, where applicable, they should obtain a copy of the state's current generic substitution drug formulary. (6) It is the policy of the AMA that the only text currently available for determining equivalence among drug products, i.e., Approved Drug Product With Therapeutic Equivalence Evaluations (the Orange Book or The List) should be revised as follows: Although the FDA is mandated to do so, single-source drugs should be eliminated. The manufacturing source for all multisource drug products should be included, even if it requires a rapid update system, possibly on-line, for the pharmacist. The inclusion of decisional criteria for determining bioequivalency and therapeutic equivalency of selected agents is recommended. (7) It is the policy of the AMA that the FDA proceed without undue delay to implement an imprint coding system for all solid oral dosage forms that allows identification of the manufacturing source of the product even if a non-manufacturing distributor is involved. This will markedly aid the physician, the pharmacist, and the patient to know when drug substitution has occurred and will help to resolve causality if a drug product failure has occurred. (8) It is the policy of the AMA that selected post marketing surveillance systems (other than spontaneous reporting) of adverse events be explored by the FDA. Especially meaningful might be studies that provide data on (a) a comparison of elderly patients with associated multiple diseases and/or on multiple drug therapy in whom the drug will be used, but who are not representative of the group in which the drug was tested for bioequivalency; (b) studies in patients compared with the group in whom the drug was tested when a number of active metabolites of a drug are known to be present in different proportions than the test group; and (c) studies when the therapeutic index of a drug is quite narrow. (9) It is the policy of the AMA that Congress support the generic drug review and approval process with adequate personnel and financial resources for the FDA. (BOT Rep. K, A-90; Reaffirmed: BOT Rep. 53-A-94)

H-125.998 Generic Substitution of Prescribed Drugs
Our AMA: (1) will assist states in maintaining and establishing laws to protect patients against the automatic substitution of critical-dose prescription drugs; (2) reaffirms its opposition to the revision of state laws and pharmacy regulations which prohibit unauthorized substitution of prescription drug products as contrary to the public interest; (3) urges physicians to supplement medical considerations with cost considerations in selecting the drug of choice for an individual patient; and (4) recommends that when a physician desires to delegate selection of the source of a particular drug to the pharmacist, he do so by writing the prescription using the generic name or, if a brand name is used, by the notation, generic substitution allowed. (Sub. Res. 45, I-76; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Appended: Res. 507, I-00)

H-125.999 Drug Substitutes
Our AMA (1) supports continued efforts to inform the public and the profession of the potential problems and risks should a physician's choice of therapeutic agents be delegated to non-physicians; and (2) asks that state medical associations provide scientific and economic reasons in support of this position to state legislatures considering enactment of laws on substitution of drug products other than those prescribed or agreed upon by an attending physician. (Sub. Res. 27, A-74; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmation A-99)
## Appendix II.
Specialty Society Positions on Generic Substitution

<table>
<thead>
<tr>
<th>Organization</th>
<th>Year of Statement</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>American College of Cardiology</td>
<td>1988</td>
<td>The American College of Cardiology and the American Heart Association strongly oppose legislation that would permit prescription &quot;therapeutic substitution&quot; by pharmacists as an action that is not consistent with quality of patient care and may pose an unnecessary risk to the patient's well-being. This statement should not be construed to represent opposition to generic substitution, the act of dispensing a different brand or an unbranded drug product that is the same chemical entity and bioequivalent to the drug product prescribed.</td>
</tr>
<tr>
<td>American Academy of Asthma, Allergy, and Immunology</td>
<td></td>
<td>Position Statement 27. Generic drugs, if they are used, should be proven bioavailable in patients with the disease for which they are approved for treatment or therapeutically effective by a proper scientific method.</td>
</tr>
<tr>
<td>American College of Rheumatology</td>
<td>2000</td>
<td>Opposes legislation or regulation that would permit prescription therapeutic substitution by pharmacists. Generic substitution may be appropriate when, in the judgement of the physician, different brands of the same drug will provide equivalent efficacy and safety.</td>
</tr>
<tr>
<td>American Academy of Neurology</td>
<td>1990</td>
<td>Patient safety and drug efficacy may be unduly compromised by indiscriminate switching to, from, or between generic drugs for patients taking phenytoin or carbamazepine. Physicians should avoid switching between formulations of AEDs except when medically necessary, particularly with carbamazepine or phenytoin. They should also monitor blood levels closely at the time of any known or suspected switch to a different formulation. Medication doses should be readjusted accordingly.</td>
</tr>
<tr>
<td>American Academy of Family Physicians</td>
<td>2000</td>
<td>There appears to be no substantive evidence that bioequivalence does not equal therapeutic equivalence. While physicians should always maintain vigilance, products approved by the FDA should be expected to be clinically equivalent to brand-name products.</td>
</tr>
<tr>
<td>American Academy of Pediatrics</td>
<td>1996</td>
<td>Supports the concept of prescribing the least costly medication if safety and efficacy are not compromised. Generic prescribing may be appropriate when, in the judgment of the physician, different brands of the same drug will provide equivalent efficacy and safety. Committee on Drugs does not support a blanket recommendation for generic substitution.</td>
</tr>
</tbody>
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EXECUTIVE SUMMARY

This Board of Trustees report is in response to the first resolve of Resolution 212, which was adopted, and Resolutions 215 and 222, which were referred by the House of Delegates, at the 2004 Annual Meeting. These resolutions ask the American Medical Association to either study (Resolution 212) or support (Resolutions 215 and 222) the importation of prescription drugs into the United States (US) if patient safety can be assured. Prescription drug importation involves weighing the legitimate concerns over the lack of access to affordable prescription drugs in the US against the legitimate concerns over the safety of imported prescription drugs.

The report provides background information on: 1) the evolution of the US drug regulatory system during the 20th century; 2) the evolution of the drug importation debate since 2000; and 3) AMA polices and activities related to this debate. The report then focuses on the nature of the AMA’s comments to the Department of Health and Human Services (HHS) Task Force on Drug Importation, which reflect the AMA’s current best judgment on what needs to be done to assure patient safety if drug importation is legalized.

The US drug supply currently is among the safest in the world because the US has an outstanding drug regulatory system and a reasonably closed drug distribution system. However, there are reasons for concern. Drug counterfeiting within the US has increased in recent years and the influx of unapproved, adulterated, and counterfeit drugs into the US from “rogue” Internet Web sites has become a major problem. The legalization of drug importation into the US likely would exacerbate these patient safety-related problems, unless mechanisms can be put into place that will assure the safety of the US drug supply.

In its comments to the HHS Task Force on Drug Importation, the AMA has identified three areas that need to be addressed. First, the AMA encouraged the Task Force to make certain that all prescription drugs for sale to patients in the US, including drugs that might be legally imported, be Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to US laws and regulations. Second, to address vulnerabilities in the drug distribution chain, the AMA recommended that, if importation is legalized, the drug distribution system be “closed” and all drug products be subject to reliable, “electronic” track and trace technology. If these two areas are effectively addressed, including the granting of the necessary authority and resources to the FDA, it may be feasible to ensure the authenticity and integrity of drugs that are imported by US wholesale distributors and pharmacies. Third, the AMA raised significant concerns about personal importation, i.e., importation by individuals, via the Internet because so many Internet Web sites currently sell prescription drugs illegally, i.e., based only on an online questionnaire or with no prescription whatsoever. Even if changes in federal law are made to address the Internet problem, it would be prudent to initially limit dispensing of prescription drugs to domestic Internet pharmacies to determine if patient safety can be assured.

The report of the HHS Task Force on Drug Importation is scheduled to be released to the public in the late fall of 2004. Because this Task Force had far greater resources and expertise than the AMA to study the impact of legalized drug importation on patient safety, the AMA also should review the recommendations of this Task Force and, as appropriate, revise its position on whether or how patient safety can be assured under legalized importation.
REPORT OF THE BOARD OF TRUSTEES

Subject: Prescription Drug Importation and Patient Safety
(Resolutions 215 and 222, A-04)

Presented by: J. James Rohack, MD, Chair

Referred to: Reference Committee L
(Andrew W. Gurman, MD, Chair)

At the 2004 Annual Meeting, the House of Delegates adopted Resolution 212 and referred Resolutions 215 and 222. The first resolve of Resolution 212, introduced by the District of Columbia delegation, asks our American Medical Association (AMA) to “explore reasonable mechanisms for medications to be safely re-imported, under Food and Drug Administration (FDA) guidance, from other countries.” Resolution 215, introduced by the Illinois delegation, asks our AMA to “endorse appropriate testing and labeling of drugs imported by individuals for their personal use to assure safety and efficacy; and to urge adoption of legislation or regulation necessary to permit the procurement and use of medications from non-US sources by residents of the United States (US) once the safety of those drugs is assured.” Resolution 222, introduced by the Michigan delegation, asks our AMA to “seek national legislation to make it legal for Americans to purchase prescription drugs from other countries for medications that are currently legal in the United States and that meet the same quality standards.”

This Board report focuses on the controversial subject of prescription drug importation and patient safety. Prescription drug importation involves weighing the legitimate concerns over the lack of access to affordable prescription drugs in the United States against the legitimate concerns over the safety of imported prescription drugs.

BACKGROUND

Evolution of Drug Regulation in the United States During the 20th Century. It is widely accepted that the US drug supply currently is among the safest in the world, and this largely reflects a drug regulatory system that represents a gold standard for other countries. However, it took most of the 20th century for the US drug regulatory system to achieve this high level of quality and it has been an evolutionary process, often in response to catastrophes. This is illustrated by the following major changes in US drug law during the past century.

- In 1906, the Congress passed the Pure Food and Drugs Act, which prohibited interstate commerce of misbranded and adulterated foods and drugs. This law was enacted because of widespread misbranding and adulteration of foods and drugs at the time.
- In 1938, the Congress passed the Food, Drug, and Cosmetic Act (FDCA); the key provision of the FDCA was that all drugs required pre-distribution clearance for safety by the FDA before a manufacturer could commercially distribute a new drug. In large part, the FDCA was passed in

1Resolution 212 (adopted, A-04) had four Resolves. Only the first Resolve is addressed in this Board report. The second Resolve was satisfied by the adoption of Resolution 211 at the 2004 Annual Meeting, and the third and fourth Resolves are being addressed in Council on Medical Service Report 3, “Reducing Prescription Drug Prices,” that also will be considered at the 2004 Interim Meeting.

Action of the AMA House of Delegates 2004 Interim Meeting: Board of Trustees Report 3
Recommendations Adopted as Amended and Remainder of Report Filed.
response to the elixir of sulfanilamide disaster of 1937, where 107 persons were killed by diethylene glycol (antifreeze), which was used as a solvent for the drug.

- In 1951, Congress passed the Durham-Humphrey Amendments to the FDCA. While not in response to a catastrophe, this law recognized that some drugs were more toxic and/or could not be used directly by consumers in a safe manner. Thus, the current classification of drugs into “prescription only” and “over-the-counter (OTC)” was established. Since 1951, federal law requires that prescription drugs can only be dispensed pursuant to a prescription by a licensed practitioner, usually a physician.

- In 1962, Congress passed the Kefauver-Harris Amendments to the FDCA, largely in response to the thalidomide disaster in Europe. Among this law’s many provisions were the requirements that 1) drug manufacturers must show proof of both effectiveness and safety before FDA approval for marketing; 2) manufacturers must conform to “current good manufacturing practices” in the manufacture of drugs; 3) the FDA has the authority to inspect establishments where drugs are manufactured, processed, packed and held; and 4) manufacturers must provide full disclosure of information about their prescription drugs in the form of a “package insert.”

- In 1987, Congress passed the Prescription Drug Marketing Act (PDMA). Because of concerns about counterfeit drugs being diverted into the US drug supply at that time, a provision in this law made the importation of pharmaceuticals into the US illegal except when a manufacturer imported (or re-imported, i.e., manufactured in the US, exported, and then imported back into the US) its own products. (Note: The FDA has allowed a “personal use exemption” whereby individuals may bring in medicines, otherwise not available in the US, for their personal use if supervised by a physician.)

- In addition to changes in federal law, individual states passed laws during the 20th century to regulate the prescribing of drugs by physicians and the dispensing of drugs by pharmacists to ensure that patients are adequately protected.

Thus, throughout the 20th century, laws were incrementally passed to ensure that prescription drugs used by American patients today are safe, effective, and properly prescribed and dispensed. Today, drug manufacturers must prove to the FDA that their products are safe and effective prior to marketing; the manufacture and distribution of these products is tightly controlled by the FDA; and prescription drugs must be prescribed by a licensed practitioner (usually a physician) and dispensed by a licensed pharmacist. It is important that this history not be forgotten in light of the current debate over drug importation and patient safety.

Evolution of the Drug Importation Debate in the United States since 2000. In 2000, in response to the rapidly rising prices of prescription drugs in the US, Congress debated whether to allow importation of pharmaceuticals into the US from Canada where prices are lower due to Canadian price controls. Unlike the FDA’s personal use exemption, the drugs under discussion already were available for sale within the US. Despite strong opposition from the US pharmaceutical industry and the FDA, Congress passed legislation that would allow such importation by wholesalers and pharmacists (but not individuals), and this law became Section 804 of the FDCA (21USC384).

A provision of Section 804 of the FDCA required that the Secretary of Health and Human Services (HHS) demonstrate to Congress that drug importation poses no additional risk to the public health and safety, and that the law would result in a significant reduction in the cost of prescription drugs to American consumers. Neither Secretary Donna Shalala (under President Bill Clinton) nor Secretary Tommy Thompson (under President George W. Bush) was able to guarantee the safety of these imported prescription drug products. Therefore, Section 804 has never been implemented and, for practical purposes, the importation of pharmaceuticals into the US remains illegal.
In 2003, as part of the debate on a Medicare outpatient prescription drug benefit, the Congress again considered drug importation as an alternative way to lower the costs of prescription drugs to American citizens. The Senate included a provision in its bill (S.1) that was very similar to the 2000 law in that it would require the Secretary of HHS to demonstrate that importation did not pose an additional risk to the public health and safety. However, the House passed H.R. 2427, the Gutknecht-Emerson bill. After conference committee reconciliation, the Senate version ultimately became part (Sec. 1121) of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (P.L. 108-173). In addition, a provision (Sec. 1122) was included in the law that required the Secretary of HHS to establish a Task Force to assess the feasibility of drug importation.

Unlike the 2000 law and what was passed in the MMA, H.R. 2427 would not have required the Secretary of HHS to certify that drug importation could be done safely, as this provision had been eliminated from the bill. Furthermore, this bill would have allowed individual citizens, in addition to wholesalers and pharmacists, to import prescription drugs from many countries (not just Canada). The pharmaceutical industry, many pharmacy organizations, the Bush Administration, and many senators, both liberal and conservative, opposed H.R. 2427 because it did not ensure the safety of the drug supply. On the other hand, the House of Representatives (see above) and many insurers and consumer groups supported this legislation.

Subsequent to passage of the MMA in 2003, most Democrats and some Republicans complained that the new Medicare outpatient prescription drug benefit would fail to give Medicare beneficiaries sufficient relief from high drug prices. Also, Americans have become increasingly dissatisfied with perceived unfair pricing practices by the pharmaceutical industry, where US citizens pay much higher drug prices to subsidize pharmaceutical research and development (R & D) for the rest of the world where government price controls exist. With strong support from the AARP and governors from states, including Illinois, Wisconsin, Minnesota, and others, a strong grassroots campaign has been ongoing for most of 2004 to legalize the importation of prescription drugs. Despite the fact that federal law still makes it illegal to import prescription drugs unless the Secretary certifies that it does not pose an additional risk to the public health and safety, some states (e.g., Wisconsin, Minnesota) have established state government-sponsored Web sites that allow citizens of the state to buy prescription drugs directly from Canadian Internet pharmacies. The FDA has threatened legal action. However, while the Agency has closed down some Web sites, it has not taken any legal action against state governments.

Three bills to legalize the importation of pharmaceuticals have been introduced in Congress in 2004: S.2307 by Sen. Grassley (R-IA), S.2328 by a bi-partisan group of Senators headed by Sen. Dorgan (D-ND), and S.2493 by Sen. Gregg (R-NH). At the time this report was written, it was unclear if any of these bills will be enacted into law in 2004. The Dorgan bill, in particular, is being vigorously opposed by the pharmaceutical industry. S.2328 would allow importation of prescription drugs by wholesalers and pharmacists from multiple countries and would allow personal importation by individuals from Canada. Personal importation could start immediately on passage of the bill, and certification by the Secretary of HHS that drugs can be safely imported is not required. Furthermore, the Dorgan bill would allow the federal government to prosecute a pharmaceutical company with an antitrust violation if it refused to sell its drug products to a foreign wholesaler or pharmacy at the same low (government-controlled) price that it charges for drugs not being exported. This provision, if legal, would prevent companies from cutting off supplies to wholesalers and pharmacies in countries like Canada to prevent importation to the US.

In addition to state activities and the federal bills, Secretary Thompson established the HHS Task Force on Drug Importation, as directed by the MMA, in early 2004 and named Richard Carmona, MD, US Surgeon General, as its chairman. Dr. Carmona and the Task Force held a number of hearings in the spring of 2004, soliciting comments from organizations representing consumers, health professionals (e.g., physicians, pharmacists, and nurses), payers, the pharmaceutical industry, drug wholesalers, state
governments, and others. The report of this Task Force is expected to be made public in the late fall of
2004.

Whether patient safety can be assured under legalized drug importation remains at the core of the debate.
The patient safety issue includes consideration of the impact of widespread importation on the viability of
both the US drug regulatory and drug distribution systems. Other questions include whether the supply of
foreign drugs will be adequate to support legalized importation into the US; whether any money will be
saved (a 2004 Congressional Budget Office analysis is pessimistic about any savings); and whether
pharmaceutical innovation will be adversely affected. These latter three questions, although important,
will not be considered further in this report.

AMA POLICIES AND ACTIVITIES

AMA Policies. Currently, the AMA does not have a policy that directly addresses whether legalized drug
importation into the United States can be done in a manner that ensures patient safety. However, the
AMA has a number of policies that indirectly affect this issue.

• Policy H-100.969 (AMA Policy Database) supports 1) the inspection of all foreign manufacturers of
pharmaceutical chemicals and products which are exported to the United States to assure compliance
with US standards; and 2) periodic surveillance inspections of all foreign pharmaceutical
manufacturers with timely follow-up inspection of all foreign manufacturers that have been identified
as having serious manufacturing deficiencies.

• Policy H-100.980 states 1) that a strong and adequately funded FDA is essential to ensuring that safe
and effective medical products are made available to the American public as efficiently as possible; 2)
that our AMA (a) continue to monitor and respond appropriately to legislation that affects the FDA
and to regulations proposed by FDA; (b) continue to work with the FDA on controversial issues
concerning food, drugs, biologics, radioactive tracers and pharmaceuticals, and devices to try to
resolve concerns of physicians and to support FDA initiatives of potential benefit to patients and
physicians; and (c) continue to affirm its support of an adequate budget for the FDA so as to favor the
agency’s ability to function efficiently and effectively; and 3) that our AMA will continue to monitor
and evaluate proposed changes in FDA and will respond as appropriate.

• Policy H-35.999 states that 1) the contribution of pharmacy as an independent profession in assisting
physicians toward the constant goal of improved patient care is recognized and commended; and 2)
the AMA urges physicians to encourage and support the continued growth of pharmacy as a valuable
and necessary member of the health team.

• Policy H-100.989 states that the AMA supports the present classification of drugs as either
prescription or over-the-counter items and opposes the establishment of a third transitional class of
drugs.

• Policy H-120.956 states that our AMA will: (1) develop principles describing appropriate use of the
Internet in prescribing medications; (2) support the use of the Internet as a mechanism to prescribe
medications with appropriate safeguards to ensure that the standards for high quality medical care are
fulfilled; (3) work with state medical societies in urging state medical boards to ensure high quality
medical care by investigating and, when appropriate, taking necessary action against physicians who
fail to meet the local standards of medical care when issuing prescriptions through Internet Web sites
that dispense prescription medications; (4) work with the Federation of State Medical Boards and
others in endorsing or developing model state legislation to establish limitations on Internet
prescribing; (5) continue to work with the National Association of Boards of Pharmacy and support
their "Verified Internet Pharmacy Practice Sites" program so that physicians and patients can easily
identify legitimate Internet pharmacy practice sites; (6) work with federal and state regulatory bodies
to close down Internet Web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States; and (7) keep pace with changes in technology by continually updating standards of practice on the Internet.

**AMA Activities.** Over the years, the AMA has publicly supported the FDA’s “personal use exemption” because it was important for patients to have access to drugs that otherwise might not be available in the US. On the other hand, the AMA frequently has expressed concern about the authenticity and quality of prescription drugs, already available in the US, that have been purchased by US citizens in Mexico and from other foreign (e.g., offshore) sites. Since 1999, the AMA also has expressed deep concern about foreign Internet sites that illegally sell prescription drugs to American consumers, often without a prescription. Again, FDA-approved versions of these drugs already are available in the US.

In 2000, when Congress first passed drug importation legislation, which included the provision that the HHS Secretary must demonstrate that importation poses no additional risk to public health and safety, the AMA took a position of “non-support” for the legislation because of concerns about patient safety.

At the 2003 Annual Meeting, our House of Delegates did not adopt Resolution 518, which had asked the AMA to support importation of pharmaceuticals. In light of this and based on an analysis of H.R. 2427, i.e., the Gutknecht-Emerson bill, the AMA opposed this bill. Again, the primary concern was patient safety. The AMA was especially concerned that this legislation deleted the important safety provision that required the HHS Secretary to demonstrate that importation did not pose an additional risk to public health and safety. The AMA also was concerned that H.R. 2427 allowed individuals to import drugs from multiple countries and believed the excellent US drug regulatory system would have been in jeopardy if the FDA had no control over a large subset of imported drugs. At the 2003 Interim Meeting, the House of Delegates also did not adopt a resolution (Resolution 922) that asked the AMA to support importation if the drugs could be assured to be safe and effective.

In 2004, the AMA was asked to testify before the HHS Task Force on Drug Importation regarding the legalization of drug importation. Consistent with House actions, the AMA took the position that patient safety must be assured if the importation of pharmaceuticals into the US were to be legalized. Because the report of the HHS Task Force has yet to be released, this Board report will focus on the AMA’s comments to the HHS Task Force. Based on currently available information, the Board believes the AMA’s comments to the HHS Task Force reflect our best judgment on what should be done to assure patient safety if drug importation is legalized. Views could change upon release of the report of the HHS Task Force.

**ASSURING PATIENT SAFETY UNDER LEGALIZED DRUG IMPORTATION: AMA COMMENTS TO THE HHS TASK FORCE ON DRUG IMPORTATION**

**Only FDA-Approved Drugs Should be Imported.** In 2004, essentially every stage in the life of a prescription drug is regulated by the FDA. This includes (but is not limited to):

- Approval of an Investigational New Drug Application (IND) so that an investigational drug can be studied in humans;
- Oversight of human clinical trials on the investigational drug that are conducted by the drug’s manufacturer;
- Oversight of all other testing of the drug by the manufacturer, such as for product stability, potency, bioavailability, and the detection of impurities;
- Approval of the drug manufacturer’s New Drug Application (NDA) to allow the marketing of the drug product as safe and effective for its labeled indications;
• Oversight of the manufacture of the drug product after approval through inspections of the
manufacturing sites and by ensuring that manufacturers meet all current Good Manufacturing
Practices (cGMP) requirements;
• Oversight of all drug product labeling, packaging and promotion; and
• Postmarketing oversight of the drug product related to reporting of adverse reactions, modifications
to labeling, product recalls, etc.

Consistent with AMA Policies H-100.980 and H-100.969, the AMA encouraged the HHS Task Force on
Drug Importation to make certain that all drugs for sale to patients in the US, including drugs that might
be legally imported, be FDA-approved and meet all other FDA regulatory requirements, as described
above.

To require less has two potential negative consequences. First, patient safety cannot be assured if the
prescription drugs that patients consume fall outside of FDA regulation. This is not meant to indict all
foreign regulatory bodies as inferior to the FDA. Rather, it is inappropriate to subject American patients
to drug products with different standards. Drug products regulated by a foreign regulatory body may look
different, be of different formulation, have different bioequivalence, or have different labeling (perhaps
not in English) than the FDA-regulated versions. For example, a patient who is stabilized on an FDA-
regulated product and then receives a refill containing a foreign-regulated product with different
bioequivalence could experience therapeutic failure or more side effects. Would the physician or patient
know that a foreign-regulated drug was substituted? Also, what does a physician do if one country’s
product is subject to a recall and another country’s product is not subject to a recall?

The other potential negative consequence of allowing foreign-regulated versions of drug products to be
sold in the US is that the FDA, itself, could be marginalized because a subset of products would fall
outside its regulation. Thus, a century of evolution of the US drug regulatory system into the gold
standard for the world could be compromised by such an action.

For these reasons, if drug importation is to be legalized, only FDA-regulated products should be allowed
to be imported. It is very likely that the FDA will require additional authority and resources to effectively
regulate these drug products, and the Congress must provide the needed authority and appropriations.

The Integrity of the Drug Distribution System Must be Assured. As discussed in the Background to this
report, the PDMA was passed by Congress in 1987 because of concerns about counterfeit drugs being
diverted into the US. This is still a concern in 2004.

While the US drug supply remains among the safest in the world, it is still vulnerable to counterfeit drugs
and this problem appears to be increasing. In the late 1990s, the FDA conducted about five counterfeit
drug investigations per year. However, in 2001, 2002, and 2003, more than 20 such investigations were
conducted annually. Prescription drugs, such as Lipitor, Combivir, Procrit, Neupogen, Epogen, Serostim,
Lupron, Zyprexa, and Viagra, all have been subject to counterfeiting within the US in the past four years.
Counterfeit drug products closely resemble legitimate drugs yet may contain only inactive ingredients,
incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated
(adulterated). Drug counterfeiting poses a real threat to patient safety and the public health.

To respond to this emerging threat to our domestic drug supply, the FDA Commissioner established a
Counterfeit Drug Task Force in July 2003; the report of this Task Force titled, “Combating Counterfeit
Drugs: A Report of the Food and Drug Administration,” was made public in February 2004. The Task
Force recommended a multi-pronged approach to combating the growing threat of counterfeiting to our
domestic drug supply. The Task Force’s recommendations included:

• Adoption of reliable “electronic” track and trace technologies, most likely using radiofrequency
identification (RFID) tagging of drug products, by 2007 so that an accurate drug pedigree, i.e., a
record of each distribution of a drug from the sale by a manufacturer through acquisition and sale
by any wholesale distributor, repackager, and/or pharmacy, can be provided to ensure the
authenticity and integrity of a drug product throughout the drug distribution chain (Note: A paper
pedigree requirement of the PDMA never was implemented because of concerns about
administrative burdens and costs to small wholesale distributors; also, paper pedigrees can be
forged or falsified);

- Use of overt and covert authentication technologies, such as color shifting inks and holograms, for
pharmaceuticals;
- Increased regulatory enforcement of wholesale distributors by state governments, who are
responsible for their licensure and oversight;
- Increased criminal penalties to deter counterfeiting and more adequately punish those convicted;
- Adoption of more secure business practices by all participants in the drug supply chain;
- Development of a more effective reporting system for counterfeit drugs, including the
establishment of a “Counterfeit Alert Network” to provide timely and effective notification to
affected health professionals and the public whenever a counterfeit drug is identified (Note: The
AMA is a formal member of the Counterfeit Alert Network.);
- Education of consumers and health professionals about the risks of counterfeit drugs and how to
protect against these risks; and
- Collaboration with foreign stakeholders to develop strategies to deter and detect counterfeit drugs
globally.

Given these concerns about the security of our domestic drug supply, what would be the expected impact
of widespread legalized drug importation into the US? The World Health Organization (WHO) has
estimated that approximately 10% of the worldwide drug supply is counterfeit. In July 2004 alone, the
FDA reported cases of counterfeit versions of the drugs Zocor and carisoprodol being imported from
Mexico, and cases of fake, substandard and potentially dangerous versions of Ambien, Viagra, and
Lipitor purchased from a Web site advertised as Canadian. Thus, there is the potential for exacerbation of
the counterfeit problem in the US through importation of counterfeit drugs, unless steps are taken to
prevent this.

In addition to concerns about counterfeiting, there also is evidence that many of the prescription drugs
currently being imported – illegally – into the US are unapproved and/or adulterated (e.g., contaminated,
or manufactured, stored, handled or shipped improperly). In both the summer and fall of 2003, the FDA
and US Customs and Border Protection (Customs) did a series of “blitz” examinations of international
mail facilities in the US to determine if shipments of drug products of foreign origin were unapproved,
adulterated, and/or counterfeit. These spot examinations were conducted at mail facilities in Miami, New
York (JFK International Airport), San Francisco, and Carson, CA, in the summer, and in Buffalo, Dallas,
Chicago, and Seattle in the fall.

Of 1,153 imported drug products examined in the summer blitz, 88% were unapproved products
originating from countries, such as Canada (16%), India (14%), Thailand (14%), and the Philippines
(8%). Unapproved versions of hazardous drugs, such as warfarin, Dilantin, Accutane, and codeine were
among the drug products found. Also, drugs with inadequate labeling or inappropriate packaging,
veterinary drugs, and drugs withdrawn from the US market were being imported into the US.

In the fall blitz, 80% of 1,006 parcels examined contained unapproved drugs. Most of these drugs were
exported from Canada (80%), but some also came from Mexico (16%) and other countries. Again,
unapproved versions of hazardous drugs, such as warfarin, tamoxifen, carbamazepine, diazepam, and
human growth hormone were among the drug products found. Also, improperly labeled drugs and
potentially recalled drugs were being imported into the US.
The above discussion illustrates current vulnerabilities of the US domestic drug distribution chain and the probability that this would be exacerbated by legalizing drug importation. Thus, the AMA expressed concern to the HHS Task Force on Drug Importation that if prescription drugs are allowed to be legally imported into the US from foreign countries, counterfeit or adulterated drugs will be more likely to enter our - now reasonably well protected - drug distribution system unless that distribution system can be secured. The AMA recommended that, if the US legalizes drug importation, the drug distribution system should be “closed” and all drug products should be subject to reliable, “electronic” track and trace technology, so the authenticity and integrity of these products can be assured throughout the drug distribution chain.

Undoubtedly, this would require rigorous regulatory standards, registration requirements, and inspection programs specifically designed to ensure that all those engaged in exporting and importing prescription drugs are suitably qualified and possess the skills and infrastructure to protect the integrity of the drug supply chain. Furthermore, the development, implementation, and validation of technologies, such as RFID, to effectively track and trace drug products would need to be completed before such a distribution system could be activated. Whether such a distribution system can be put in place, and the cost and time required to accomplish this, are uncertain.

Personal Importation via the Internet Raises Patient Safety Concerns. If a system can be put into place that ensures only FDA-approved drug products are imported, and that the authenticity and integrity of these products is not altered throughout the distribution chain, then allowing importation by US wholesale distributors and pharmacies may be feasible. However, allowing direct importation by patients, i.e., personal importation, raises other issues of concern.

Currently in the US, most prescriptions are filled in community pharmacies by pharmacists who are licensed by individual states. This is very similar to how physicians are licensed to practice medicine. Under this established system, pharmacists provide a valuable checks-and-balances role in ensuring the right medicine is dispensed and important information about the medicine is provided directly to the patient (AMA Policy H-35.999). However, allowing patients to order prescription drugs directly from foreign countries essentially bypasses this safety system. Much as the FDA’s role in drug regulation would be diminished if foreign versions of FDA-approved drugs could be imported, so would the important role of the pharmacist be diminished if patients could buy their prescription drugs directly from foreign sources. The AMA should continue to support the role of the US licensed pharmacist, in assuring that prescriptions are properly filled and that patients understand how to take their medicines.

The above concerns are amplified because the primary vehicle used by individuals to personally import drugs into the US is the Internet. Since 1999, the AMA has been a strong advocate for finding ways to ensure that prescription drugs sold over the Internet come only from bona fide US licensed pharmacies that dispense prescription drugs, and only pursuant to valid prescriptions that are written by US licensed physicians who have done a history and physical examination on the patient (see AMA Policies H-120.956 and H-120.949). Unfortunately, there currently are hundreds, if not thousands, of Internet sites that sell prescription drugs, including controlled substances, based only on an online questionnaire or with no prescription whatsoever. Some of these sites are domestic, but many are of foreign origin. Unfortunately, one really does not know about their origin, because little information about these “rogue” Internet pharmacies is disclosed on their Web sites. The net result is that a real “buyer beware” situation exists when it comes to buying drugs via the Internet.

Legalizing importation directly by patients will only exacerbate this already large problem of Internet sales of prescription drugs. The finding of large quantities of unapproved, adulterated and counterfeit drugs by the FDA and Customs during inspections of drug products at multiple international mail facilities in the US is likely due, in large part, to purchases of these products via the Internet. Clearly, the fake and substandard drug products (Ambien, Viagra, and Lipitor) purchased by the FDA from “CanadianGenerics,” a bogus Canadian Web site (see above), is another illustration of the problem.
There also is evidence to suggest that even Canadian Internet pharmacies that are recommended by the states of Minnesota and Wisconsin have posed patient safety problems, such as using unsupervised technicians to fill prescriptions; failing to label dispensed prescription drugs properly; failing to properly refrigerate certain drugs; and selling products not authorized by the state programs.

Recently, Canadian Internet pharmacies have acknowledged that they are obtaining supplies of prescription drugs for US importation from other countries, such as England, Ireland, other European countries, Australia, New Zealand, Israel, and Chile. The “trans-shipment” through Canada of drugs that originated in other countries further raises concerns about the authenticity and integrity of the drug products being received by US patients.

Finally, for a prescription to be dispensed by a Canadian pharmacy, a Canadian physician must re-write the original prescription from a US-licensed physician. This raises ethical concerns. Moreover, there have been documented cases where the Canadian physician has re-written the prescription for a quantity of drug (e.g., number of tablets) to satisfy a unit-of-use bottle size, but that was different from the quantity originally prescribed. Thus, patients could be receiving too much or too little medication.

The sale of prescription drugs via the Internet without valid prescriptions threatens the very distinction between “prescription only” and OTC drugs, a distinction that has been in US law since 1951 and is supported by the AMA (Policy H-100.989). Clearly, some type of federal legislation is necessary to address the Internet problem. The AMA has advocated for federal legislation on two occasions in testimony before Congress, and the AMA emphasized the importance of this issue to the HHS Task Force on Drug Importation. While the AMA has not endorsed any specific bill, an effective federal law, at least for domestic Internet pharmacies, might include the following elements:

- **Internet Pharmacy.** Any seller of prescription drugs over the Internet should be a licensed and Verified Internet Pharmacy Practice Sites (VIPPS)- or HHS-certified pharmacy, use only US licensed pharmacists to dispense prescriptions, and dispense prescription drugs pursuant only to valid prescriptions as defined below.

- **Valid Prescription.** A valid prescription must be authorized by a US licensed physician and require a valid patient-physician relationship, as defined in AMA Policy H-120.949;

- **Pharmacy Disclosure.** Any Internet pharmacy should disclose identifying information on its Web site home page; at a minimum, this information should include name, address, and telephone number of the pharmacy; states (or countries) where the pharmacy is licensed; and names of pharmacists and their states (or countries) of licensure.

- **Mandatory Certification.** Any Internet pharmacy should obtain mandatory certification, either through the VIPPS program of the National Association of Boards of Pharmacy (supported by the AMA in Policy H-120.956) or, alternatively, by a certification program established by the Secretary of HHS; certified Internet pharmacies should show a seal that links back to the certifying body.

- **Requirements of ISPs.** The federal government should have the authority to require Internet Service Providers (ISPs) (e.g., Google, Yahoo) to prevent access (linkage) to noncertified Internet sites that sell prescription drugs.

- **Requirements of Credit Card Companies.** The federal government should have the authority to require credit card companies (e.g., Visa, MasterCard) to prohibit transactions with noncertified Internet sites that sell prescription drugs.
CONCLUSION

The US drug supply currently is among the safest in the world because the US has an outstanding drug regulatory system and a reasonably closed drug distribution system. However, there are reasons for concern. Drug counterfeiting within the US has increased in recent years and the influx of unapproved, adulterated, and counterfeit drugs into the US from “rogue” Internet Web sites has become a major problem. The legalization of drug importation into the US likely will exacerbate these patient safety-related problems, unless mechanisms can be put into place that will assure the safety of the US drug supply.

In its comments to the HHS Task Force on Drug Importation, the AMA has identified three areas that need to be addressed. First, the AMA encouraged the Task Force to make certain that all prescription drugs for sale to patients in the US, including drugs that might be legally imported, be FDA-approved and meet all other FDA regulatory requirements, pursuant to US laws and regulations. Second, to address vulnerabilities in the drug distribution chain, the AMA recommended that, if importation is legalized, the drug distribution system be “closed” and all drug products be subject to reliable, “electronic” track and trace technology. If these two areas are effectively addressed, including the granting of necessary additional authority and resources to the FDA, it may be feasible to ensure the authenticity and integrity of drugs that are imported by US wholesale distributors and pharmacies. Third, the AMA raised significant concerns about personal importation via the Internet under current federal law. Even if changes in federal law are made to address the Internet problem, it would be prudent to initially limit dispensing of prescription drugs to domestic Internet pharmacies to determine if patient safety can be assured.

The report of the HHS Task Force on Drug Importation is scheduled to be released to the public in the late fall of 2004. Because this Task Force has far greater resources and expertise than the AMA to study the impact of legalized drug importation on patient safety, the AMA also should review the recommendations of this Task Force and, as appropriate, revise its position on whether or how patient safety can be assured under legalized importation.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolutions 215 and 222 (A-04), and that the remainder of this report be filed.

1. That our American Medical Association support the legalized importation of prescription drug products by wholesalers and pharmacies only if: (a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations; (b) the drug distribution chain is “closed,” and all drug products are subject to reliable, “electronic” track and trace technology; and (c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported. (Directive to Take Action)

2. That our AMA oppose personal importation of prescription drugs via the Internet until patient safety can be assured. (Directive to Take Action)

3. That our AMA review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation. (Directive to Take Action)

4. That our AMA reaffirm Policies H-120.949 and H-120.956 (AMA Policy Database) on Internet prescribing. (Reaffirm HOD Policy)
5. That our AMA educate its members regarding the risks and benefits associated with drug importation and reimportation efforts. **(Directive to Take Action)**

No fiscal impact
Whereas, Medical research in the US is threatened by the diminishing pool of physician scientists, which has decreased by 25%, due to recent graduates not choosing a career in research; and

Whereas, Less than 10% of US graduates pursue a career in research; and

Whereas, There are eminent IMG physician scientists who are exemplary role models and many young IMG physicians would like to devote their careers to research, but are unable to do so due to visa restrictions after completion of graduate medical education training, and

Whereas, The J-1 Visa waiver program is a model for increasing manpower in medically underserved areas that has been successfully implemented since 1994; therefore be it

RESOLVED, That our American Medical Association urge Congress to create a new Visa waiver program exclusively for research for IMG physicians who choose to pursue a research career in medicine, which will help improve the shortage of physician scientists in the US. (Directive to Take Action)

Fiscal Note:

Received: 05/14/09

RELEVANT AMA POLICY

H-255.971 J-1 Visas and Waivers - It is the policy of the AMA to: (1) support the Conrad-30 program, a program authorizing states to place 30 physicians annually in either Health Professional Shortage Areas or Medically Underserved Areas, as one of several strategies to help alleviate physician shortages in underserved areas; and (2) recognize that the security interests of the U.S. are of utmost importance and thorough background checks must be conducted on all visa applicants. (BOT Rep. 11, I-02)

H-255.975 J-1 Exchange Visitor Program (J-1 Visa) - Policy of the AMA states: the purpose of the physician J-1 Visa Exchange Program is to ameliorate physician specialty shortages in other countries; and the AMA will work to correct the problems of inconsistency, lack of accountability, and non-compliance in the administration of the physician J-1 Visa Exchange Program. (CME Rep. 2, A-97; Modified and Reaffirmed: CME Rep. 2, A-07)

D-255.985 Conrad 30 - J-1 Visa Waivers - Our AMA will: (1) lobby for the reauthorization of the Conrad 30 J-1 Visa waiver program; and (2) advocate that the J-1 Visa waiver slots be increased from 30 to 50 per state. (Res. 233, A-06)

D-255.988 J-1 Visa Waiver Application - Our AMA will lobby the relevant federal agencies to process the paperwork for J-1 Visa waivers expeditiously. (Res. 712, I-05)
D-255.993 J-1 Visas and Waivers - (1) The AMA shall encourage HHS and other interested government agencies to continue sponsorship of the J-1 visa waiver program. (2) If the USDA does not continue in its role as an interested government agency (IGA), the AMA encourage HHS to expand its J-1 visa waiver program. (3) The AMA will work with federal agencies to ensure better coordination of federal, state, and local agencies in monitoring the placement and enforcement of physicians’ service requirements through the J-1 waiver and Conrad-30 programs with a report back at A-03. (BOT Rep. 11, I-02)

D-255.987 J-1 Visa Service Requirement - Our AMA will lobby the US Department of State to change the current J-1 Visa waiver policy to allow for exceptions on a "case-by-case" basis where the continuous service requirement can be waived, such as in cases of documented abusive and intolerable employment conditions. (BOT Rep. 11, A-06)

D-255.989 Expeditious Security Clearance and Visa Processing of Physicians - Our AMA will: (1) lobby the relevant federal agencies to process J-1 and B-1 visa applications and security clearances more expeditiously for IMGs already accepted into residency programs than those in the general pool of visa applicants; (2) lobby the relevant federal agencies to issue J-1 visas to IMGs for the entire duration of their residency program up to a maximum of 7 years; and (3) urge federal agencies and residency programs not to discriminate against any IMGs, particularly those from Pakistan. (Res. 236, A-05)

D-255.991 Visa Complications for IMGs in GME - Our AMA will: (1) work with the ECFMG to minimize delays in the visa process for International Medical Graduates applying for visas to enter the US for postgraduate medical training and/or medical practice; (2) promote regular communication between the Department of Homeland Security and AMA IMG representatives to address and discuss existing and evolving issues related to the immigration and registration process required for International Medical Graduates; and (3) work through the appropriate channels to assist residency program directors, as a group or individually, to establish effective contacts with the State Department and the Department of Homeland Security, in order to prioritize and expedite the necessary procedures for qualified residency applicants to reduce the uncertainty associated with considering a non-citizen or permanent resident IMG for a residency position. (Res. 844, I-03)

D-310.992 Limits on Training Opportunities for J-1 Residents - Our AMA will request that the Bureau of Educational and Cultural Affairs, Accreditation Council for Graduate Medical Education (ACGME), American Board of Medical Specialties and the Educational Commission for Foreign Medical Graduates develop criteria by which J-1 exchange visitor physicians could seek extension of the length of their visa beyond the 7-year limit in order to participate in fellowship or subspecialty programs accredited by the ACGME. (Res. 303, A-01)
Existing Policy Recommended for Reaffirmation (Res 525, A-09):

H-460.995 Support for Careers in Research
Our AMA: (1) recognizes the serious decline in the number of physicians seeking to prepare for a career in research, which is fundamental to the advancement of the practice of medicine, and urges that: (a) medical students be made aware of the challenging and important career option of biomedical research, and (b) schools of medicine be made aware of the impending shortage and provide increased opportunities for students to participate in research; and (2) supports policies and legislation designed to increase the number of physician-investigators. Such support should include encouragement for training of physicians in careers in biomedical research and for supportive legislation to make physician-investigators eligible for forgiveness in certain government scholarship and loan programs for qualified candidates in numbers consistent with national needs. (Sub. Res. 79, I-79; Reaffirmed: CLRPD Rep. B, I-89; Reaffirmed: Sunset Report, A-00)

H-460.994 Support for Careers in Research
Our AMA: (1) supports joining with other public and private bodies in encouraging multiple approaches at local, state and national levels in support of the development of physician-investigators, and specifically encourages research and training grants without a pay-back provision; (2) encourages the several specialty boards through the Interspecialty Advisory Board to allow one or more years of clinical investigative training, as long as it has some relevance to that specialty, in lieu of a year of post-doctoral clinical experience, where appropriate; and (3) encourages the NIH to increase the stipends for NIH research traineeships and fellowships without reducing the actual number of available positions. (CSA Rep. G, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00)

D-255.991 Visa Complications for IMGs in GME
Our AMA will: (1) work with the ECFMG to minimize delays in the visa process for International Medical Graduates applying for visas to enter the US for postgraduate medical training and/or medical practice; (2) promote regular communication between the Department of Homeland Security and AMA IMG representatives to address and discuss existing and evolving issues related to the immigration and registration process required for International Medical Graduates; and (3) work through the appropriate channels to assist residency program directors, as a group or individually, to establish effective contacts with the State Department and the Department of Homeland Security, in order to prioritize and expedite the necessary procedures for qualified residency applicants to reduce the uncertainty associated with considering a non-citizen or permanent resident IMG for a residency position. (Res. 844, I-03)
Memo to: Roger L. Brown
From: Steve J. Currier
Patrick H. O’Keefe
Date: May 28, 2009
Subject: Reaffirmation Resolutions, A-2009 – Reference Committee F

As staff to Reference Committee F, we have reviewed the assigned resolutions for A-2009, and believe that the following resolution is covered by existing policy. A copy of the resolution is attached along with the existing policy recommended for reaffirmation and additional relevant background.

Resolution 602 – Control and Use of Physician Data
Resolution 602 includes five resolve clauses. Resolve clauses two and four are considered to be redundant as are resolve clauses three and five; thus, the resolution calls upon the AMA to take only three actions: (1) continue to support an opt out mechanism against the release of physician data, (2) notify all physicians about the option to opt out, and (3) provide a web site link with which to opt out.

The first resolve calls upon the AMA to “continue” current action, which is mandated by existing AMA Policy D-315.988, the AMA will (1) work to control the use of physician-specific prescribing data by the pharmaceutical industry as follows: (a) implement a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data... The “opt-out” mechanism referenced in existing AMA Policy D-315.988 is prominently featured on the AMA web site (see attached background) and includes the ability for individuals to refer colleagues to the web site, which was deemed a more efficient and effective notification mechanism than a one-time mailing to the entire physician population.

Since existing policy and the ongoing actions in response to that policy address the requests contained in Resolution 602, it is recommended that existing AMA Policy D-315.988 be reaffirmed in lieu of Resolution 602.

/sjc

4 Attachments
Whereas, Information technology can benefit or harm physicians and their patients; and

Whereas, Information technology currently funds the AMA in part; and

Whereas, This is reflected in the AMA’s 2007 annual statement that reported revenue from membership dues is only $45.2 million out of $289.5 million total revenue (16%); and

Whereas, AMA also reported stock in Medem.com, an information technology company that collaborates with iHealthRecord, SureScripts and Google; and

Whereas, AMA earns income by licensing data mined from physician records; therefore be it

RESOLVED, That our American Medical Association continue to support the ability of physicians to opt-out of the release of their primary source data by the AMA (Directive to Take Action); and be it further

RESOLVED, That our AMA notify all physicians of the ability to opt-out of the release of their primary source data (Directive to Take Action); and be it further

RESOLVED, That our AMA provide a prominent, easily accessible link to the opt-out option on the AMA website (Directive to Take Action); and be it further

RESOLVED, That our AMA advise physicians of their ability to opt-out of having AMA release their primary source data to third parties (Directive to Take Action); and be it further

RESOLVED, That our AMA include on its website a link to the AMA Masterfile opt-out feature. (Directive to Take Action)

Fiscal Note: Estimated cost ranges from $287,000 (3rd Class Mail) to $557,000 (1st Class Mail) for a one time mailing to the one million physicians on the AMA Masterfile. If notification were to be limited to available and free electronic media, the cost would be reduced to $17,000.

Received: 05/01/09
RELEVANT AMA POLICY

D-315.988 Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry
Our AMA will (1) work to control the use of physician-specific prescribing data by the pharmaceutical industry as follows: (a) implement a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data to pharmaceutical sales reps by including appropriate restrictions in the AMA data licensing agreements; (b) communicate to physicians the resources available to them in reporting inappropriate behavior on the part of pharmaceutical sales representatives and the work the AMA has done and will continue to do on their behalf; and (c) work with Health Information Organizations (HIOs) to describe to physicians how their prescribing data are used and work to create access for physicians to view reports on their own prescribing data to enhance their clinical practice; and (2) assume a leadership position in both developing a Prescribing Data Code of Conduct for the Pharmaceutical Industry that dictates appropriate use of pharmaceutical data, behavior expectations on the part of industry, and consequences of misuse or misconduct, and in convening representatives from HIOs and the pharmaceutical companies to promulgate the adoption of the code of conduct in the use of prescribing data. (BOT Rep. 24, I-04; Reaffirmed in lieu of Res. 624, A-05)

D-630.991 Use of Physicians' Identity Data
(1) Our AMA will continue to exert its best efforts to ensure that all licensing of AMA physician and student data protect the privacy and confidentiality of member and non-member physicians and medical students. (2) Our AMA (a) proactively inform physicians and students with identity data in the Masterfile of their rights to elect "No Contact," and (b) report back at the 2002 Annual Meeting about the educational actions undertaken, definitions of "No Contact" options, and the implications of selecting such options. (3) Our AMA will continue its current practice (in effect since July 2001) to cease releasing physician Social Security Numbers for any reason absent a national emergency. (Prior to July 2001, the AMA released physician Social Security Numbers only to credentialers for matching purposes to expedite the granting of hospital privileges and inclusion of physicians into managed care plans.) (4) Our AMA will continue to monitor collection and licensing of AMA Masterfile physician and medical student identity data and implement enhancements of Best Business Practices to try to minimize improper or inaccurate identity of a particular physician or student which might cause the physician or student substantial risk, economic loss, risk of identity theft or fraud. (5) Our AMA will disclose publicly on the AMA website a general view of data elements collected in any AMA Masterfile along with the purpose, benefits, and types of firms that license the data. (BOT Rep. 12, I-01)
D-315.988 Use of Physician and Patient Prescribing Data in the Pharmaceutical Industry

Our AMA will (1) work to control the use of physician-specific prescribing data by the pharmaceutical industry as follows: (a) implement a suitable "opt-out" mechanism for the AMA Physician Masterfile governing the release of physician-specific prescribing data to pharmaceutical sales reps by including appropriate restrictions in the AMA data licensing agreements; (b) communicate to physicians the resources available to them in reporting inappropriate behavior on the part of pharmaceutical sales representatives and the work the AMA has done and will continue to do on their behalf; and (c) work with Health Information Organizations (HIOS) to describe to physicians how their prescribing data are used and work to create access for physicians to view reports on their own prescribing data to enhance their clinical practice; and (2) assume a leadership position in both developing a Prescribing Data Code of Conduct for the Pharmaceutical Industry that dictates appropriate use of pharmaceutical data, behavior expectations on the part of industry, and consequences of misuse or misconduct, and in convening representatives from HIOS and the pharmaceutical companies to promulgate the adoption of the code of conduct in the use of prescribing data. (BOT Rep. 24, I-04; Reaffirmed in lieu of Res. 624, A-05)
AMA Database Licensing

Physician Data Restriction Program (PDRP)

The choice is yours

The AMA Physician Data Restriction Program (PDRP) offers physicians the opportunity to restrict their prescribing data from pharmaceutical sales representatives.

Q&A article on PDRP (PDF)

Restricting access to prescribing data should be every physician's individual choice. The AMA Physician Data Restriction Program (PDRP) puts the choice in doctor's hands.

I want to register for PDRP

Restrict pharmaceutical sales representatives' access to your prescribing information.

Register for PDRP

I want to report a complaint about the use of prescribing data

Report complaints against sales representatives or pharmaceutical companies who you believe are using your prescribing data inappropriately.

Report a complaint

I want to refer a colleague

Send an e-mail to tell a fellow physician about PDRP.

Refer a colleague

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Q: What is the AMA Physician Data Restriction Program and how is it benefiting physicians?

A: The American Medical Association (AMA) Physician Data Restriction Program (PDRP) offers physicians the option to withhold their prescribing data from pharmaceutical sales representatives while still making it available for medical research purposes. The program also allows physicians to register complaints against sales representatives or pharmaceutical companies who they believe are using their prescribing data inappropriately.

The PDRP is available to all physicians, both AMA members and nonmembers, and we’re pleased to offer it as a way to give physicians a choice about the accessibility of their prescribing data.

Q: Does the AMA collect prescribing data or provide data to pharmaceutical companies?

A: No, the AMA does not collect, license, sell or have access to physician prescribing data. Health care information organizations (HIOs) collect and compile physician prescribing data and sell it to pharmaceutical companies. The AMA does, however, license physician demographic data to HIOs.

Q: Why did the AMA launch the PDRP?

A: A few years ago, the AMA became aware that some physicians had concerns regarding the inappropriate use of their prescribing data by pharmaceutical sales representatives. As the nation’s largest physician advocate, the AMA conducted a Gallup survey of physician attitudes regarding the use of physician prescribing data by pharmaceutical companies. Through that survey, we found that the majority (84 percent) of physicians said either they were not concerned about the release of prescribing data or that the ability to opt out of the release of their data to pharmaceutical sales representatives would alleviate their concerns. In response to these findings, the AMA created the PDRP, launched in 2006, to provide physicians the option to restrict pharmaceutical sales representatives from accessing their prescribing data.

Q: How are physicians responding to the PDRP?

A: We are proud to say that the PDRP is working very well and is meeting the needs of participating physicians. Of the physicians who expressed an opinion about the PDRP in a recent market research study, 96 percent were either satisfied or very satisfied with the program. This high level of satisfaction resulted in more than half (56 percent) of respondents telling a colleague about the program.

Q: Are pharmaceutical companies obligated to adhere to the PDRP?

A: Through licensing agreements with HIOs, the AMA can exert influence over how the HIOs and their clients use prescribing data. These licensing contracts require the pharmaceutical companies to honor PDRP physician opt-outs. Companies found to be in violation could lose access to AMA data altogether.

Q: Does a PDRP registration expire after a certain number of years?

A: When the program was originally launched in 2006, renewals were required after a certain timeframe. This is NO LONGER the case (as of 2007). Now,
when physicians register for PDRP their data is restricted indefinitely unless a physician decides to reverse the registration at some point.

**Q: How long does it take for a physician's PDRP registration to become effective?**

**A:** Companies have up to 90 days to comply but most process physician PDRP restrictions on a monthly basis.

**Q: Will physicians stop receiving visits from pharmaceutical sales reps if they register for PDRP?**

**A:** Restricting the use of prescribing data will not prohibit pharmaceutical sales reps from calling on physicians. The number of sales calls may increase or decrease as a result of reps no longer having access to physician prescribing preferences.

**Q: How can physicians register for the PDRP?**

**A:** To enroll in the PDRP, visit [www.ama-assn.org/go/prescribingdata](http://www.ama-assn.org/go/prescribingdata) or call the AMA at (800) 621-8335.
We have reviewed the resolutions assigned to Reference Committee G for A-2009, and believe that the following resolutions reaffirm existing policy. Copies of the resolutions are attached along with the existing policy recommended for reaffirmation.

Resolution 704 – Physician Owned Hospitals
This resolution asks the AMA to endorse the concept of physician owned hospitals, which is addressed by the following policies: **H-140.984**, which says the AMA opposes an across-the-board ban on self-referrals because of benefits to patients including increased access and competition, and states that the opportunity to invest in the medical or health care facility established by a health care service(s) (HCS) financial arrangement should be open to all individuals who are financially able and interested in the investment; **H-215.968**, which says the AMA supports and encourages competition between and among health facilities as a means of promoting the delivery of high-quality, cost-effective health care; and **D-215.995**, which says the AMA will oppose efforts to either temporarily or permanently extend the 18-month moratorium on physician referrals to specialty hospitals in which they have an ownership interest and the enactment of federal certificate of need (CON) legislation.

Resolution 704 is also addressed by the following actions:

- The AMA has written letters that expressed its opposition to any amendments or provisions that would arbitrarily restrict or ban physician ownership of hospitals. In one letter, the AMA stated that “Physician-owned hospitals are a win-win for patients and for the health care system as we work to improve care.”
- During consideration by the House and Senate of State Children’s Health Insurance Program (SCHIP) reauthorization, mental health parity, the Farm Bill and war supplemental legislation, AMA advocated against restrictions on and efforts to ban physician-owned hospitals.

Policies **H-140.984**, **H-215.968** and **D-215.995** should be reaffirmed.

Resolution 705 – Office Payment
This resolution asks the AMA to seek methods of rapid, efficient payment of office visits including electronic adjudication, approval of claims, and cash payment at the time of service by patients. Extensive AMA policy and activity address these requests. **H-190.964** states that ALL third party payers should acknowledge receipt of each electronic claim received within 24 hours and accept or reject each electronic claim within 10 business days. **H-190.983** states that the AMA will take a leadership role in representing the interests of the medical profession in all major efforts to develop and implement Electronic Data Interchange (EDI) technologies related to electronic claims submission and claims payment. **H-385.926** supports the right of patients and physicians to privately contract for health care services, supports the freedom of physicians to choose their method of earning a living (fee-for-service, salary, capitation, etc.) and supports the right of physicians to charge their patients their usual fee that is fair, irrespective of insurance/coverage arrangements between the patient and the insurers. **H-380.994** supports the concept that health insurance should be treated like any other insurance (i.e., a contract
between a patient and a third party for indemnification for expense or loss incurred by virtue of obtaining medical or other health care services.)

Resolution 705 is also addressed by the following:

- The AMA has established “Guiding Principles for Operating a Cash-based Practice.”
- The AMA chairs the National Uniform Claim Committee, created to develop a standardized data set for use by the non-institutional health care community to transmit claim and encounter information to and from all third-party payers.
- The AMA is a participating organization in the Committee on Operating Rules for Information Exchange, which works to simplify administrative data exchange by streamlining the way eligibility and benefits, claim status and other healthcare administrative information is exchanged electronically.
- The AMA’s “Heal the Claims Process” campaign strives to hold payers accountable by calling for full transparency and accurate payment the first time a claim is submitted and to comply fully with the Health Insurance Portability and Accountability Act (HIPAA) electronic standard transactions. The AMA also calls on payers to provide full transparency with respect to fee schedules, medical payment policies and other information necessary to maximize efficiency.
- The AMA has developed the following model state legislation: “An Act Concerning Timely Reimbursement of Health Insurance Claims.”
- The AMA tracks the implementation of prompt payment state laws, which have been enacted in all 50 states.
- The AMA's Practice Management Center has developed the following claims management revenue cycle resources to help physicians and their practice staff understand and navigate the claims process and to receive timely and accurate payment: “Prepare That Claim,” “Follow That Claim,” and “Appeal That Claim.”

Policies H-190.964, H-190.983, H-380.994 and H-385.926 should be reaffirmed.

Resolution 706 – Standardized Medical Insurance Cards
This resolution asks the AMA to support the establishment and adoption of a standardized health insurance identification card, which is fully addressed by the following policy: D-185.999, which says the AMA will continue to work with payers, the federal and state governments, and standards organizations to adopt and implement appropriate policies, technologies (e.g., smart cards, telephone hot lines, electronic data interchange, and website access), and national technology standards to provide physicians with accurate and real time verification of patient eligibility, co-payment due, deductible payable information, and claims processing.

Resolution 706 is also addressed by the following actions:

- The AMA is an official supporter of the Medical Group Management Association (MGMA) SwipeIT campaign.
- The AMA contributed to the content of the Workgroup on Electronic Data Interchange (WEDI) white paper regarding standardized ID cards.

Policy D-185.999 should be reaffirmed.

Resolution 707 – Price Transparency
This resolution asks the AMA to support legislation that requires insurance companies to provide online pricing information for patients and providers. The following policies address this request: H-165.846, which says the AMA supports mechanisms to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services and H-
Resolution 707 is also addressed by the following AMA activity:

The AMA is a participating organization in the Committee on Operating Rules for Information Exchange, which works to simplify administrative data exchange by streamlining the way eligibility and benefits, claim status and other healthcare administrative information is exchanged electronically. Easier, more reliable access to this information at the point of care reduces the amount of time providers spend on administration by improving the accuracy of claims submitted, providing enhanced information on patient financial responsibility and checking the status of a patient claim.

Policies H-165.846 and H-155.960 should be reaffirmed.

Resolution 708 – Health Insurance and Pharmacies Advise Physicians to Take Action

This resolution asks that the AMA oppose the unwanted and unwarranted participation of health care insurance companies and pharmacies in patient diagnosis, treatment and health management. The following policy addresses this issue: H-285.954 states that certain professional decisions critical to high quality patient care should always be the ultimate responsibility of the physician practicing in a health plan, whether in primary care or another specialty, either unilaterally or with consultation from the plan, including but not limited to the following:

- what diagnostic tests are appropriate;
- when and to whom in-plan physician referral is indicated;
- when and to whom out-of-plan physician referral is indicated;
- when and with whom consultation is indicated;
- when non-emergency hospitalization is indicated;
- when hospitalization from the emergency department is indicated;
- choice of in-plan service sites for specific services (office, outpatient department, home care, etc.);
- hospital length of stay;
- frequency/length of office/outpatient visits or care;
- use of out-of formulary medications;
- when and what surgery is indicated;
- when termination of extraordinary/heroic care is indicated;
- recommendations to patients for other treatment options, including non-covered care;
- scheduling on-call coverage;
- terminating a patient-physician relationship;
- whether to work with, and what responsibilities should be delegated to, a mid-level practitioner;
- determination of the most appropriate treatment methodology.

H-450.941 states that the AMA pledges an unshakable and uncompromising commitment to the primacy of the patient-physician relationship free from intrusion from third parties and H-120.988 states the AMA’s strong support for the autonomous clinical decision-making authority of a physician.

Policies H-285.954, H-450.941, and H-120.988 should be reaffirmed.
Resolution 710 – Identifying Abusive, Hostile or Non-Compliant Patients

This resolution asks for the development of a modifier and/or add-on code to E&M codes identifying non-compliant patients. The HOD is not the appropriate avenue for addressing CPT issues. Policy H-70.919 states that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers.

This resolution is also addressed by the following:

Modifier 2P (Performance Measure Exclusion Modifier Due to Patient Reasons) is currently available to report non-compliant patients. The list of reasons for this modifier include (1) “patient declined”, (2) “economic, social, or religious reasons”, and (3) “other patient reasons”. This modifier is intended to be used with performance measure Category II codes. CPT Category II Performance Measurement codes are intended to facilitate data collection about the quality of care rendered by coding certain services and test results that support nationally established performance measures and that have an evidence base as contributing to quality patient care. These codes describe clinical components that may be typically included in evaluation and management services or clinical services and, therefore, do not have a relative value associated with them.

Policy H-70.919 should be reaffirmed.

Resolution 711 – Physician Representation on Hospital Boards

This resolution asks the AMA to seek policy from the Joint Commission to mandate that hospitals maintain non-hospital-employed, practicing physician membership on their operating boards. This is addressed by the following policies: H-225.983, which states that physicians who are members of the medical staff shall be eligible for, and should be included in, full membership on hospital governing bodies and their action committees in the same manner as are other knowledgeable and effective individuals; and H-225.957, which states that the organized medical staff has elected appropriate medical staff member representation to attend hospital governing board meetings, with rights of voice and vote, to ensure appropriate organized medical staff input into hospital governance.

Policies H-225.983 and H-225.957 should be reaffirmed.

Resolution 712 – Development of a Payment Code for Prior Authorization

This resolution asks for the establishment of a CPT code that would allow physicians to seek reimbursement for participating in the prior authorization process with third-party payers and managed care entities. The HOD is not the appropriate avenue for addressing CPT issues. Policy H-70.919 states that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers. H-285.998[5] states that when inordinate amounts of time or effort are involved in providing case management services required by a third party payer which entail coordinating access to other health care services needed by the patient, or in complying with utilization review requirements, the physician may charge the payer or the patient for the reasonable cost incurred. "Inordinate" efforts are defined as those "more costly, complex and time-consuming than the completion of standard health insurance claim forms, such as obtaining preadmission certification, second opinions on elective surgery, certification for extended length of stay, and other authorizations as a condition of payer coverage."

Policies H-70.919 and H-285.998 should be reaffirmed.
Resolution 713 – “Advance Directives for All” Campaign

This resolution asks for CPT code(s) to be developed for advance directive counseling. The HOD is not the appropriate avenue for addressing CPT issues. Policy H-70.919 states that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers. This intent of this resolution is addressed by the following polices: H-390.916, which encourages payment for medical conferences with patients and/or relatives and guardians regarding medical management and future medical management, particularly as it relates to the discussion of advance directives (i.e., living wills and durable powers of attorney for health care) and H-385.977, which urges all physicians not only to counsel their patients with respect to serious medical problems, but also to use the CSN/CPT codes for counseling when billing patients or third parties for medical services.

This resolution is also addressed by the following:

A CPT coding mechanism already exists. “Counseling” is a part of each of the Evaluation and Management service codes. It is included as a defined component of “intraservice” of the E/M service. The face-to-face time for Evaluation and Management services is defined as only that time that the physician spends face-to-face with the patient and/or family. This intraservice time includes the time in which the physician performs such tasks as obtaining a history, performing an examination, and counseling the patient. For the purposes of the services provided in an E/M service, counseling is a discussion with a patient and/or family concerning one or more of the following areas:

- Diagnostic results, impressions, and/or recommended diagnostic studies
- Prognosis
- Risks and benefits of management (treatment) options
- Instructions for management (treatment) and/or follow-up
- Importance of compliance with chosen management (treatment) options
- Risk factor reduction
- Patient and family education

Each E/M code includes the statement that, “Counseling and/or coordination of care with other providers or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs.” When counseling and/or coordination of care dominates (more than 50%) the physician/patient and/or family encounter (face-to-face time in the office or other outpatient setting or floor/unit time in the hospital or nursing facility), then time may be considered the key or controlling factor to qualify for a particular level of E/M services. This includes time spent with parties who have assumed responsibility for the care of the patient or decision making whether or not they are family members (eg, foster parents, person acting in loco parentis, legal guardian). The extent of counseling and/or coordination of care must be documented in the medical record.

Policies H-70.919, H-390.916 and H-385.977 should be reaffirmed.

Resolution 718 – Hospital Restrictions on Access to Medical Records

The intent of this resolution is to ensure that patients and physicians have access to medical records. This is addressed by the following policies: H-315.997, which states that allowing patients access to information in their medical records will have, on the whole, a favorable impact on patient care and physician-patient relationships; and H-140.989, which states that a patient should have access to the information in his or her health record, except for that information which, in the opinion of the health care professional, would cause harm to the patient or to other people. AMA Policy E-7.025 states that only physicians or other health care professionals who are involved in managing the patient, including
providing consultative, therapeutic, or diagnostic services, may access the patient’s confidential medical information. All others must obtain explicit consent to access the information.

Policies H-315.997 and H-140.989 should be reaffirmed.

**Resolution 721 – Uniform Overhead Emergency Codes**
The intent of this resolution, to facilitate the adoption of a uniform system of hospital emergency codes, is fully addressed by the following policy: H-215.971, which says the AMA urges the development of standardized emergency paging nomenclature for hospitals.

Policy H-215.971 should be reaffirmed.

**Resolution 724 – Reimbursement for Services**
This resolution asks the AMA to ensure that physicians and other providers receive payment from insurance companies in a timely fashion and that principles of transparency and accountability are applied to the insurance industry. Extensive AMA policy and activity address this resolution. Policy H-190.991, which states that the AMA opposes unexplained delays in processing and payment by third party insurance carriers where a completed standard claim form for reimbursement has been submitted and H-385.952, which states that the AMA opposes both CMS' and local carriers' efforts to reduce or deny physician payments for appropriate services and will work to assure that all evaluation and management services are appropriately reimbursed. In addition, H-320.968 states that the AMA supports the development of legislative initiatives to assure that payers provide their insureds with information enabling them to make informed decisions about choice of plan, and to assure that payers take responsibility when patients are harmed due to the administrative requirements of the plan and H-285.945, states that the AMA supports the liability of managed care organizations, including ERISA plans, for damages resulting from their policies, procedures, or administrative actions taken in relation to patient care.

Resolution 724 is also addressed by the following:

- The AMA’s “Heal the Claims Process” campaign strives to hold payers accountable by calling for full transparency and accurate payment the first time a claim is submitted and to comply fully with the Health Insurance Portability and Accountability Act (HIPAA) electronic standard transactions. The AMA also calls on payers to provide full transparency with respect to fee schedules, medical payment policies and other information necessary to maximize efficiency.
- The AMA’s Advocacy Resource Center has produced the following legislative template: “Managed Care Campaign: Fair Contracting and Transparency in the Private Health Care Market.”
- The AMA has developed the following model state legislation: “An Act Concerning Timely Reimbursement of Health Insurance Claims.”
- The AMA tracks the implementation of prompt payment state laws, which have been enacted in all 50 states.
- The AMA's Practice Management Center has developed the following claims management revenue cycle resources to help physicians and their practice staff understand and navigate the claims process and to receive timely and accurate payment: “Prepare That Claim,” “Follow That Claim,” and “Appeal That Claim.”

Resolution 727 – Medical Directors as “Peer” Reviewers When Pre-Adjudicating Prescribed Tests and Procedures
This resolution asks the AMA to ensure that there is managed care accountability in the precertification/preauthorization process, which is addressed by the following policies: H-285.998 states that a physician of the same specialty must be involved in any decision by a utilization review or management program and that the reviewing physician be licensed to practice medicine and is actively practicing in the same jurisdiction as the reviewed physician. The identity and credentials of the reviewing physician should be provided on request. Furthermore, any health plan using managed care techniques should be subject to legal action for any harm incurred by the patient resulting from application of such techniques and the reviewing physician should be professionally and individually accountable for his or her decisions. H-285.945 states the AMA’s support for federal legislation to prohibit the exemption from liability of managed care organizations, including ERISA plans, for damages resulting from their policies, procedures, or administrative actions taken in relation to patient care, and D-285.968 requests that the AMA develop a Health Insurer "Code of Conduct" setting forth clear and concise principles addressing both medical care policies and payment issues, and seek concurrence among health insurers in complying with this "Code of Conduct.” The Code of Conduct is currently being developed and is planned to be released at the end of 2009.


Resolution 728 – Physician Profiling/Grading and Report Cards
This resolution asks the AMA to reaffirm the Guidelines for Pay-for-Performance, H-450.947, and to create legislation so that insurance company grading/rating systems do not encourage deselecting of high-risk patients nor encourage the deselecting of physicians. This is addressed by the following policy, H-450.941, which strongly opposes the use of tiered and narrow physician networks that deny patient access to, or attempt to steer patients towards, certain physicians primarily based on cost of care factors.

This resolution is also addressed by the following activity:

- The AMA has developed model state legislation: “An Act Relative to Physician Profiling Programs,” which mandates the transparency, accuracy and oversight necessary to ensure that physician profiling does not undermine the patient-physician relationship nor incentivize physicians to avoid the sickest and poorest patients. The Legislation also prohibits physician rankings based solely on cost and requires profiling at the group level, the rationale for the profiling determination, and opportunities for physicians to make corrections and appeal.
- The AMA Private Sector Advocacy Practice Management Center has issued the following resource: “Physician Profiling: How to Prepare Your Practice.”

Policies H-450.947 and H-450.941 should be reaffirmed.

Resolution 730 – Medical Staff Self-Governance
This resolution asks the AMA to encourage the Joint Commission to mandate specific medical staff voting processes, including those for medical staff elections, and bylaws adoption, amendments and deletions. These issues are addressed by H-225.957, which states that the organized medical staff bylaws, and processes for fair hearings and appeals, shall be adopted or amended by a vote of the voting membership of the organized medical staff; that medical staff bylaws should establish the procedures for electing and removing its organized medical staff officers and all organized medical staff members elected to serve as voting members of the Medical Executive Committee; and that the hospital governing body/administration is to comply with the bylaws, rules, regulations, policies and procedures of the organized medical staff and not authorized to, nor shall unilaterally amend the bylaws, rules, regulations, policies or procedures of the organized medical staff.
Resolution 730 is also addressed by the following action:

The Joint Commission Standard MS.01.01.01 (formerly MS.1.20) and all of its Elements of Performance with the exception of EP 19 has been fully effective since January 1, 2008. Following concerns received from professional organizations and hospitals related to the cost and burden of the newly adopted MS.1.20, The Joint Commission Board established an 18-member Task Force to analyze the potential impact of implementing the revised standard. The AMA is well represented on the Task Force. The Task Force was convened in January 2008. As of May 2009, the Task Force was reaching consensus.

Policy H-225.957 should be reaffirmed.

Resolution 733 – Medical Smart Cards
This resolution asks the AMA to study and develop a white paper on the issue of medical smart cards and aligned technology. This is addressed by the following policy: D-185.999, which says the AMA will continue to work with payers, the federal and state governments, and standards organizations to adopt and implement appropriate policies, technologies (e.g., smart cards, telephone hot lines, electronic data interchange, and website access), and national technology standards to provide physicians with accurate and real time verification of patient eligibility, co-payment due, deductible payable information, and claims processing.

Resolution 733 is also addressed by the following actions:

- The AMA contributed to the content of the Workgroup on Electronic Data Interchange (WEDI) white paper regarding standardized ID cards, a prominent white paper on this issue.
- The AMA is an official supporter of the Medical Group Management Association (MGMA) SwipeIT campaign.

Policy D-185.999 should be reaffirmed.

Resolution 734 – National Practitioner Data Bank: Length of Time for Storing Medical Malpractice Data
The intent of this resolution is to establish a time frame for storing physician entries within the National Practitioner Data Bank of ten years. This is fully addressed by the following policies: H-355.999 and H-355.995, which both state that reports, other than licensure revocation, in the Data Bank should be purged after five years.

Policies H-355.999 and H-355.995 should be reaffirmed.
Whereas, New and varied programs for health care provision are being considered; and
Whereas, A large proportion of health care is provided in hospitals; and
Whereas, Physician ownership of hospitals has been limited, but shown to be appropriate and valuable; therefore be it
RESOLVED, That the American Medical Association endorse the concept of physician owned hospitals. (New HOD Policy)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09

H-140.984 Physicians' Involvement in Commercial Ventures
Our AMA opposes an across-the-board ban on self-referrals because of benefits to patients including increased access and competition, but proposes a list of standards to ensure ethical and acceptable financial arrangements: (1) Opportunity to Invest - The opportunity to invest in the medical or health care facility established by a health care service(s) (HCS) financial arrangement should be open to all individuals who are financially able and interested in the investment. This would include non-physicians. The only exception allowed would be for a sole community health care provider where ownership could be limited to potential referring physicians or their immediate family due to a lack of other individuals who have sufficient capital and interest to establish the facility. (2) Real Investment at Risk - Each investor should be undertaking a real financial risk similar to that which might occur in any other similar commercial investment. A referring physician should not be allowed to become involved in the HCS investment without incurring a real financial risk. The ability of a physician to refer patients must not be considered "capital" to become an investor in the facility. Each investor in the medical facility must be at risk by virtue of a binding commitment to capitalize the venture, such as a commitment to contribute money, property or services. (3) Patient Referral Requirement - No investor in the medical facility can be required or coerced in any manner to refer patients to the facility. No investor can be required to divest his or her investment for failure to refer patients. No investor can be required to divest because he or she moves from the area or ceases practicing medicine. (4) Distribution of Profit or Equity - Distribution should be based generally on the amount contributed to capital. Remuneration or profit distribution may not be related to patient referrals. (5) Disclosure of Ownership Interest - A physician or other health care professional or provider with an ownership interest in a medical or other health care facility or service to which the physician refers patients must disclose to the patients this ownership interest. A general disclosure can be made in a manner which is appropriate to his or her practice situation. (6) Request for Care - Each
patient of a physician with an ownership interest (or whose immediate family member has an interest) must be provided with a physician's request for ancillary care to enable the patient to select a facility for such care. However, in accordance with the physician's ethical responsibility to provide the best care for the patient, the physician must be free to recommend what in the physician's judgment is the most appropriate facility, including his or her own facility. (7) Notification of Ownership Interest to Payer - If the physician (or immediate family member) has an ownership interest in a medical or health care facility or service to which he or she refers patients who are Medicare beneficiaries, this physician should identify the ownership interest on the Medicare claim form. If the Medicare carrier detects a pattern suggesting inappropriate utilization, the matter could be referred to the PRO for follow-up pursuant to the existing PRO review process. Such PRO review would have to be conducted in a uniformly fair, open-minded manner. (8) Internal Utilization Review Program - Each medical facility with referring physician owners (or immediate family members) must have an internal utilization review program to monitor referrals by such physicians. Regular reports from this internal program should be made available to the Medicare carrier on request. (9) Compliance with Standards - Failure to comply with any one individual standard or compliance with all the standards, in and of itself, would not be sufficient to find that the arrangement is illegal. The entire arrangement needs to be examined to determine whether it is merely a sham arrangement to conceal a kickback scheme or whether it is "legal." Failure to comply with standards would subject the HCS investment arrangement to further scrutiny. (BOT Rep. ZZ, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: Res. 201, I-00; Reaffirmation A-02; Reaffirmation I-04)

H-215.968 Specialty Hospitals and Impact on Health Care
Our AMA supports and encourages competition between and among health facilities as a means of promoting the delivery of high-quality, cost-effective health care. (BOT Rep. 15, I-04)

D-215.995 Specialty Hospitals and Impact on Health Care
Our AMA will: (1) oppose efforts to either temporarily or permanently extend the 18-month moratorium on physician referrals to specialty hospitals in which they have an ownership interest; (2) support changes in the inpatient and outpatient Medicare prospective payment systems to eliminate the need for cross-subsidization by more accurately reflecting the relative costs of hospital care; (3) support federal legislation and/or regulations that would fix the flawed methodology for allocating Medicare and Medicaid Disproportionate Share Hospital (DSH) payments to help ensure the financial viability of safety-net hospitals so they can continue to provide adequate access to health care for indigent patients; (4) encourage physicians who contemplate formation of a specialty hospital to consider the best health interests of the community they serve. Physicians should explore the opportunities to enter into joint ventures with existing community hospitals before proceeding with the formation of a physician-owned specialty hospital; (5) oppose the enactment of federal certificate of need (CON) legislation and support state medical associations in their advocacy efforts to repeal current CON statutes and to oppose the reinstatement of CON legislation or its expansion to physician-owned ambulatory health care facilities; and (6) continue to monitor the specialty hospital issue and report back to the House of Delegates at the 2005 Annual Meeting. (BOT Rep. 15, I-04)
January 26, 2009

The Honorable Harry Reid
Senate Majority Leader
S-221 U.S. Capitol Building
Washington, DC  20510

Dear Majority Leader Reid:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express our support for the “Children’s Health Insurance Program Reauthorization Act of 2009,” as reported by the Senate Finance Committee on January 15, 2009. Expanding coverage to the millions of uninsured Americans is a top priority for the AMA, especially during these challenging economic times.

Reauthorizing the State Children’s Health Insurance Program (SCHIP) is a crucial first step in expanding coverage for the millions of children without health insurance. SCHIP provides a critical health insurance safety net for children from low-income families and has been successful in significantly reducing the number of children without coverage. Physicians see the benefits of SCHIP on a daily basis: parents who work hard but are unable to afford health insurance are able to obtain the care their children need to stay healthy and strong.

In addition to our strong support of SCHIP reauthorization, the AMA is opposed to any amendments that would arbitrarily restrict physician ownership of hospitals. Physician-owned hospitals are a win-win for patients and for the health care system as we work to improve care. Government-funded studies of physician-owned specialty hospitals provide unambiguous evidence of their benefits to patient care. The results of a congressionally-mandated study published in Health Affairs in 2006 found significantly lower risk-adjusted 30-day mortality rates than community hospitals and very high Medicare patient satisfaction. The study also found that physician-owned specialty hospitals provide more net community benefits through uncompensated care and taxes than their not-for-profit competitors.
Physician-owned hospitals have injected competition into the hospital market, forcing traditional hospitals to improve and innovate. Government studies have demonstrated that physician-owned hospitals pose no threat to the viability of community hospitals. If arbitrary restrictions on physician-owned hospitals were to become law, many highly rated hospitals, including some that provide care to medically underserved rural communities, would have no choice but to reduce employment or close. During a time of economic peril, this would be antithetical to the critical goals of enhancing access to quality care and stemming rising unemployment. The important work of reauthorizing SCHIP should focus on providing care to children in need and not on limiting access or choice for Medicare beneficiaries.

Accordingly, we strongly urge you to support the SCHIP Reauthorization Act to ensure that the millions of uninsured children have quality health insurance coverage and oppose any amendments that would restrict Medicare beneficiaries’ access to quality care in physician-owned hospitals.

Sincerely

Michael D. Maves, MD, MBA
Whereas, The primary care physician is the keystone of our health care system, and patient access to primary care physicians is essential to guide patients through the complexities of modern health care, regardless of the type of health plan; and

Whereas, Patient access to primary care physicians is impeded by the alarming decrease in the number of young physicians entering primary care, the 2008 Matriculating Student Questionnaire and the Graduate Questionnaire by the Academy of American Medical Colleges showing that only 24.1% of medical students and 29.1% of graduating medical students are planning a career in primary care, including family practice (4.8), pediatrics (9.1%) and internal medicine (16%); and

Whereas, Poor compensation and high office overhead expense make primary care unattractive to medical school graduates; and

Whereas, The current billing procedure are inefficient (submission of the bill to the third party payer by the physician; waiting for adjudication and approval by the third party payer; notification of the patient and the physician of the explanation of benefits (EOB); and notification of the patient and payment of any allowable balance to be paid by the patient to the physician) for fees that are often less than $300 requires increased office staff, increases office overhead and reduces net income; and

Whereas, Most referral specialties also have many low cost office charges that are processed in the same inefficient manner; and

Whereas, The cost of this inefficient method of processing low cost office billing may also be a needless source of overhead for third party payers; and

Whereas, Systems of electronic, time-of-service adjudication and approval of office bills are under development and may soon become commercially available products; and

Whereas, A system of payment at the time of service by the patient (as in any other type of insurance claim); submission of the bill to the third party payer by the patient (as in other types of insurance), excluding those patients or surrogates unable to do so and Medicare patients; and subsequent reimbursement of the patient by the payer would eliminate adjudication, approval, and submission of an EOB and would result in prompt payment and lower office overhead for primary care physicians; therefore be it
RESOLVED, That our American Medical Association seek methods of rapid, efficient payment of office visits, including (1) evaluation and promotion of electronic adjudication and approval of claims and (2) cash or check payment at the time of service with subsequent reimbursement of the patient by the third party payers and refunds to the patient by the physician, if obligated by contract (Directive to Take Action); and be it further

RESOLVED, That our AMA support change in the payment mechanism of low cost billing in all Medicare programs. (New HOD Policy)

Fiscal Note: Implement accordingly at estimated staff cost of $12,000.

Received: 05/05/09

**H-190.964 Electronic Claims**

*Our AMA policy is that ALL third party payers: (1) acknowledge receipt of each electronic claim received within 24 hours; and (2) accept or reject each electronic claim within 10 business days.*

(Res. 707, A-01; Reaffirmation I-04)

**H-190.983 Submission of Electronic Claims Through Electronic Data Interchange**

The AMA: (1) will take a leadership role in representing the interests of the medical profession in all major efforts to develop and implement EDI technologies related to electronic claims submission, claims payment, and the development of EDI standards that will affect the clinical, business, scientific, and educational components of medicine; (2) supports aggressive time tables for implementation of EDI as long as the implementation is voluntary, and as long as all payers are required to receive standard electronic claims and provide electronic reconciliation prior to physicians being required to transmit electronic claims; (3) supports the acceptance of the ANSI 837 standard as a uniform, but not exclusive, standard for those physicians who wish to bill electronically; and (4) will continue to monitor the cost effectiveness of EDI participation with respect to rural physicians. (CMS Rep. 1, I-93; Reaffirmation A-04)

**H-380.994 Physicians' Freedom to Establish Their Fees**

*Our AMA (1) affirms that it is a basic right and privilege of each physician to set fees for service that are reasonable and appropriate, while always remaining sensitive to the varying resources of patients and retaining the freedom to choose instances where courtesy or charity could be extended in a dignified and ethical manner; (2) supports the concept that health insurance should be treated like any other insurance (i.e., a contract between a patient and a third party for indemnification for expense or loss incurred by virtue of obtaining medical or other health care services); and (3) believes that the contract for care and payment is between the physician and patient.* (BOT Rep. JJ, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: Sub. Res. 704 and Reaffirmation A-01)

**H-385.926 Physician Choice of Practice**

*Our AMA: (1) encourages the growth and development of the physician/patient contract; (2) supports the freedom of physicians to choose their method of earning a living (fee-for-service, salary, capitation, etc.); (3) supports the right of physicians to charge their patients their usual fee that is fair, irrespective of insurance/coverage arrangements between the patient and the insurers. (This right may be limited by contractual agreement.) An accompanying responsibility of the physician is to provide to the patient adequate fee information prior to the provision of the service. In circumstances where it is not feasible to provide fee information ahead of time, fairness in application of market-based principles demands such fees be subject, upon complaint, to expedited professional review as to appropriateness; and (4) encourages physicians when setting their fees to take into consideration the out-of-pocket expenses paid by patients under a system of individually selected and owned health insurance.* (BOT Rep. QQ, I-91; Reaffirmed: BOT Rep. TT, I-92; Reaffirmed: Ref. Cmte. A, A-93; Reaffirmed: BOT Rep. UU, A-93; Reaffirmed: CMS Rep. G, A-93; Reaffirmed: CMS Rep. E, A-93; Reaffirmed: Sub.
IN THE GENERAL ASSEMBLY
STATE OF ______________

An Act Concerning Timely Reimbursement of
Health Insurance Claims

Be it enacted by the People of the State of ______________, represented in the General Assembly:

Section 1. Title. This Act shall be known and may be cited as the "Timely Reimbursement of Health Insurance Claims Act."

Section 2. Purpose. The Legislature hereby finds and declares that:

(a) Patients and physicians often do not receive the reimbursements to which they are entitled from covered entities in a timely manner, even when the claim is submitted on a completed standard claim form and does not contain attachments or does not require additional information for processing.

(b) Such delays are unnecessary and costly, often causing patients and physicians to spend considerable time and resources attempting to secure reimbursement.

(c) This state has a strong public interest in ensuring that health care claims are paid on a timely basis. This practice adds to the efficient functioning of the state’s health care system and assures continued protection of the health and welfare of the citizens in this state.
Section 3. Definitions.

(a) The term “covered entity” includes, but is not limited to, any entity responsible for payment of health care services, including but not limited to all entities that pay or administer claims on behalf of other entities.

_Drafting Note: The above definition is designed to promote the most comprehensive application of these requirements possible and to avoid preemption under ERISA._

(b) The term “complete claim” is a timely claim for payment of covered health care expenses that: (i) if submitted non-electronically contains all of the required data elements necessary for adjudication and (ii) if covered by the Health Insurance Portability and Accountability Act (HIPAA) in such form and substance to be in compliance with that Act.

(c) The term “incomplete claim” is a claim that cannot be adjudicated because it fails to include all of the required data elements necessary for adjudication.

(d) The term “contested claim” is a claim that is denied during the benefit determination process.

Section 4. Requirements.

(a) Timeframe for payment of complete claim - All covered entities shall pay all complete and uncontested claims within 14 days of claim submission when the claim is filed electronically, and within 30 days when the claim is submitted on paper.

(b) Procedures involving electronically submitted claims –
(1) A covered entity shall, within 24 hours after beginning of the next business day after claim submission, provide electronic acknowledgement of the receipt of the claim to the claimant.

(2) A covered entity shall notify the claimant, in writing, that the claim is incomplete within 10 days of claim submission. Notice of the covered entity’s action on the claim is considered made on the date the notice was mailed or electronically transferred.

(3) Notification of the covered entity’s determination of an incomplete claim shall specify all deficiencies and shall list, in writing, all additional information or documents needed for proper processing and payment of the claim.

(4) A claim is deemed to be complete if a covered entity does not provide notification to the claimant of any deficiency in the claim within 10 days of the date of its submission.

(5) Any uncontested portion of the claim shall be paid in accordance with Section 4(a).

(6) If the covered entity notifies the claimant that additional information or documents are required, the covered entity has 10 days following the receipt of such information to pay or deny the claim.

(7) If a claim is not paid or contested within the timeframes set forth in this section, the covered entity is under an uncontestable obligation to pay the claim.
(c) Procedures of all non-electronically submitted claims –

(1) A covered entity shall, within 10 days after claim submission, provide acknowledgment of receipt of claim to the claimant.

(2) A covered entity shall notify the claimant, in writing, that the claim is incomplete within 10 days of claim submission. Notice of the covered entity's action on the claim is considered made on the date the notice was mailed or electronically transferred.

(3) Notification of the covered entity’s determination of an incomplete claim shall specify all deficiencies and shall list, in writing, all additional information or documents needed for proper processing and payment of the claim.

(4) A claim is deemed to be complete if a covered entity does not provide notification to the claimant of any deficiency in the claim within 10 days of the date of its submission.

(5) Any uncontested portion of the claim shall be paid in accordance with Section 4(a).

(6) If the covered entity notifies the claimant that additional information or documents are required, the covered entity has 10 days following the receipt of such information to pay or deny the claim.

(7) If a claim not paid or contested within the timeframes set forth in this section, the covered entity is under an uncontestable obligation to pay the claim.
(d) Payment of claim is considered made on the date the payment was received by the physician.

_Drafting Note_: Another option is to have payment of claim be considered made on the date the payment “was mailed or electronically transferred.”

(e) Interest Schedule

(1) For electronically submitted claims, any covered entity that does not comply with Section 4(a) shall pay the claimant as follows:

(A) 1 ½% from the 15th day through the 45th day;
(B) 2% per month from the 46th day through the 90th day; and
(C) 2 ½ % per month after the 90th day.

(2) For non-electronically submitted claims, any covered entity that does not comply with Section 4(a) shall pay the claimant as follows:

(A) 1 ½% from the 31st day through the 60th day;
(B) 2% per month from the 61st day through the 120th day; and
(C) 2 ½% per month after the 120th day.

(3) For contested claims, once deemed complete, the interest schedule for noncompliance shall attach to timeframes consistent with Sections (e)(1) and (e)(2).

(f) Within 24 hours after the date of acknowledgement of receipt of claim, consistent with timeframes set forth in this section, a covered entity shall provide the claimant with electronic access to the status of a submitted claim.
(g) Fines and Penalties – Where it is established that the covered entity willfully and knowingly violated this Act or has a pattern of repeated violations of this Act, the State Department of Insurance and/or the State Attorney General shall impose a fine not to exceed one thousand dollars per day per claim for each day beyond the date specified for response. In the event that three separate fines are levied within five years for failure to comply with this section, the State Department of Insurance and/or the State Attorney General is authorized to levy a penalty in an amount not to exceed ten thousand dollars per claim. (1)

Where it is established that the covered entity willfully and knowingly violated this Act or has a pattern of repeated violations, the State Department of Insurance and/or the State Attorney General shall require the covered entity to submit a remedial action plan and contact claimants regarding the delays in their processing of claims and inform claimants of steps being taken to improve the delays.

(h) Private Right of Action – Nothing in this Act prohibits or limits any claim or action for a claim that the claimant has against the covered entity.

(i) Attorney’s Fees – Reasonable attorney’s fees for advising and representing a claimant on an overdue claim or action for an overdue claim must be paid by the covered entity if overdue.

1 The State shall determine the proper percentage of the penalty and/or fine to be paid directly to the claimant.
(j) benefits are recovered in an action against the covered entity or if overdue benefits are paid after receipt of notice of the attorney’s representation.

(k) Upon entering into a contract with a physician, the covered entity shall provide an example of a properly completed complete claim.

(l) Upon entering into a contract with a physician to pay a capitated fee, the covered entity shall begin to make such capitated payment in the month in which the contract is signed. Such payments may be prorated in the first month. This subsection shall apply to capitated fees adjusted for subsequent patient elections or referrals to the contracting physician.

(m) Audits –

(1) Conduct of Annual Audit - Within 60 days of the end of each fiscal year the covered entity shall contract with a qualified independent third party auditor to conduct an annual audit of claims to determine the degree to which the covered entity is in compliance with this section.

(2) Items Included in Audit – Such audit shall include:

(A) the average number of days in which the covered entity processed and paid complete claims;

(B) the percent of complete claims processed and paid within the time specified in Section 4(a);

(C) the percent of claims processed (and unprocessed in part) within the times specified in Section 4(a);
(D) the percent of claims in which the covered entity requested additional information for processing; and

(E) the percent of claims denied (and denied in part).

(3) Certification – Each audit shall be certified by the auditor and submitted to the State Department of Insurance or other appropriate State agency.

(4) Results Available to the Public – The covered entity shall make available to the public without charge a copy of the results of the certified audit.

(5) Annual Publication – On an annual basis, the State Department of Insurance and/or other appropriate State agency shall publish a list reflecting each covered entity’s average payment per claim, payment delays, timeliness of payments, total interest paid on late claims, total fines paid, contested claim percentages, denied claims and partially paid claims.

(6) Payment of Costs by the Covered Entity – The cost of such audit shall be paid by the covered entity.

(n) Anti-Retaliation – In coordination with relevant state law, no covered entity may retaliate against a claimant for exercising the right of action provided under this Act.

Section 5. Effective Date. This Act shall become effective immediately upon being enacted into law.
Section 6. Severability. If any provision of this Act is held by a court to be invalid, such invalidity shall not affect the remaining provisions of this Act, and to this end the provisions of this Act are hereby declared severable.
Whereas, Non-standardized, non-machine readable patient medical insurance identification cards have a nonstandard appearance and content and contributes to a higher error rate in manual transcription and entry of patient information; and

Whereas Many cards have photos, illustrations and dark colors that make accurate photocopying difficult; and

Whereas, The lack of machine-readable data requires manual data entry with higher labor cost and higher potential for human error; and

Whereas, There exists a significant cost to physicians and their practices, in labor and materials in making copies of patient's medical insurance identification cards; and

Whereas, Current insurance cards may be out of date when presented to the physician's office; and

Whereas, Patients and physicians will have less aggravation from denied claims, providers will save money on labor and copying, and will be paid more quickly and accurately with a standard insurance card; and

Whereas, Insurers, including Medicaid and Medicare, and other payers will save money by doing less manual work on rejected claims; and

Whereas, Employers and other payers should see savings from less growth in health care costs; and

Whereas, The technology is available to provide for such a system; therefore be it

RESOLVED, That our American Medical Association support the creation of a uniform Workgroup for Electronic Data Interchange (WEDI)-compliant standard to establish a standardized health insurance identification card (New HOD Policy); and be it further

RESOLVED, That our AMA encourage all medical insurance providers, including state Medicaid programs and Medicare, to adopt a standardized machine/computer-read insurance card with accurate and timely information for insureds (Directive to Take Action); and be it further

RESOLVED, That, if necessary, our AMA support or introduce legislation to compel all medical payers to adopt a standard insurance card. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $14,263.

Received: 05/05/09
D-185.999 Information Included On Health Insurance Identification Cards
Our AMA will continue to work with payers, the federal and state governments, and standards organizations to adopt and implement appropriate policies, technologies (e.g., smart cards, telephone hot lines, electronic data interchange, and website access), and national technology standards to provide physicians with accurate and real time verification of patient eligibility, co-payment due, deductible payable information, and claims processing. (Sub. Res. 828, A-99; Modified: Sub. Res. 713, A-08)
Health Identification Card Implementation Guide

This implementation guide specifies WEDI Health Identification Card Implementation of the American National Standard, Identification Cards—Health Care Identification Cards, INCITS 284 as revised. INCITS is accredited by ANSI.

~ Version 1.0 ~
~ November 30, 2007 ~

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Health Identification Card Implementation Guide

1.0 PURPOSE, SCOPE, IMPLEMENTATION STRATEGY, GENERAL INFORMATION

1.1 Purpose of This Implementation Guide

The intent of this implementation guide is to enable automated and interoperable identification using standardized health identification cards. The guide standardizes present practice and brings uniformity of information, appearance, and technology to the over 100 million cards now issued by health care providers, health plans, government programs, and others.

A card serves as an access key to obtain information and initiate transactions. It is used by a consumer to convey identification to providers or others. A card may convey patient identifiers to providers. It may convey insurance identifiers for multiple benefits involving different administrators on a single card. It may combine bank and health ID cards.

1.2 The Underlying ANSI Standard

This implementation guide specifies the WEDI Health Identification Card implementation of the American National Standard, Identification Cards—Health Care Identification Cards, INCITS 284 as revised. INCITS is accredited by ANSI. The standard is an application of International card standards (ISO Standards) to health care applications in the United States.

1.3 Scope of This Implementation Guide Is Identification

The scope of this Implementation Guide is to convey identification. It is an access key for obtaining information and enabling transactions. For example, although the card may facilitate access to a medical record, the guide does not specify the data content from that record. It does not specify diagnostic, prescriptive, encounter, bio-security, non-identifying demographic, or other data about the cardholder. It specifies identifiers, and it permits other information.

1.4 Types of Health Identification Cards (Examples only, not specifications)

Example of Provider-Issued Repeat Admission Card

Example of Health & Drug Multi-Benefit Card

Example of Combined Bank & Insurance Card

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1 Definition: an Implementation Guide applies a standard to specific uses. A standard frequently offers more capability than may be needed for the use. This Implementation Guide focuses the health ID card standard to needs of health care providers and health plans or payers for identification. For example, a hospital may issue a card to identify a recurring patient. A plan may issue a card to identify an insurance plan and subscriber. A RHIO may issue a card to identify a patient's consolidated medical records.

2 Revision of INCITS 284 is expected 2nd or 3rd quarter 2008. This guide is premised on that revision.
This implementation guide specifies different types of health ID cards, including the following:

<table>
<thead>
<tr>
<th>Type of Card</th>
<th>Essential Required Information</th>
</tr>
</thead>
</table>
| 1.4.1 Provider-issued card for repeated admission or treatment | Card Issuer ID*  
Provider National Provider Identifier (NPI)*. Refer to 3.4.  
Cardholder ID  
Patient or Medical Record ID.  
Cardholder Name  
Name of Patient. |
| 1.4.2 Health Benefit or Insurance ID card.        | Card Issuer ID*  
Standard PlanID* described in 3.4.  
Cardholder ID  
Subscriber ID or Member ID assigned by plan.  
Cardholder Name  
Name of Subscriber or Member; see 3.2. |
| 1.4.3 Health ID & Bank card.                      | Bank card with health ID card information added.                                               |
| 1.4.4 Other Health ID card.                       | Card Issuer ID*  
Standard Trading* Partner ID described in 3.4.  
Cardholder ID  
ID for person, record, or other object, assigned by issuer.  
Cardholder Name  
Name of cardholder, that is, person, record, or other object being identified |
| 1.4.5 Card Assigning ISO U.S. Healthcare ID such as for Atypical Provider | Card Issuer ID*  
Standard ID for entity that is card issuer.  
Cardholder ID  
Standard ID for cardholder such as an Atypical Provider  
Cardholder Name  
Name of cardholder such as an Atypical Provider |

* This implementation guide specifies card issuer numbers to be ISO Standard U.S. Health Care Identifiers issued under authority of ISO Standard 7812. For example, the National Provider Identifier (NPI) is such a number. Refer to 3.4 for more complete description.

**Illustrations are examples only.** Illustrations in this implementation guide are examples of compliant cards. The guide's requirements allow significant variation from these examples.

### 1.4.1 Provider-issued card for repeated admission or treatment (Refer to 3.0 and 8.0)

A typical provider-issued card is for identification of the patient who is admitted or treated repeatedly such as for rehabilitation or other treatment. On readmission, the patient presents the card so that completely accurate identification on the card allows the patient and provider to identify the patient's medical records and to avoid a full admission process.

Essential information consists of (1) Patient Name, (2) Patient or Medical Record ID (either proprietary or standard), and (3) National Provider Identifier (NPI). Refer to 3.0 and 8.0.

---

3 Essential Information is a defined term meaning Cardholder Name, Cardholder ID, and Card Issuer ID. Refer to 2.0.

4 A standard Trading Partner ID is an ISO Standard U.S. Healthcare Identifier for a clearinghouse, billing service, provider network, RHIO, public health reporting agency, or other entity that is not identified with an NPI or PlanID. Some health plans, while identified by PlanID, also use a Trading Partner ID to identify an EDI portal.
1.4.2 **Health Benefit or Insurance Card (Refer to 3.0 and 5.0)**

A health plan issues a health benefit ID card to a subscriber or a member, who presents the card to a health care provider to convey with accuracy and clarity the benefit identifying information that the provider needs in order to conduct transactions such as eligibility inquiry and claim submission. Refer to 3.0 and 5.0 for further detail.

Essential information consists of (1) Subscriber or Member Name, (2) Subscriber or Member ID, and (3) Standard Health Plan ID. Refer to 3.6 for placement options for essential information. The examples also illustrate some discretionary data elements in addition to the essential information.

![Health Plan LOGO & Name and Health & Drug Card Logo](image)

Example Showing Name First (See 3.6)  Example Showing Card Issue First

1.4.3 **Optional Health ID Card and Bank Card Combo (Refer to 3.0, 5.0, and 7.0)**

This implementation guide permits, but does not require, a health identification card to be added on the same card to a standard credit or debit card. Essential information consists of standard bank card information plus health ID card information. The following is illustrative only. Refer to 3.0, 5.0, and 7.0 for detail.

![Combo Bank & Insurance](image)

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1.4.4 Other Health ID Cards (Refer to 3.0 and 9.0)

Entities other than health care providers or health plans may issue health ID cards. For example, a Regional Health Information Organization (RHIO) may issue an ID card for access and maintenance of a patient’s consolidated medical records. Other examples include cards issued by health data banks, blood banks, American Red Cross, social services, and others. Essential information consists of (1) Patient Name, (2) Either proprietary or standard confidential patient record ID, (3) Standard card issuer ID such as a RHIO. The following is an example. Refer to 3.0 and 9.0 for detail.

**RHIO Logo & Name**

**Patient Record Identifier**

Issuer: (80840)  
9312 567 598  
Patient ID: MRN 123456  
Patient: SUSAN B JONES-SMITH

**Confidential Patient ID**

Patient: SUSAN B JONES-SMITH  
Confidential Patient ID: 808400 123456 789012  
Issuer (80840)  
9312 567 598

Other Entity-Issued Card with a Proprietary Patient Record ID  
Other Entity-Issued Card with a Standard Patient Record ID

1.4.5 Standard Health ID Card to Assign Standard Identifiers (Refer to 10.0)

When an ISO Standard U.S. Healthcare Identifier is issued to an entity, the most convenient means to convey this identifier may be an identification card. The following is an example in which a health plan arranges for a standard Atypical Provider Identifier (API) to be assigned to an Atypical Provider and a card to convey the API to that provider. Essential information consists of (1) Standard Card Issuer identifier of the entity arranging the assignment (e.g. the Medicaid state plan), (2) Standard ID being assigned to the Entity, and (3) the Entity Name. The card issuer is a health plan, provider, or other trading partner authorized to arrange assignment of standard IDs to Atypical Providers, bill reviewers, or others. Refer to 10.0.

**Logo of Plan Assigning APIs**

**Standard Atypical Provider ID**

Use Your API Number on Healthcare Claims

Provider: YELLOW CAB OF AUSTIN  
Your API: 9312 567 598  
Issuer (80840) 9210 567 898  
Issued: 05/14/06

Card to Convey ISO Standard U.S. Healthcare Identifier
1.5 Essential Information Common to All ID Cards

Every ID card of any kind must convey two essential identifications:

1) **Card Issuer.** Identifies the authority or sponsor who is responsible for issuance of the card; in card language, this is called the *card issuer*. What is new for health cards, other than a BIN number identifying the benefit manager on drug benefit cards, is identifying the card issuer with a *standard ID* rather than text. This is the most important new element for standardization of a health ID card. Machine-readability requires it.

2) **Cardholder.** Identifies the person, family, record, bank account, or other object being identified; in card language, the object being identified is called the *cardholder*. The cardholder is identified with two data elements:

   - **Cardholder ID.** An identifier for the cardholder. This ID has meaning within the context of the card issuer.
   - **Cardholder Name.** The name for the cardholder. Must correspond to the Cardholder ID; both ID and Name must identify the same person or object.

Three examples showing card issuer and cardholder:

<table>
<thead>
<tr>
<th>Social Security Card</th>
<th>Bank Card</th>
<th>Minimum Health ID Card</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Sixth-Ninth National Bank</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Credit Card</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Health ID Card; Shows New Card Issuer ID</td>
</tr>
</tbody>
</table>

a) **Social Security Card.** A Social Security Card identifies the Social Security Administration with text and the person with an ID. But because SSN is so ubiquitous, a card issuer *identifier* for the Social Security Administration is not included nor warranted.

b) **Bank Card.** A bank card identifies both the bank and the account at the bank. The first six digits of the card number identify the bank using an ID assigned internationally under ISO Standard 7812, the same standard used for NPI and PlanID. Processing of bank cards is easily automated because the bank is identified by this ISO standard identifier.

c) **Health Identification Card.** Until now, health ID cards, other than drug benefit cards, identify the card issuer only with text, not with an identifier. As a result, processing of a health benefit ID card has required a person in the provider’s office to interpret the card, look up the health plan, and enter a code into the provider’s systems in order to instruct the provider’s systems who is the health plan and where to send transactions.

In this guide the Health Identification Card introduces a standard card issuer identifier, such as a NPI, PlanID, or trading partner identifier, which is assigned for U.S. health applications under authority of ISO Standard 7812.
1.6 Economic Benefits from a Machine-Readable Card with Standard Card Issuer ID

This section describes qualitative benefits that may be expected from machine-readable health identification cards as standardized in this implementation guide.

1) For providers. Machine-readable health identification cards (1) help to eliminate patient and insurance benefit identification errors, (2) reduce costs and aggravation of rejected claims, (3) reduce lengthy admission processes, and (4) contribute to smoother office procedures and patient satisfaction. (5) Significant reduction in claim errors will enhance provider relations with plans. (6) The costs of traditional photocopying the front and back of cards, manual lookup and key entry of card information, and filing paper copies can be eliminated over time. (7) When integrated with enhanced provider systems, machine-readable identification cards will facilitate immediate automatic transactions such as eligibility inquiries. (8) Even in phone conversations, the simplicity of needing only two identifiers aids both patient and provider to convey insurance benefit information or medical record identification quickly with complete accuracy.

2) For health plans and administrators. Patient and insurance benefit identification errors significantly increase processing and service costs for plans; they aggravate providers; and they contribute to member dissatisfaction. Elimination of patient identification errors will benefit health plans to: (1) improve subscriber or member satisfaction, (2) improve employer and plan sponsor satisfaction, (3) reduce cost to return and subsequently reconcile claims with errors, (4) reduce significantly the cost of both provider and member help desks and administrative record searches, and (5) improve plan-provider relations. (6) In addition, the universal health plan identifier conveyed by the card is one ingredient for improved coordination of benefits. (7) With multiple-benefit cards, administrators and medium sized payers are able more easily to provide a convenient range of benefit plans to meet the needs of employers.

3) For patients or consumers. (1) Elimination of patient and insurance identification errors significantly reduces the hassle factor and increases patient and subscriber satisfaction. (2) Consumers desire simplicity, and they want a single card for multiple benefits and functions. This implementation guide, using only two identifiers, enables multiple benefits on a single card. (3) Patients can more easily and accurately read the essential identifiers from a card to a provider over a telephone. (4) It also permits an option to combine an insurance card with a bank card on the same card.

4) For employers. (1) Employers desire to improve employer-employee satisfaction and reduce costs. Elimination of patient and insurance identification errors increases employee satisfaction with the company’s benefit plans and reduces cost of helping employees resolve insurance benefit problems. (2) With a multiple-benefit card, employers are able more competitively to purchase multiple benefits using different administrators while presenting to an employee only a single, simple card.

5) For clearinghouses. (1) The standard health plan identifier conveyed by the card assists all-plan routing without requiring translation of trading-partner specific identifiers. (2) Reduction of errors will reduce expense and increase client satisfaction. (3) Multi-benefit cards enable clearinghouses to support increased value to providers.
1.7 Economic Strategy to Achieve Industry Implementation

In order for full value to be realized from cards specified in this implementation guide, three investments must be made:

1) For Card Issuers the investment is adoption of this implementation guide for cards when reissued, especially including the standard card issuer ID and machine-readable technology. A card issuer may need to issue standard cards in anticipation of future return. For a card issuer, the incremental investment at the time it is issuing cards anyway is only a marginal cost.

2) For Card Users the investment is primarily in the systems capability to process automatically the two identifiers on a standard card; so it is reasonable for a provider or other card user to desire a significant percentage of cards to be standard before justifying the investment. There are various potential levels of system capability that a provider may elect to install; for example:
   - The user may elect to defer any changes and operate the same as presently.
   - The user may use the two identifiers to populate Direct Data Entry screens.
   - The user's system may accept and store the two identifiers for transactions.
   - The user's system may machine-read the card information.
   - The user's system may automatically generate standard transactions, such as eligibility inquiries and claims based on the two identifiers, which might be machine-read or entered manually (such as when received over the phone).

For a card user such as a provider, the investment in system enhancement may be significant such that, to be justified, there must be reasonably high frequency of use although a plan or other entity may elect to fund some of the user's investment.

3) For Clearinghouses the investment is to use standard card issuer IDs and direct transactions to multiple payers and administrators.

When the card issuer is a provider, then the provider controls the environment for use of the cards and would determine ROI based on its own operations.

When the card issuer is a health plan or administrator, then:

- Before providers implement machine-readability and integrate the card into their systems, providers and plan may obtain a good portion of the error reduction potential, realize more error-free telephone communication of identifiers between a consumer and provider, and be able to combine multiple benefits on a single card.

- After providers implement machine-readability and integrate the card into their systems, the full return can be realized by plans, providers, employers, clearinghouses, and consumers described in 1.6.

- The key to success is therefore for health plans, as cards are reissued, to adopt this implementation guide now—especially including the standard card issuer ID and machine-readability—to help build a large industry population of standard, machine-readable cards. Providers will enhance their systems to obtain the returns from card standardization as the population of standard cards increases.
1.8 Other Principles of this Implementation Guide

1) Simplicity and Permitting Maximum Card Issuer Discretion

The design philosophy of this implementation guide and the underlying standard is that only the most essential information and format should be required. It should require the least information necessary. In general, additional information is discretionary unless explicitly disallowed or discouraged. The simplicity design principle maximizes flexibility by maximizing card issuer options. The design philosophy’s central premise is that a card issuer desires the best value for its card, and after meeting requirements, will effectively balance objectives of usefulness, simplicity, card life, and other factors. This guide encourages card issuers to accept the simplicity principle.

Important to simplicity for consumers, providers, plans, and other card users is uniformity and placement of information. For example, the two essential identifiers—card issuer and cardholder ID—should be adjacent to each other in predicable location as, for example, bank cards always place these two identifiers in the same location.

Simple Test of Simplicity. The simplicity test is the ease by which a consumer, coached by a provider over a telephone, is able easily and accurately to read the card’s printed information and convey the two essential identifiers and name to the provider.

2) Process Neutrality

The card should meet stakeholders’ needs. It should be neutral to the conduct of business. For example, it should permit but not require multi-functional cards. It should permit host and home plan structures, geographical or regional plan structures, provider networks, and any other such arrangement. It should support different types of benefit plans such as medical, dental, drug, vision, supplemental; and it should permit but not require combinations of benefit plans. It should have flexibility to permit new business structures and processes in the future, including potential financial transactions.

Its processes should be open, and supporting directories should be publicly accessible to responsible participants in healthcare electronic commerce.

3) Card Must be Effective for all User Environments

The card must work in all user environments regardless whether or not the user has system capability for machine readability.

4) This Implementation Guide and the Underlying Standard are Voluntary

The potential benefits to the health care industry—to patients, health care providers, and health plans—are very significant, especially from multiple functions, uniformity, efficiency, automation, and error elimination; however, implementation of this guide is voluntary.5

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5 The authors recognize certain state regulations require the NCPDP Implementation Guide, which includes the underlying standard by reference, for prescription drug plan identification cards. Also, Medicare Part-D guidelines are based on the NCPDP implementation guide, this implementation guide, and the underlying standard. So it may happen that, while implementation of this implementation guide is voluntary, some states may decide to require all or part of it.
5) **Conformance**

A health identification card is in conformance with this Implementation Guide if it meets all requirements specified directly or by reference contained in this Implementation Guide and the underlying standard, INCITS 284 as revised. See 1.2. To this end, this implementation guide is designed to permit maximum user discretion within minimum requirements. Cards not conforming to all requirements are not in conformance.

6) **This Card is not a National Personal Identification Card**

This is not a national ID card. The individual, family, medical record, or other ID number on the card continues to be the same identifier that card issuers now put on their cards. Cardholder ID has meaning only in context with the card issuer identifier. This implementation guide does not require a national individual identifier.

7) **Limitations Imposed by this Implementation Guide**

The design philosophy in this implementation guide is to simplify; so this implementation guide requires a card to have only a single set of identifiers—one card issuer identifier, one cardholder identifier and name. With two exceptions described below, when a single card combines benefits, each benefit must employ the same set of identifiers (refer to Section 6.0 for exception for combined medical and drug benefit cards).

If the sets of identifiers for multiple benefits on a card cannot be the same for all benefits, this Implementation Guide requires the health plan to issue separate cards for each benefit plan, and it further recommends benefit plans explore means to employ only a single set of identifiers. This may be accomplished through coordination among the benefit plans to use the same identifiers, or through an electronic cross-walk or directory (refer to 3.4 and 5.3). Use of a single set of identifiers for a multi-benefit card conforms to the simplicity design principle that is central to the objectives of this guide.

However, there are two exceptions to the simplicity principle. A card may have additional identifiers in the following circumstances:

1. When a drug benefit card is combined on a single card with another benefit plan. Refer to Section 6 for specifications to align this guide with the NCPDP implementation guide.

2. When a commercial plan is combined on a single card with a Medicare plan, which employs a Medicare-assigned subscriber number for each member.

8) **Requirement for Machine-readability**

This implementation guide requires that a card include machine-readable technology, either 3-track magnetic stripe and/or PDF417 2-dimensional bar code, specified in 12.0 and 13.0.
9) Information and technology not Addressed in this Implementation Guide

In general, information and technology not addressed in this guide is additional to what is required and is at the discretion of the card issuer.

10) Information Sources Listed in Attachment A

Refer to Attachment A for sources of the INCITS 284 standard, other implementation guides, legacy formats, code values, and card issuer identifiers.
MGMA Project SwipeIT: FAQs

Project SwipeIT FAQ

Project SwipeIT is an industry wide initiative launched by the Medical Group Management Association (MGMA) in January 2009 to advance the adoption of standardized patient health-insurance identification (ID) cards containing machine-readable information. MGMA estimates that the health care industry wastes as much as $1 billion annually as a result of nonstandardized cards.

- Why are nonstandardized, nonmachine-readable cards so costly to the industry?
- Who benefits from standardized ID cards?
- Why is MGMA launching this campaign now?
- Are Medicare and Medicaid included in your initiative?
- What is the WEDI implementation guide for health insurance ID cards?
- Why haven’t health insurance ID card standards been widely accepted and implemented yet?
- Won’t it be costly for insurers to redesign and reissue cards to their beneficiaries?
- You are asking stakeholders to pledge their support, but how will you ensure compliance?
- How much will adopting this technology cost your MGMA members?
- How does this initiative complement or contrast with the health system reform expected under the Obama administration?
- Are you calling for legislative action to standardize cards? When will standardized cards be fully implemented?
- Who needs to get involved and how can they take part in the project?
- Who can I contact for additional information?

Why are nonstandardized, nonmachine-readable cards so costly to the industry?

- Nonstandard appearance and content contribute to a higher error rate in manual transcription and entry of patient information. Many cards have photos, illustrations and dark colors that make accurate photocopying difficult.
- Lack of machine-readable data requires manual data entry with high labor cost and high potential for human error.
- Cost of making copies of patients' ID cards (labor and materials).

All these factors lead to rework for providers and costly manual intervention for insurers.

Who benefits from standardized ID cards?

Everyone. Patients will have less hassle from denied claims. Providers will save money on labor and copying, and will get paid more quickly and accurately. Insurers will save by doing less manual work on rejected claims. Ultimately, employers should see savings from less growth in health care costs.

Why is MGMA launching this campaign now?

Because this is an area where a simple change can save immense amounts of money. Standards for patient health-insurance ID cards were developed in 1997, but have not yet been widely implemented.

Economic pressure – exacerbated by the nation’s credit crisis – squeezes our health care system to the breaking point. It's time for the industry to look inward at the duplicative, wasteful and valueless processes that drive up health care costs for all stakeholders.

The time is very much past due. We are taking the lead to make it happen NOW.
Are Medicare and Medicaid included in your initiative?
Yes, absolutely. We have invited government insurers to be among the first to pledge to adopt standardized patient health-insurance ID cards.

What is the WEDI implementation guide for health insurance ID cards?
The Workgroup for Electronic Data Interchange (WEDI) developed an implementation guide to enable automated identification using standardized health-insurance ID cards. The guide standardizes present practices and brings uniformity of information, appearance and technology to the more than 100 million cards issued by health care providers, health plans, government programs and others.

Why haven't health insurance ID card standards been widely accepted and implemented yet?
Primarily because of inertia. It is difficult for one insurer to make the change alone. The market requires a critical mass of companies to make it worthwhile for providers to use the new technology.

Won't it be costly for insurers to redesign and reissue cards to their beneficiaries?
Estimates are that the cost of a WEDI-compliant, machine-readable card is 50 cents — only a fraction more than the nonstandardized, plastic or paper cards that most insurers use now. The savings that insurers will see from reduced claim denials, provider inquiries, re-work and labor will far exceed this cost.

You are asking stakeholders to pledge their support, but how will you ensure compliance?
In Phase 1 of the project, we are asking insurers to agree to issue WEDI-compliant, machine-readable cards by January 2010. In Phase 2, we will publicly recognize payers that have met their pledge and issued standardized, machine-readable health ID cards. We will publicly identify those that haven't.

How much will adopting this technology cost your MGMA members?
A card reader costs less than $200. Practice management system (PMS) vendors tell us that connecting the reader to a PMS is a simple, inexpensive upgrade. We estimate that the current system costs providers as much as $1 billion in wasted administrative expenses each year. Eliminating that waste will make these small start-up costs pale in comparison.

How does this initiative complement or contrast with the health system reform expected under the Obama administration?
It is wholly consistent with the expected Obama effort to reduce administrative costs in our health care system. We've invited the secretary of the Department of Health and Human Services to take the lead by asking Medicare to be among the first to pledge to issue WEDI-compliant, machine-readable ID cards.

Are you calling for legislative action to standardize cards? When will standardized cards be fully implemented?
Some states have already mandated this change through legislation. We are urging the health insurance industry to adopt standardized cards voluntarily. We believe the logic is so compelling that legislation will not be required. However, if voluntary efforts don’t succeed, legislation should be enacted to ensure that change occurs.

Who needs to get involved and how can they take part in the project?

Insurers, employers, practice management-system vendors, hospitals, medical practices, associations, medical societies and government should all be involved to ensure this effort succeeds.

- Insurers must pledge to issue new cards that are WEDI-compliant and machine-readable.
- PMS vendors must pledge to make inexpensive interfaces available between card readers and their PMS products.
- Employers – self-insured and fully insured – must demand that their health insurers or administrative services organizations issue WEDI-compliant, machine-readable cards.

Who can I contact for additional information?

MGMA is leading the charge for this effort. If you are an insurer, provider or vendor who wants to get involved, please e-mail us at swipeit@mgma.com.

Visit wedi.org for more information about the WEDI Implementation Guide.

5/21/2009
In addition, the authors wish to credit many other individuals who worked to create the underlying standard in 1992-97, especially Tom Keane of Blue Cross Blue Shield of Florida, Joel Ackerman, the members of ASC INCITS B10, and Harvey Rosenfeld of ANSI.

### 14.3 Major Stakeholders Panel

The authors wish to credit the following individuals and organizations who contributed generously of their time and perspective as members of a special ad hoc panel of major stakeholders established to address data content, technology, financial card combination, and usage. Participation on the panel does not constitute endorsement of this guide.

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Whereas, Health care spending in the United States has grown to be the most expensive in the world among industrialized countries, totaling $2.2 trillion in 2007, approaching 16.2% of Gross Domestic Product (GDP) and outpacing inflation\(^1\); and

Whereas, Fifty-seven million Americans were part of families that had difficulty paying medical bills in 2007 with the majority of those possessing health insurance\(^2\); and

Whereas, Prices for investigations and treatments may not be readily accessible and may be desired by consumers, legislators, and payers\(^3\); and

Whereas, Patients are unlikely to know the total cost or percentage of physicians’ fees associated with interventions\(^4\) or what drugs are included in their formularies and the co-payments associated with those drugs\(^5\); and

Whereas, Physicians are unlikely to know the price charged for a particular investigation or therapy\(^6,7,8,9,10\) and they are "often unaware of the preferred medications on the formulary, the patients' co-payment amounts, or the price of the drugs prescribed"\(^11\); and

Whereas, Different investigations (diagnostic services) and therapies with similar efficacy may vary in price, including pharmacological therapies, i.e., generic vs brand-name drugs\(^12\); and

Whereas, "Providing reliable cost and quality information empowers consumer choice. Consumer choice creates incentives at all levels, and motivates the entire system to provide better care for less money"\(^13\); therefore be it

RESOLVED, That our American Medical Association support legislation that requires insurance providers to provide an online resource for patients and physicians to calculate charges and out-of-pocket expenses associated with investigations and therapies in an effort to better educate patients and physicians on health care costs, equip patients to recognize value in health care, empower patients to participate in the spending of their health care dollars, and promote one-time and long-term patient savings in an effort to reduce economic strains on health care systems. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $9,294.

Received: 05/05/09

H-165.846 Adequacy of Health Insurance Coverage Options
Our AMA supports the following principles to guide in the evaluation of the adequacy of health insurance coverage options: 1. Any insurance pool or similar structure designed to enable access to age-appropriate health insurance coverage must include a wide variety of coverage options from which to choose. 2. Existing federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the US Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations) should be used as a reference when considering if a given plan would provide meaningful coverage. 3. Provisions must be made to assist individuals with low-incomes or unusually high medical costs in obtaining health insurance coverage and meeting cost-sharing obligations. 4. **Mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services.** (CMS Rep. 7, A-07; Reaffirmation I-07)

H-155.960 Strategies to Address Rising Health Care Costs
Our AMA: (1) recognizes that successful cost-containment and quality-improvement initiatives must involve physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government; (2) supports the following broad strategies for addressing rising health care costs: (a) reduce the burden of preventable disease; (b) make health care delivery more efficient; (c) reduce non-clinical health system costs that do not contribute value to patient care; and (d) promote "value-based decision-making" at all levels; (3) will continue to advocate that physicians be supported in routinely providing lifestyle counseling to patients through: adequate third-party reimbursement; inclusion of lifestyle counseling in quality measurement and pay-for-performance incentives; and medical education and training; (4) will continue to advocate 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; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers; (5) will continue to advocate 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 and without imposing undue administrative burden, including: clinical guidelines and protocols; relative cost-effectiveness of alternative diagnostic services and treatments; quality measurement and pay-for-performance criteria; **patient-specific clinical and insurance information;** prompts and other functionality to support lifestyle counseling, disease management, and case management; and alerts to flag and avert potential medical errors; (6) encourages the development and adoption of clinical performance and quality measures aimed at reducing overuse of clinically unwarranted services and increasing the use of recommended services known to yield cost savings; (7) encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are reduced for maintenance medications used to treat chronic medical conditions, particularly when non-compliance poses a high risk of adverse clinical outcome and/or high medical costs. Consideration should be given to tailoring cost-sharing requirements to patient income and other factors known to impact compliance; and (8) supports ongoing investigation and cost-effectiveness analysis of non-clinical health system spending, to reduce costs that do not add value to patient care. (CMS Rep. 8, A-07; Reaffirmed: CMS Rep. 7, A-08; Reaffirmed in lieu of Res. 828, I-08)
Whereas, Health insurance companies and pharmacies increasingly access patients’ medical, pharmacy and laboratory claims data and then advise primary care physicians to order procedures, perform an examination or prescribe a specific medication; and

Whereas, Physicians know their patients better than the insurance company or pharmacy and are in the best position to diagnose and treat within the context of the patient’s complete health status; and

Whereas, Most of the unsolicited advice from insurance companies and pharmacies is unnecessary and only increases healthcare cost, not effectiveness; therefore be it

RESOLVED, That our American Medical Association adopt policy to oppose the unwanted and unwarranted participation of health care insurance companies and pharmacies in patient diagnosis, treatment and health management. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/05/09

H-285.954 Physician Decision-Making in Health Care Systems
AMA policy states: (1) That certain professional decisions critical to high quality patient care should always be the ultimate responsibility of the physician regardless of the practice setting, whether it be a health care plan, group practice, integrated or non-integrated delivery system or hospital closed department, whether in primary care or another specialty, either unilaterally or with consultation from the plan, group, delivery system or hospital. Such decisions include, but are not limited to, the following: (a) What diagnostic tests are appropriate, (b) When and to whom physician referral is indicated, (c) When and with whom consultation is indicated, (d) When non-emergency hospitalization is indicated, (e) When hospitalization from the emergency department is indicated, (f) Choice of service sites for specific services (office, outpatient department, home care, etc.), (g) Hospital length of stay, (h) Frequency/length of office/outpatient visits or care, (i) Use of out-of-formulary medications, (j) When and what surgery is indicated, (k) When termination of extraordinary/heroic care is indicated, (l) Recommendations to patients for other treatment options, including non-covered care, (m) Scheduling on-call coverage, (n) Terminating a patient-physician relationship, (o) Whether to work with, and what responsibilities should be delegated to, a mid-level practitioner, (p) Determination of the most appropriate treatment methodology. (2) The AMA encourages state medical associations to consider development and wide dissemination of guidelines for the extent of practicing physician involvement in plan, group, system or hospital department medical decisions and policies. Such guidelines should be relevant to their jurisdiction, allow for variation in plan, group, system or hospital department sponsorship and structure, and optimize patient care. (3) The AMA encourages organizations and entities that accredit or develop and
apply performance measures for health plans, groups, systems or hospital departments to consider
inclusion of plan, group, system or hospital department compliance with any applicable state medical
association or medical staff-developed decision-making guidelines in their evaluation criteria. (4) The
AMA encourages physicians in integrated health plans and systems to have a functioning medical staff
structure in place. (CMS Rep. 5, I-96; Amended by CMS Rep. 12, A-97; Reaffirmation A-97; Reaffirmed

H-450.941 Pay-For-Performance, Physician Economic Profiling, and Tiered and Narrow Networks
1. Our AMA will collaborate with interested parties to develop quality initiatives that exclusively benefit
patients, protect patient access, do not contain requirements that permit third party interference in the
patient-physician relationship, and are consistent with AMA policy and Code of Medical Ethics,
including Policy H-450.947, which establishes the AMA’s Principles and Guidelines for Pay-for-
Performance and Policy H-406.994, which establishes principles for organizations to follow when
developing physician profiles, and that our AMA actively oppose any pay-for-performance program that
does not meet all the principles set forth in Policy H-450.947. 2. Our AMA strongly opposes the use of
tiered and narrow physician networks that deny patient access to, or attempt to steer patients towards,
certain physicians primarily based on cost of care factors. 3. Our AMA pledges an unshakable and
uncompromising commitment to the welfare of our patients, the health of our nation and the
primacy of the patient-physician relationship free from intrusion from third parties. 4. Because
there are reports that pay-for-performance programs may pose more risks to patients than benefits, our
AMA will prepare an annual report on the risks and benefits of pay-for-performance programs, in general
and specifically the largest programs in the country including Medicare, for the House of Delegates over
the next three years, beginning at the 2007 Interim Meeting. This report should clearly delineate
between private pay-for-performance programs and voluntary public pay-for-reporting and other related
quality initiatives. 5. Our AMA will continue to work with other medical and specialty associations to
develop effective means of maintaining high quality medical care which may include physician
accountability to robust, effective, fair peer review programs, and use of specialty-based clinical data
registries. 6. As a step toward providing the Centers for Medicare and Medicaid Services (CMS) with data
on special populations with higher health risk levels and developing variable incentives in achieving
quality, our AMA will continue to work with CMS to encourage and support pilot projects, such as the
Physician Quality Reporting Initiative (PQRI), by state and specialty medical societies that are developed
collaboratively to demonstrate effective incentives for improving quality, cost-effectiveness, and
appropriateness of care. 7. Our AMA will advocate that physicians be allowed to review and correct
inaccuracies in their patient specific data well in advance of any public release, decreased payments, or
forfeiture of opportunity for additional compensation. (BOT Rep. 18, A-07; Reaffirmed in lieu of Res.
729, A-08)

H-120.988 Patient Access to Treatments Prescribed by Their Physicians
The AMA confirms its strong support for the autonomous clinical decision-making authority of a
physician and that a physician may lawfully use an FDA approved drug product or medical device for an
unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion;
and affirms the position that, when the prescription of a drug or use of a device represents safe and
effective therapy, third party payers, including Medicare, should consider the intervention as
reasonable and necessary medical care, irrespective of labeling, should fulfill their obligation to
their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses
of drugs on their formulary. (Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified
by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02;
Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04; Reaffirmation I-07; Reaffirmed: Res. 819, I-
07)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 710
(A-09)

Introduced by: Michigan Delegation

Subject: Identifying Abusive, Hostile or Non-Compliant Patients

Referred to: Reference Committee G
(J. Leonard Lichtenfeld, MD, Chair)

Whereas, Many patients are becoming more abusive and hostile toward physicians for many reasons not limited to the economy, increasing co-pays and deductibles, unreasonable expectations and demands, a lack of instantaneous cure, arrogance and/or the belief that they “own” their physicians; and

Whereas, There are decreasing numbers of physicians both in primary care and specialties especially in terms of access; and

Whereas, Increasing noncompliance with treatment can reflect negatively on physicians during black box audits by insurance companies and oversight governmental agencies; and

Whereas, Abusive, hostile, and noncompliant patients result in increasing office resources adding to office overhead and added stress on all of the office personnel, which can lead to potential ill health; and

Whereas, The stress of dealing with ungrateful patients is adding to the stress of physicians leading to decreased physician satisfaction; and

Whereas, Any complaint to any oversight investigative regulatory body leads to uncompensated expenditure of time, resources, and monies to defend physicians or the “guilty until proven innocent” principal; and

Whereas, Physicians need to own the data to simplify patient collection and identification to defend themselves as well as alert outside investigating agencies to the potential nature of the patient’s records; therefore be it

RESOLVED: That our American Medical Association ask its CPT Editorial Panel to investigate for data collection and report back at Annual 2010 meeting: 1) developing a modifier for the E&M codes to identify non-compliant patients and/or 2) develop an add-on code to E&M codes to identify non-compliant patients. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09

H-70.919 Use of CPT Editorial Panel Process
Our AMA reinforces that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes.
descriptors, guidelines, parenthetic statements and modifiers. (BOT Rep. 4, A-06; Reaffirmation A-07; Reaffirmation I-08)
Whereas, Physician-hospital relations are becoming increasingly strained due to declining reimbursement and a more competitive medical environment; and

Whereas, Hospital administrative decisions directly impact physician practices; and

Whereas, There are no requirements to include practicing physicians in hospital decisions; therefore be it

RESOLVED, That our American Medical Association seek policy from The Joint Commission to mandate that hospitals maintain non hospital-employed, practicing physician membership on their operating boards. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09

H-225.983 Physician Representation on Hospital Governing Boards
(1) It is the policy of the AMA that physicians who are members of the medical staff shall be eligible for, and should be included in, full membership on hospital governing bodies and their action committees in the same manner as are other knowledgeable and effective individuals. Other physicians also should be considered eligible for membership on the governing body. The hospital medical staff should have the right of representation at all meetings of the governing body by medical staff members elected by the medical staff having the right of attendance, voice and, if appropriate, vote. Compensation to medical staff members for service to the hospital should not preclude the physician’s membership on the hospital governing board. (2) Hospital conflict of interest policies should include physician medical staff members of hospital governing boards. (Sub. Res. 820, I-92; Reaffirmed: CMS Rep. 10, A-03; Modified: Res. 714, A-04)

H-225.957 Principles for Strengthening the Physician-Hospital Relationship
The following twelve principles are AMA policy: PRINCIPLES FOR STRENGTHENING THE PHYSICIAN-HOSPITAL RELATIONSHIP . . . 9. The organized medical staff has elected appropriate medical staff member representation to attend hospital governing board meetings, with rights of voice and vote, to ensure appropriate organized medical staff input into hospital governance. These members should be elected only after full disclosure to the medical staff of any personal and financial interests that may have a bearing on their representation of the medical staff at such meetings. The members of the organized medical staff define the process of election and removal of these representatives. 10. Individual members of the organized medical staff, if they meet the established criteria that are applicable to hospital governing body members, are eligible for full membership on the hospital governing body. Conflict of interest policies developed for members of the organized medical
staff who serve on the hospital’s governing body are to apply equally to all individuals serving on the hospital governing body. . . . (Res. 828, I-07)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 712
(A-09)

Introduced by: Michigan Delegation

Subject: Development of a Payment Code for Prior Authorization

Referred to: Reference Committee G
(J. Leonard Lichtenfeld, MD, Chair)

Whereas, Prior authorization is a task that takes time; and

Whereas, The requirements to participate in that task are established by third-party payers and managed care entities; and

Whereas, Participation and prior authorization represents a cost to physicians and their practices; and

Whereas, There is no way to recoup reimbursement for that time without the establishment of a reimbursement code for prior authorization activity; therefore be it

RESOLVED, That our American Medical Association pursue establishment of a CPT code that would allow physicians to seek reimbursement for participating in the prior authorization process with third-party payers and managed care entities. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09

H-70.919 Use of CPT Editorial Panel Process
Our AMA reinforces that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers. (BOT Rep. 4, A-06; Reaffirmation A-07; Reaffirmation I-08)

H-285.998 Managed Care
(5) Utilization Review When inordinate amounts of time or effort are involved in providing case management services required by a third party payer which entail coordinating access to other health care services needed by the patient, or in complying with utilization review requirements, the physician may charge the payer or the patient for the reasonable cost incurred. "Inordinate" efforts are defined as those "more costly, complex and time-consuming than the completion of standard health insurance claim forms, such as obtaining preadmission certification, second opinions on elective surgery, certification for extended length of stay, and other authorizations as a condition of payer coverage." Any health plan or utilization management firm conducting a prior authorization program should act within two business days on any patient or physician request for prior authorization and respond within one business day to other questions regarding medical necessity of services. Any health plan requiring prior authorization for covered services should provide enrollees subject to such requirements with consent forms for release of medical information for utilization review purposes, to be executed by the enrollee at the time services requiring prior authorization are
recommended by the physicians. In the absence of consistent and scientifically established evidence that preadmission review is cost-saving or beneficial to patients, the AMA strongly opposes the use of this process. (Joint CMS/CLRDPD Rep. I-91; Reaffirmed: CMS Rep. I-93-5; Reaffirmed: Res. 716, A-95; Modified: CMS Rep. 3, I-96; Modified: CMS Rep. 4, I-96; Reaffirmation A-97; Reaffirmed: CMS Rep. 3, I-97; Reaffirmed: CMS Rep. 9, A-98; Reaffirmed: Sub. Res. 707, A-98; Reaffirmed: CMS Rep. 13, I-98; Reaffirmed: Res. 717, A-99; Reaffirmation A-00; Reaffirmation A-02; Reaffirmation I-04; Reaffirmed in lieu of Res. 839, I-08)
Introduced by: Michigan Delegation

Subject: “Advance Directives for All” Campaign

Referred to: Reference Committee G
(J. Leonard Lichtenfeld, MD, Chair)

Whereas, Advance directives are important in avoiding futile care at the end of life; and
Whereas, Physicians’ offices are among the best places to organize such a directive; and
Whereas, Reimbursing physicians for their time to help patients complete an advance directive will encourage them to actively participate in such an endeavor; therefore be it

RESOLVED, That our American Medical Association seek a new CPT code(s) for advance directive counseling. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09

H-70.919 Use of CPT Editorial Panel Process
Our AMA reinforces that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers. (BOT Rep. 4, A-06; Reaffirmation A-07; Reaffirmation I-08)

H-390.916 Payment for Patient Conferences Regarding Advance Directives
Our AMA encourages payment for medical conferences with patients and/or relatives and guardians regarding medical management and future medical management, particularly as it relates to the discussion of advance directives (i.e., living wills and durable powers of attorney for health care). (Res. 1, I-90; Reaffirmed: Sunset Report, I-00; Modified in lieu of Res. 101, A-07)

H-385.977 Counseling - Serious Medical Problems
The AMA (1) affirms that physician counseling of patients and their families with respect to serious medical problems is a vital medical service; (2) believes that insurance companies, third party carriers, and governmental agencies involved in medical care should regard and treat counseling by physicians as an important medical service; and (3) urges all physicians not only to counsel their patients with respect to serious medical problems, but also to use the CSN/CPT codes for counseling when billing patients or third parties for medical services. (Res. 56, A-88; Reaffirmed: Sunset Report, I-98)
Whereas, HIPAA regulations require that an individual may have access to their own medical records; and

Whereas, Physicians have specialized skills and interests in reviewing medical records; and

Whereas, The electronic medical record is merely an extension of the current medical records kept today for which confidentiality is paramount; and

Whereas, Some hospital entities have made it a specific violation for an individual, including a physician, to review their own record for any purpose; therefore be it

RESOLVED, That our American Medical Association reiterate its support of patients’ rights to review their own medical records and oppose any efforts to restrict those reviews (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for the right of physicians to review any medical record pursuant to a written or verbal request from the patient, or if a minor, by the authorized guardian (Directive to Take Action); and be it further

RESOLVED, That clarification be requested from the Centers for Medicare & Medicaid Services concerning the rights of patients to examine their own medical records under the Health Insurance Portability and Accountability Act (HIPAA). (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $1,900.

Received: 04/22/09

H-315.997 Patients' Access to Information Contained in Medical Records
Allowing patients access to information in their medical records will have, on the whole, a favorable impact on patient care and physician-patient relationships, provided that appropriate safeguards are incorporated in the enabling legislation enacted by states. (CMS Rep. I, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00)

H-140.989 Informed Consent and Decision-Making in Health Care
(1) Health care professionals should inform patients or their surrogates of their clinical impression or diagnosis; alternative treatments and consequences of treatments, including the consequence of no
treatment; and recommendations for treatment. Full disclosure is appropriate in all cases, except in rare situations in which such information would, in the opinion of the health care professional, cause serious harm to the patient. (2) Individuals should, at their own option, provide instructions regarding their wishes in the event of their incapacity. Individuals may also wish to designate a surrogate decision-maker. When a patient is incapable of making health care decisions, such decisions should be made by a surrogate acting pursuant to the previously expressed wishes of the patient, and when such wishes are not known or ascertainable, the surrogate should act in the best interests of the patient. (3) A patient's health record should include sufficient information for another health care professional to assess previous treatment, to ensure continuity of care, and to avoid unnecessary or inappropriate tests or therapy. (4) Conflicts between a patient's right to privacy and a third party's need to know should be resolved in favor of patient privacy, except where that would result in serious health hazard or harm to the patient or others. (5) Holders of health record information should be held responsible for reasonable security measures through their respective licensing laws. Third parties that are granted access to patient health care information should be held responsible for reasonable security measures and should be subject to sanctions when confidentiality is breached. (6) A patient should have access to the information in his or her health record, except for that information which, in the opinion of the health care professional, would cause harm to the patient or to other people. (7) Disclosures of health information about a patient to a third party may only be made upon consent by the patient or the patient's lawfully authorized nominee, except in those cases in which the third party has a legal or predetermined right to gain access to such information. (BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: Res. 408, A-02; Reaffirmed: BOT Rep. 19, I-06; Reaffirmation A-07)
Whereas, Hospital overhead emergency codes are not uniform across the country; and
Whereas, Physicians and other medical personnel train and work at more than one location; and
Whereas, Confusion exists regarding the meanings of these codes; therefore be it
RESOLVED, That our American Medical Association facilitate the adoption of a uniform system of hospital overhead codes (perhaps the one recommended by the American Hospital Association in 2002) (Directive to Take Action); and be it further
RESOLVED, That our AMA members suggest to local hospitals that they adopt this uniform system (Directive to Take Action); and be it further
RESOLVED, That our members ask their local hospitals to educate doctors and other personnel regarding the new system. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/06/09

H-215.971 Standardization of Emergency Paging Nomenclature
Our AMA urges the development of standardized emergency paging nomenclature for hospitals. (Sub. Res. 805, A-00)
Whereas, The health care system in the United States is built primarily upon a system of third-party reimbursement for services rendered; and
Whereas, A significant percentage of Americans rely on health insurance for their health care needs; and
Whereas, These patients pay their premiums in a timely and contractual fashion; and
Whereas, Physicians and other providers of medical services enter into contractual arrangements with these third-party systems to provide services; and
Whereas, Physicians render services to patients as provided by the terms of these contracts; and
Whereas, If claims are not filed in a timely manner as defined by the contract, they are summarily dismissed by insurance companies; and
Whereas, There is a reasonable expectation among patients who pay the premiums and providers who render the services and file the claims that third-party payers will remit payments in a timely and contractual fashion; and
Whereas, Many third-party payers delay payments to providers for their own financial gain; and
Whereas, The insurance companies that unnecessarily delay payment are in breach of contract with both the patient and the providers; therefore be it

RESOLVED, That our American Medical Association, Congress and appropriate federal agencies support efforts to ensure that physicians and other providers receive payment from insurance companies in a timely fashion (Directive to Take Action); and be it further

RESOLVED, That our AMA ascertain that any legislative or regulatory solution shall ensure that principles of transparency and accountability are applied to the insurance industry. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $9,294.

Received: 05/01/09

H-190.991 Excessive Requests for Information from Insurance Carriers and Delays in Processing Insurance Claims
It is the policy of our AMA (1) to continue to oppose excessive and unnecessary requests for additional information and unexplained delays in processing and payment by third party insurance carriers where a completed standard claim form for reimbursement has been submitted, and (2) that state medical societies should pursue existingAMA model legislation to require the payment of claims with interest where clean claims are not paid on a timely basis. (Sub. Res. 69, A-91; Modified: Sunset Report, I-01; Reaffirmation I-04)

H-385.952 Appropriate Physician Reimbursement by Centers for Medicare & Medicaid Services
Our AMA: (1) opposes both CMS's and local carriers' efforts to reduce or deny physician payments for appropriate services; and (2) will work to assure that all evaluation and management services are appropriately reimbursed. (Res. 118, I-95; Reaffirmation A-00; Reaffirmation A-02; Reaffirmation A-06)

H-320.968 Approaches to Increase Payer Accountability
Our AMA supports the development of legislative initiatives to assure that payers provide their insureds with information enabling them to make informed decisions about choice of plan, and to assure that payers take responsibility when patients are harmed due to the administrative requirements of the plan. Such initiatives should provide for disclosure requirements, the conduct of review, and payer accountability. (1) Disclosure Requirements. Our AMA supports the development of model draft state and federal legislation to require disclosure in a clear and concise standard format by health benefit plans to prospective enrollees of information on (a) coverage provisions, benefits, and exclusions; (b) prior authorization or other review requirements, including claims review, which may affect the provision or coverage of services; (c) plan financial arrangements or contractual provisions that would limit the services offered, restrict referral or treatment options, or negatively affect the physician's fiduciary responsibility to his or her patient; (d) medical expense ratios; and (e) cost of health insurance policy premiums. (Ref. Cmt. G, Rec. 2, A-96; Reaffirmation A-97) (2) Conduct of Review. Our AMA supports the development of additional draft state and federal legislation to: (a) require private review entities and payers to disclose to physicians on request the screening criteria, weighting elements and computer algorithms utilized in the review process, and how they were developed; (b) require that any physician who recommends a denial as to the medical necessity of services on behalf of a review entity be of the same specialty as the practitioner who provided the services under review; (c) Require every organization that reviews or contracts for review of the medical necessity of services to establish a procedure whereby a physician claimant has an opportunity to appeal a claim denied for lack of medical necessity to a medical consultant or peer review group which is independent of the organization conducting or contracting for the initial review; (d) require that any physician who makes judgments or recommendations regarding the necessity or appropriateness of services or site of service be licensed to practice medicine in the same jurisdiction as the practitioner who is proposing the service or whose services are being reviewed; (e) require that review entities respond within two business days to patient or physician requests for prior authorization, and that they have personnel available by telephone the same business day who are qualified to respond to other concerns or questions regarding medical necessity of services, including determinations about the certification of continued length of stay; (f) require that any payer instituting prior authorization requirements as a condition for plan coverage provide enrollees subject to such requirements with consent forms for release of medical information for utilization review purposes, to be executed by the enrollee at the time services requiring such prior authorization are recommended or proposed by the physician; and (g) require that payers compensate physicians for those efforts involved in complying with utilization review requirements that are more costly, complex and time consuming than the completion of standard health insurance claim forms. Compensation should be provided in situations such as obtaining preadmission certification, second opinions on elective surgery, and certification for extended length of stay. (3) Accountability. Our AMA believes that draft federal and state legislation should also be developed to impose similar liability on health benefit plans for any harm to enrollees resulting from failure to disclose prior to enrollment the information on plan provisions and operation specified under Section 1 (a)-(d) above. (BOT Rep. M, I-90; Reaffirmed by Res. 716, A-95; Reaffirmed by CMS Rep. 4, A-95; Reaffirmation I-96; Reaffirmed: Rules and Cred. Cmt., I-97;
Reaffirmed: CMS Rep. 13, I-98; Reaffirmation I-98; Reaffirmation A-99; Reaffirmation I-99; Reaffirmation A-00; Reaffirmed in lieu of Res. 839, I-08)

**H-285.945 Establishment of Liability of Managed Care Organizations**
Our AMA supports changes in federal law to prohibit the exemption from liability of managed care organizations, including ERISA plans, for damages resulting from their policies, procedures, or administrative actions taken in relation to patient care. (Sub. Res. 220, I-97; Reaffirmation A-99; Reaffirmed: BOT Rep. 18, I-00)
Whereas, The practice of medicine includes the application of knowledge regarding clinical problems to
prescribe medications, therapies, tests and procedures for patients; and
Whereas, Physicians passing judgment on and certification of the appropriateness of prescribed studies
and treatments for patients assuming positions of authority and expertise; and
Whereas, The lack of timely review and discussion affect the outcome of treatment; and
Whereas, Therefore, interferences with timely interventions needed occur out of the control of the treating
physician due to delays caused by physicians serving as pre-certification and approval for tests and
procedures reviewers; therefore be it
RESOLVED, That our American Medical Association adopt and promote policy establishing:

1. That medical determinations of pre-certification/pre-authorization requests be conducted by
health plan physicians in the same medical specialty as the physician requesting such
determinations;
2. That pre-certification/pre-authorization denials or patient treatment decision modifications create
physician/patient relationships incumbent with all the ethical and legal responsibilities and
consequences;
3. That physicians participating in pre-certification/pre-authorization decisions should have to
provide their name, address, specialty and training as well as medical license information to the
patient and requesting physician if a medical service is denied or modified as a result of such a
review; and
4. That insurance companies, workers’ compensation carriers, and the medical directors employed
or utilized by them be made aware of these principles. (New HOD Policy)

Fiscal Note: Implement accordingly at estimated staff cost of $1,914.

Received: 05/06/09

H-285.998 Managed Care
(1) Introduction The needs of patients are best served by free market competition and free choice by
physicians and patients between alternative delivery and financing systems, with the growth of each
system determined not by preferential regulation and subsidy, but by the number of persons who prefer
that mode of delivery or financing. (2) Definition "Managed care" is defined as those processes or techniques used by any entity that delivers, administers, and/or assumes risk for health care services in order to control or influence the quality, accessibility, utilization, or costs and prices or outcomes of such services provided to a defined enrollee population. (3) Techniques Managed care techniques currently employed include any or all of the following: (a) prior, concurrent, or retrospective review of the quality, medical necessity, and/or appropriateness of services or the site of services; (b) controlled access to and/or coordination of services by a case manager; (c) efforts to identify treatment alternatives and to modify benefits for patients with high cost conditions; (d) provision of services through a network of contracting providers, selected and deselected on the basis of standards related to cost-effectiveness, quality, geographic location, specialty, and/or other criteria; (e) enrollee financial incentives and disincentives to use such providers, or specific service sites; and (f) acceptance by participating providers of financial risk for some or all of the contractually obligated services, or of discounted fees. (4) Case Management Health plans using the preferred provider concept should not use coverage arrangements which impair the continuity of a patient's care across different treatment settings. With the increased specialization of modern health care, it is advantageous to have one individual with overall responsibility for coordinating the medical care of the patient. The physician is best suited by professional preparation to assume this leadership role. The primary goal of high-cost case management or benefits management programs should be to help to arrange for the services most appropriate to the patient's needs; cost containment is a legitimate but secondary objective. In developing an alternative treatment plan, the benefits manager should work closely with the patient, attending physician, and other relevant health professionals involved in the patient's care. Any health plan which makes available a benefits management program for individual patients should not make payment for services contingent upon a patient's participation in the program or upon adherence to treatment recommendations. (5) Utilization Review The medical protocols and review criteria used in any utilization review or utilization management program must be developed by physicians. Public and private payers should be required to disclose to physicians on request the screening and review criteria, weighting elements, and computer algorithms utilized in the review process, and how they were developed. A physician of the same specialty must be involved in any decision by a utilization management program to deny or reduce coverage for services based on questions of medical necessity. All health plans conducting utilization management or utilization review should establish an appeals process whereby physicians, other health care providers, and patients may challenge policies restricting access to specific services and decisions to deny coverage for services, and have the right to review of any coverage denial based on medical necessity by a physician independent of the health plan who is of the same specialty and has appropriate expertise and experience in the field. A physician whose services are being reviewed for medical necessity should be provided the identity of the reviewing physician on request. Any physician who makes judgments or recommendations regarding the necessity or appropriateness of services or site of services should be licensed to practice medicine and actively practicing in the same jurisdiction as the practitioner who is proposing or providing the reviewed service and should be professionally and individually accountable for his or her decisions. All health benefit plans should be required to clearly and understandably communicate to enrollees and prospective enrollees in a standard disclosure format those services which they will and will not cover and the extent of coverage for the former. The information disclosed should include the proportion of plan income devoted to utilization management, marketing, and other administrative costs, and the existence of any review requirements, financial arrangements or other restrictions that may limit services, referral or treatment options, or negatively affect the physician's fiduciary responsibility to his or her patients. It is the responsibility of the patient and his or her health benefits plan to inform the treating physician of any coverage restrictions imposed by the plan. All health plans utilizing managed care techniques should be subject to legal action for any harm incurred by the patient resulting from application of such techniques. Such plans should also be subject to legal action for any harm to enrollees resulting from failure to disclose prior to enrollment any coverage provisions; review requirements; financial arrangements; or other restrictions that may limit services, referral, or treatment options, or negatively affect the physician's fiduciary responsibility to his or her patient. When inordinate amounts of time or effort are involved in providing case management services required by a third party payer which entail coordinating access to other health care services needed by the patient, or in complying with utilization review requirements, the physician may
charge the payer or the patient for the reasonable cost incurred. "Inordinate" efforts are defined as those "more costly, complex and time-consuming than the completion of standard health insurance claim forms, such as obtaining preadmission certification, second opinions on elective surgery, certification for extended length of stay, and other authorizations as a condition of payer coverage." Any health plan or utilization management firm conducting a prior authorization program should act within two business days on any patient or physician request for prior authorization and respond within one business day to other questions regarding medical necessity of services. Any health plan requiring prior authorization for covered services should provide enrollees subject to such requirements with consent forms for release of medical information for utilization review purposes, to be executed by the enrollee at the time services requiring prior authorization are recommended by the physicians. In the absence of consistent and scientifically established evidence that preadmission review is cost-saving or beneficial to patients, the AMA strongly opposes the use of this process. (Joint CMS/CLRPD Rep. I-91; Reaffirmed: CMS Rep. I-93-5; Reaffirmed: Res. 716, A-95; Modified: CMS Rep. 3, I-96; Modified: CMS Rep. 4, I-96; Reaffirmation A-97; Reaffirmed: CMS Rep. 3, I-97; Reaffirmed: CMS Rep. 9, A-98; Reaffirmed: Sub. Res. 707, A-98; Reaffirmed: CMS Rep. 13, I-98; Reaffirmed: Res. 717, A-99; Reaffirmation A-00; Reaffirmation A-02; Reaffirmation I-04; Reaffirmed in lieu of Res. 839, I-08)

H-285.945 Establishment of Liability of Managed Care Organizations
Our AMA supports changes in federal law to prohibit the exemption from liability of managed care organizations, including ERISA plans, for damages resulting from their policies, procedures, or administrative actions taken in relation to patient care. (Sub. Res. 220, I-97; Reaffirmation A-99; Reaffirmed: BOT Rep. 18, I-00)

D-285.968 Health Insurance Code of Conduct
Our AMA will: 1. develop a Health Insurer "Code of Conduct" setting forth clear and concise principles addressing both medical care policies and payment issues; 2. seek concurrence among health insurers in complying with this "Code of Conduct;" 3. develop a mechanism to monitor compliance with this "Code of Conduct;" and 4. widely disseminate information regarding this "Code of Conduct," and health insurer compliance, to physicians and consumers. (Res. 823, I-08)
Whereas, Providing safe, effective, affordable and accessible health care for all citizens is the primary
goal of all AMA members; and

Whereas, Our AMA vigorously opposes governmental and private sector pay-for-performance programs
that do not follow the established AMA Guidelines; and

Whereas, Several insurance companies have started providing a grading/rating system for profiling
physicians; and

Whereas, Insurance companies publish this information on their web sites or they distribute it to their
insured so as to enable the insured to choose participating providers; and

Whereas, Insurance companies are aware of the AMA’s policy statement on Pay-for-Performance (AMA
Policy H-450.947), which states that programs should be designed to improve effectiveness and safety of
patient care; that they should be fair and ethical; and that they should be patient-centered and link
evidence-based performance measures; therefore be it

RESOLVED, That our American Medical Association reaffirm its “Guidelines for Pay-for-Performance
Programs,” which augment the AMA’s “Principles for Pay-for-Performance Programs” (Reaffirm HOD
Policy); and be it further

RESOLVED, That our AMA further evaluate this issue and create and support legislation as appropriate
so that insurance company grading/rating systems do not encourage deselecting of high-risk patients so as
to bolster their profiles and thus contribute to inaccessibility to care for these patients, and not encourage
deselecting of physicians. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated staff cost of $9,294.
Fair and ethical PFP programs are committed to improved patient care as their most important mission. Evidence-based quality of care measures, created by physicians across appropriate specialties, are the measures used in the programs. Variations in an individual patient care regimen are permitted based on a physician’s sound clinical judgment and should not adversely affect PFP program rewards. 2. Foster the patient/physician relationship - Fair and ethical PFP programs support the patient/physician relationship and overcome obstacles to physicians treating patients, regardless of patients’ health conditions, ethnicity, economic circumstances, demographics, or treatment compliance patterns. 3. Offer voluntary physician participation - Fair and ethical PFP programs offer voluntary physician participation, and do not undermine the economic viability of non-participating physician practices. These programs support participation by physicians in all practice settings by minimizing potential financial and technological barriers including costs of start-up. 4. Use accurate data and fair reporting - Fair and ethical PFP programs use accurate data and scientifically valid analytical methods. Physicians are allowed to review, comment and appeal results prior to the use of the results for programmatic reasons and any type of reporting. 5. Provide fair and equitable program incentives - Fair and ethical PFP programs provide new funds for positive incentives to physicians for their participation, progressive quality improvement, or attainment of goals within the program. The eligibility criteria for the incentives are fully explained to participating physicians. These programs support the goal of quality improvement across all participating physicians.

GUIDELINES FOR PAY-FOR-PERFORMANCE PROGRAMS

Safe, effective, and affordable health care for all Americans is the AMA’s goal for our health care delivery system. The AMA presents the following guidelines regarding the formation and implementation of fair and ethical pay-for-performance (PFP) programs. These guidelines augment the AMA’s "Principles for Pay-for-Performance Programs" and provide AMA leaders, staff and members with operational boundaries that can be used in an assessment of specific PFP programs.

Quality of Care

- The primary goal of any PFP program must be to promote quality patient care that is safe and effective across the health care delivery system, rather than to achieve monetary savings.
- Evidence-based quality of care measures must be the primary measures used in any program.
  1. All performance measures used in the program must be prospectively defined and developed collaboratively across physician specialties.
  2. Practicing physicians with expertise in the area of care in question must be integrally involved in the design, implementation, and evaluation of any program.
  3. All performance measures must be developed and maintained by appropriate professional organizations that periodically review and update these measures with evidence-based information in a process open to the medical profession.
  4. Performance measures should be scored against both absolute values and relative improvement in those values.
  5. Performance measures must be subject to the best-available risk- adjustment for patient demographics, severity of illness, and co-morbidities.
  6. Performance measures must be kept current and reflect changes in clinical practice. Except for evidence-based updates, program measures must be stable for two years.
  7. Performance measures must be selected for clinical areas that have significant promise for improvement.
- Physician adherence to PFP program requirements must conform with improved patient care quality and safety.
- Programs should allow for variance from specific performance measures that are in conflict with sound clinical judgment and, in so doing, require minimal, but appropriate, documentation.
- PFP programs must be able to demonstrate improved quality patient care that is safer and more effective as the result of program implementation.
- PFP programs help to ensure quality by encouraging collaborative efforts across all members of the health care team.
- Prior to implementation, pay-for-performance programs must be successfully pilot-tested for a sufficient duration to obtain valid data in a variety of practice settings and across all affected medical specialties. Pilot testing should also analyze for patient de-selection. If implemented, the program must be phased-in over an appropriate period of time to enable participation by any willing physician in affected specialties.
- Plans that sponsor PFP programs must prospectively explain these programs to the patients and communities covered by them.

Patient/Physician Relationship

- Programs must be designed to support the patient/physician relationship and recognize that physicians are ethically required to use sound medical judgment, holding the best interests of the patient as paramount.
- Programs must not create conditions that limit access to improved care.
  1. Programs must not directly or indirectly disadvantage patients from ethnic, cultural, and socio-economic groups, as well as those with specific medical conditions, or the physicians who serve these patients.
  2. Programs must neither directly nor indirectly disadvantage patients and their physicians, based on the setting where care is delivered or the location of populations served (such as inner city or rural areas).
- Programs must neither directly nor indirectly encourage patient de-selection.
- Programs must recognize outcome limitations caused by patient non-compliance, and sponsors of PFP programs should attempt to minimize non-compliance through plan design.

Physician Participation

- Physician participation in any PFP program must be completely voluntary.
- Sponsors of PFP programs must notify physicians of PFP program implementation and offer physicians the opportunity to opt in or out of the PFP program without affecting the existing or offered contract provisions from the sponsoring health plan or employer.
- Programs must be designed so that physician nonparticipation does not threaten the economic viability of physician practices.
- Programs should be available to any physicians and specialties who wish to participate and must not favor one specialty over another. Programs must be designed to encourage broad physician participation across all modes of practice.
- Programs must not favor physician practices by size (large, small, or solo) or by capabilities in information technology (IT).
  1. Programs should provide physicians with tools to facilitate participation.
  2. Programs should be designed to minimize financial and technological barriers to physician participation.
- Although some IT systems and software may facilitate improved patient management, programs must avoid implementation plans that require physician practices to purchase health-plan specific IT capabilities.
- Physician participation in a particular PFP program must not be linked to participation in other health plan or government programs.
- Programs must educate physicians about the potential risks and rewards inherent in program participation, and immediately notify participating physicians of newly identified risks and rewards.
- Physician participants must be notified in writing about any changes in program requirements and evaluation methods. Such changes must occur at most on an annual basis.

Physician Data and Reporting

- Patient privacy must be protected in all data collection, analysis, and reporting. Data collection must be administratively simple and consistent with the Health Insurance Portability and Accountability Act
- The quality of data collection and analysis must be scientifically valid. Collecting and reporting of data must be reliable and easy for physicians and should not create financial or other burdens on physicians and/or their practices. Audit systems should be designed to ensure the accuracy of data in a non-punitive manner.

1. Programs should use accurate administrative data and data abstracted from medical records.
2. Medical record data should be collected in a manner that is not burdensome and disruptive to physician practices.
3. Program results must be based on data collected over a significant period of time and relate care delivered (numerator) to a statistically valid population of patients in the denominator.

- Physicians must be reimbursed for any added administrative costs incurred as a result of collecting and reporting data to the program.

- Physicians should be assessed in groups and/or across health care systems, rather than individually, when feasible.

- Physicians must have the ability to review and comment on data and analysis used to construct any performance ratings prior to the use of such ratings to determine physician payment or for public reporting.

1. Physicians must be able to see preliminary ratings and be given the opportunity to adjust practice patterns over a reasonable period of time to more closely meet quality objectives.
2. Prior to release of any physician ratings, programs must have a mechanism for physicians to see and appeal their ratings in writing. If requested by the physician, physician comments must be included adjacent to any ratings.

- If PFP programs identify physicians with exceptional performance in providing effective and safe patient care, the reasons for such performance should be shared with physician program participants and widely promulgated.

- The results of PFP programs must not be used against physicians in health plan credentialing, licensure, and certification. Individual physician quality performance information and data must remain confidential and not subject to discovery in legal or other proceedings.

- PFP programs must have defined security measures to prevent the unauthorized release of physician ratings.

Program Rewards

- Programs must be based on rewards and not on penalties.
- Program incentives must be sufficient in scope to cover any additional work and practice expense incurred by physicians as a result of program participation.
- Programs must offer financial support to physician practices that implement IT systems or software that interact with aspects of the PFP program.
- Programs must finance bonus payments based on specified performance measures with supplemental funds.
- Programs must reward all physicians who actively participate in the program and who achieve pre-specified absolute program goals or demonstrate pre-specified relative improvement toward program goals.
- Programs must not reward physicians based on ranking compared with other physicians in the program.
- Programs must provide to all eligible physicians and practices a complete explanation of all program facets, to include the methods and performance measures used to determine incentive eligibility and incentive amounts, prior to program implementation.
- Programs must not financially penalize physicians based on factors outside of the physician’s control.
- Programs utilizing bonus payments must be designed to protect patient access and must not financially disadvantage physicians who serve minority or uninsured patients.

(2) Our AMA opposes private payer, Congressional, or Centers for Medicare and Medicaid Services pay-for-performance initiatives if they do not meet the AMA’s "Principles and Guidelines for Pay-for-Performance." (BOT Rep. 5, A-05; Reaffirmation A-06; Reaffirmed: Res. 210, A-06; Reaffirmed in lieu of Res. 215, A-06; Reaffirmed in lieu of Res. 226, A-06; Reaffirmation I-06; Reaffirmation A-07)
H-450.941 Pay-For-Performance, Physician Economic Profiling, and Tiered and Narrow Networks

1. Our AMA will collaborate with interested parties to develop quality initiatives that exclusively benefit patients, protect patient access, do not contain requirements that permit third party interference in the patient-physician relationship, and are consistent with AMA policy and Code of Medical Ethics, including Policy H-450.947, which establishes the AMA’s Principles and Guidelines for Pay-for-Performance and Policy H-406.994, which establishes principles for organizations to follow when developing physician profiles, and that our AMA actively oppose any pay-for-performance program that does not meet all the principles set forth in Policy H-450.947.

2. Our AMA strongly opposes the use of tiered and narrow physician networks that deny patient access to, or attempt to steer patients towards, certain physicians primarily based on cost of care factors.

3. Our AMA pledges an unshakable and uncompromising commitment to the welfare of our patients, the health of our nation and the primacy of the patient-physician relationship free from intrusion from third parties.

4. Because there are reports that pay-for-performance programs may pose more risks to patients than benefits, our AMA will prepare an annual report on the risks and benefits of pay-for-performance programs, in general and specifically the largest programs in the country including Medicare, for the House of Delegates over the next three years, beginning at the 2007 Interim Meeting. This report should clearly delineate between private pay-for-performance programs and voluntary public pay-for-reporting and other related quality initiatives.

5. Our AMA will continue to work with other medical and specialty associations to develop effective means of maintaining high quality medical care which may include physician accountability to robust, effective, fair peer review programs, and use of specialty-based clinical data registries.

6. As a step toward providing the Centers for Medicare and Medicaid Services (CMS) with data on special populations with higher health risk levels and developing variable incentives in achieving quality, our AMA will continue to work with CMS to encourage and support pilot projects, such as the Physician Quality Reporting Initiative (PQRI), by state and specialty medical societies that are developed collaboratively to demonstrate effective incentives for improving quality, cost-effectiveness, and appropriateness of care.

7. Our AMA will advocate that physicians be allowed to review and correct inaccuracies in their patient specific data well in advance of any public release, decreased payments, or forfeiture of opportunity for additional compensation. (BOT Rep. 18, A-07; Reaffirmed in lieu of Res. 729, A-08)
In the General Assembly  
State of  

An Act Relative to Physician Profiling Programs

Be it enacted by the People of the State of ______________, represented in the General Assembly:

Section 1. Title. This Act shall be known and may be cited as the "Act Relative to Physician Profiling Programs."

Section 2. Purpose. The Legislature hereby finds and declares that:

(a) Health plans are profiling their network physicians through the use of economic and quality criteria in order to measure physicians’ performance and monitor the cost of care;

(b) To ensure that consumers receive reliable and accurate information when making important health care decisions, health plans should rely primarily on quality measurements when developing physician profiling programs;

(c) In order to accurately measure physician performance, health plans should work with practicing physicians and relevant state and specialty medical societies in the development of such programs; and

(d) Health plans should disclose to patients and physicians the criteria used to evaluate physicians, and allow physicians to submit data and comments and seek due process prior to the implementation of the physician profiling program when they believe there are errors in their individual or group profiles.

Section 3. Definitions.

(a) “Economic criteria” are measures health plans use to determine physician resource utilization or costs of care for specified sets of health care services.

(b) A “physician profiling program” is a program that uses physician data in order to rate or rank physician quality or efficiency of care.

(c) “Quality criteria” are measures health plans use to determine physician quality of care.

Section 4. Requirements.
(a) Developing criteria – Any health plan that uses a physician profiling program shall collaborate with practicing physicians and state and specialty medical societies in developing the quality and economic criteria used to evaluate a physician’s performance.

(b) Quality criteria – Any health plan using criteria in its physician profiling program to evaluate a physician’s quality performance shall comply with the following requirements:

1) Use measures that are based on nationally-recognized evidence-based medical standards or consensus-based guidelines.
   A. Where available, these measures shall be endorsed by the National Quality Forum (“NQF”) or other entities whose work in the area of physician quality performance is generally accepted within the health care industry.
   B. Where NQF-endorsed measures are not available, these measures shall be endorsed by the Ambulatory Care Quality Alliance (“AQA”) and its accreditors.
   C. Professional certification or accreditation may be used in determining physician quality of care, but shall not be solely relied upon, as a determinant in evaluating physician quality.

2) Use a statistically valid number of disease state or specialty specific cases, subject to review and approval by the independent oversight entity, to produce accurate and reliable measurements.

3) Ensure that risk adjustment is used to account for the characteristics of a physician’s patient population, including case mix, severity of patients’ conditions, co-morbidities, outlier episodes and other factors, subject to review and approval by the independent oversight entity.

4) Determine which physician(s) shall be held reasonably accountable for a patient’s care, subject to review and approval by the independent oversight entity.

(c) Economic criteria – Any health plan using criteria in its physician profiling program to evaluate a physician’s cost-efficiency shall comply with the following requirements:

1) Use the most comprehensive episode of care software available, subject to review and approval by the independent oversight entity.

2) Compare physicians within the same specialty within the same geographical market.

3) Use a statistically valid number of patient episodes of care, subject to review and approval by the independent oversight entity, to produce accurate and reliable measurements of a physician’s cost-efficiency.

4) Ensure that risk adjustment is used to account for the characteristics of a physician’s patient population, including case mix, severity of patients’ conditions, co-morbidities, outlier episodes and other factors, subject to review and approval by the independent oversight entity.

5) Determine the rules for attribution for cost-efficiency, subject to review and approval of the independent oversight entity.

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Advocacy Resource Center
November 2007
(d) Data accuracy – Any health plan using data collection in its physician profiling program shall ensure that the data it relies upon is accurate, including a consideration of whether medical record verification is appropriate and necessary, subject to the review and approval of the independent oversight authority.

(e) Disclosure to Patients – Any health plan with a physician profiling program shall conspicuously disclose to patients the following information on its website and in other relevant plan materials:

1) The location of physician performance ratings in the health plan’s materials or on its website;
2) Information explaining the physician rating system, including the basis upon which physician performance is measured;
3) Limitations of the data used to measure physician performance;
4) How the health plan selects physicians for inclusion into or exclusion from its network;
5) The quality and economic criteria used in its current rating system, including the measurements for each criteria and its relative weight in the overall evaluation;
6) A conspicuous written disclaimer explaining the following:
   A. Physician performance ratings should only be used as a guide to choosing a physician,
   B. Consumers should consult their existing physicians before making a health care decision based on the rating, and
   C. Ratings have a risk of error and should not be used as the sole basis for selecting a doctor.
7) How the patient may contact the independent oversight entity to register complaints about the system.

(f) Disclosure to Physicians – any health plan with a physician profiling program shall comply with the following requirements:

1) Disclose the methodologies, criteria, data, and analysis used to evaluate physicians’ quality performance and cost-efficiency rating.
2) Create and share with physicians their profile at least 60 days prior to using or publicly disclosing the results of the physician profiling program.
3) Provide physicians with the opportunity to correct errors, submit additional information for consideration, and seek review of data and performance ratings.
4) Provide physicians with the following due process appeal rights to challenge the profiling determination, which shall be completed within 45 days:
   A. The opportunity to submit a written appeal;
   B. Pending the results of the appeal, the suspension of the quality and cost-efficiency rating when a timely appeal is made; and
   C. The opportunity for review by the independent oversight entity to assess the appeal decision.
(g) Oversight – any health plan with a physician profiling program shall comply with the following requirements relating to the independent oversight entity:

1) State and specialty medical societies shall be allowed to provide input into the selection of a qualified, independent oversight entity, subject to the approval of the [STATE AGENCY].

2) The selected independent oversight entity is responsible the following:
   A. Resolving patient and physician complaints;
   B. Overseeing the physician appeals process;
   C. Monitoring the health plan’s compliance with terms and conditions set forth in this Act; and
   D. Reporting and making recommendations to [STATE AGENCY] as they relate to this Act.

(h) Fines – Where it is established that a health plan willfully and knowingly refused to completely disclose the profiling data or methodology to a physician within 60 days of implementation of the program, or published to a third party a false or misleading designation, the [STATE AGENCY] shall impose a fine of $500 for each day that it failed to disclose information and/or $500 for the representation made to each person or entity to which the false or misleading designation is published.

(i) Private Right of Action – Nothing in this Act prohibits or limits any claim or action for a claim that the claimant has against the covered entity.

Section 5. Effective Date. This Act shall become effective immediately upon being enacted into law.

Section 6. Severability. If any provision of this Act is held by a court to be invalid, such invalidity shall not affect the remaining provisions of this Act, and to this end the provisions of this Act are hereby declared severable.
Whereas, Physicians have become disenchanted with hospital self-governance because they sense that their participation is ignored; and

Whereas, Many active medical staffs lack democratic procedures that would enable them to participate in the governance of their hospitals; and

Whereas, Hospitals have usurped greater autonomy by virtue of increased numbers of employed physicians and often exercise unchallenged control of patient care; and

Whereas, Many physicians who protest on behalf of the needs of their patients find themselves vilified and the subject of their hospital’s peer review process is often without due process and protection; and

Whereas, Approval of and alternations to hospital bylaws are made by a small number of select, hospital-sanctioned physicians and are often ratified without full disclosure or the approval of the majority of the active medical staff; and

Whereas, Nominations and election of Medical Staff Officers are frequently done by a select few without the full approval of the active medical staff; and

Whereas, MS 1.20, an initiative that recognized that patient care was enhanced by full participation of the medical staff and hospital administration, and was never implemented by the Joint Commission; therefore be it

RESOLVED, That our American Medical Association encourage The Joint Commission to mandate that medical staff officers be elected by majority vote in a confidential ballot (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage The Joint Commission to mandate that medical staff bylaws and any alterations, additions or deletions, be approved by a majority vote in a confidential ballot (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage The Joint Commission to mandate that voting be conducted by the medical staff, free of interference of the hospital administration, subject to review by a teller’s committee selected by the majority of active medical staff members. (Directive to Take Action)

Fiscal Note: Staff cost estimated at less than $500 to implement.

Received: 05/14/09

H-225.957 Principles for Strengthening the Physician-Hospital Relationship
The following twelve principles are AMA policy: PRINCIPLES FOR STRENGTHENING THE PHYSICIAN-HOSPITAL RELATIONSHIP … 2. The organized medical staff, a self-governing organization of professionals, possessing special expertise, knowledge and training, discharges certain inherent professional responsibilities by virtue of its authority to regulate the professional practice and standards of its members, and assumes primary responsibility for many functions, including but not limited to: the determination of organized medical staff membership; performance of credentialing, privileging and other peer review; and timely oversight of clinical quality and patient safety. … 5. The organized medical staff bylaws are a binding, mutually enforceable agreement between the organized medical staff and the hospital governing body. The organized medical staff and hospital bylaws, rules and regulations should be aligned, current with all applicable law and accreditation body requirements and not conflict with one another. The hospital bylaws, policies and other governing documents do not conflict with the organized medical staff bylaws, rules, regulations and policies, nor with the organized medical staff’s autonomy and authority to self govern, as that authority is set forth in the governing documents of the organized medical staff. The organized medical staff, and the hospital governing body/administration, shall, respectively, comply with the bylaws, rules, regulations, policies and procedures of one another. Neither party is authorized to, nor shall unilaterally amend the bylaws, rules, regulations, policies or procedures of the other. 6. The organized medical staff has inherent rights of self governance, which include but are not limited to: a) Initiating, developing and adopting organized medical staff bylaws, rules and regulations, and amendments thereto, subject to the approval of the hospital governing body, which approval shall not be unreasonably withheld. The organized medical staff bylaws shall be adopted or amended only by a vote of the voting membership of the organized medical staff. … d) Identifying a fair hearing and appeals process, including that hearing committees shall be composed of peers, and identifying the composition of an impartial appeals committee. These processes, contained within the organized medical staff bylaws, are adopted by the organized medical staff and approved by the hospital governing board, which approval cannot be unreasonably withheld nor unilaterally amended or altered by the hospital governing board or administration. The voting members of the organized medical staff decide any proposed changes. e) Establishing within the medical staff bylaws: 1) the qualifications for holding office, 2) the procedures for electing and removing its organized medical staff officers and all organized medical staff members elected to serve as voting members of the Medical Executive Committee, and 3) the qualifications for election and/or appointment to committees, department and other leadership positions. … k) Identifying within the organized medical staff bylaws a process for election and removal of elected Medical Executive Committee members. 1) Defining within the organized medical staff bylaws the election process and the qualifications, roles and responsibilities of clinical department chairs. The Medical Executive Committee must appoint any clinical chair that is not otherwise elected by the vote of the general medical staff. … 7. Organized medical staff bylaws are a binding, mutually enforceable agreement between the organized medical staff and the hospital governing body, as well as between those two entities and the individual members of the organized medical staff. 9. The organized medical staff has elected appropriate medical staff member representation to attend hospital governing board meetings, with rights of voice and vote, to ensure appropriate organized medical staff input into hospital governance. These members should be elected only after full disclosure to the medical staff of any personal and financial interests that may have a bearing on their representation of the medical staff at such meetings. The members of the organized medical staff define the process of election and removal of these representatives. … (Res. 828, I-07)
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 733
(A-09)

Introduced by: New York Delegation

Subject: Medical Smart Cards

Referred to: Reference Committee G
(J. Leonard Lichtenfeld, MD, Chair)

Whereas, A smart card is a plastic card in which an integrated circuit, or programmable computer chip, is embedded that enables the card to store and transmit clinical information, insurance coverage and biographical information specific to the cardholder; and

Whereas, Medical smart cards represent an excellent solution for Health Insurance Portability and Accountability Act (HIPAA) compliance and support new applications that improve medical care; and

Whereas, Smart cards have a unique ability to make information access easier for users while at the same time enforcing the more robust security policies required to health care organizations to bring their environments into HIPAA compliance; and

Whereas, In addition to being an instrumental component of a system that is designed to ensure compliance with HIPAA regulations, medical smart cards can also support new applications that deliver clinical and administrative benefits for physicians and other healthcare providers; and

Whereas, Smart cards offer major advantages to the health care system, the physician and the patients with their robust security, increased storage capacity, flexibility and intelligence in transaction processing and their ability to support multiple applications and multiple functions; and

Whereas, Physicians should drive the process of determining what information is appropriate to include on these cards, and the goal to make them as universally-accepted as possible; and

Whereas, Medical smart cards are in wide use throughout Europe, the Middle East and Africa, where government-sponsored social service and health insurance programs have underwritten a large part of the cost of introducing this technology on a national scale. In addition, medical smart cards are an emerging technology throughout the United States; and

Whereas, One outgrowth of interest in the use of smart cards is that health care organizations are beginning to invest in regional health information organizations (RHIOs). RHIOs enable hospital and outpatient allied participating entities to share medical record information when necessary; and

Whereas, Although health information cards are still an emerging technology in the healthcare market, the ability of consumers to carry around a personal health record is catching on, as companies like Google and Microsoft are entering the smart card field and have started to offer different products to consumers; therefore be it
RESOLVED, That our American Medical Association study and develop a “white paper” on the issue of medical smart cards and aligned technology, including the role of organized medicine in smart card development, the emergence of regional health information organizations (RHIOs), the opportunity for state and specialty societies to obtain grants to educate and inform members of opportunities in this and similar emerging technology and to enumerate the implications which these technologies have for physicians, patients and healthcare, in general. (Directive to Take Action)

Fiscal Note: Implement accordingly at estimated cost of $9,825.

Received: 05/14/09

D-185.999 Information Included On Health Insurance Identification Cards
Our AMA will continue to work with payers, the federal and state governments, and standards organizations to adopt and implement appropriate policies, technologies (e.g., smart cards, telephone hot lines, electronic data interchange, and website access), and national technology standards to provide physicians with accurate and real time verification of patient eligibility, co-payment due, deductible payable information, and claims processing. (Sub. Res. 828, A-99; Modified: Sub. Res. 713, A-08)
Health Identification Card Implementation Guide

This implementation guide specifies WEDI Health Identification Card Implementation of the American National Standard, Identification Cards—Health Care Identification Cards, INCITS 284 as revised. INCITS is accredited by ANSI.

~ Version 1.0 ~
~ November 30, 2007 ~

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Health Identification Card Implementation Guide

1.0 PURPOSE, SCOPE, IMPLEMENTATION STRATEGY, GENERAL INFORMATION

1.1 Purpose of This Implementation Guide

The intent of this implementation guide is to enable automated and interoperable identification using standardized health identification cards. The guide standardizes present practice and brings uniformity of information, appearance, and technology to the over 100 million cards now issued by health care providers, health plans, government programs, and others.

A card serves as an access key to obtain information and initiate transactions. It is used by a consumer to convey identification to providers or others. A card may convey patient identifiers to providers. It may convey insurance identifiers for multiple benefits involving different administrators on a single card. It may combine bank and health ID cards.

1.2 The Underlying ANSI Standard

This implementation guide specifies the WEDI Health Identification Card implementation of the American National Standard, Identification Cards—Health Care Identification Cards, INCITS 284 as revised. INCITS is accredited by ANSI. The standard is an application of International card standards (ISO Standards) to health care applications in the United States.

1.3 Scope of This Implementation Guide Is Identification

The scope of this Implementation Guide is to convey identification. It is an access key for obtaining information and enabling transactions. For example, although the card may facilitate access to a medical record, the guide does not specify the data content from that record. It does not specify diagnostic, prescriptive, encounter, bio-security, non-identifying demographic, or other data about the cardholder. It specifies identifiers, and it permits other information.

1.4 Types of Health Identification Cards (Examples only, not specifications)

Example of Provider-Issued Repeat Admission Card

Example of Health & Drug Multi-Benefit Card

Example of Combined Bank & Insurance Card

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1 Definition: an Implementation Guide applies a standard to specific uses. A standard frequently offers more capability than may be needed for the use. This Implementation Guide focuses the health ID card standard to needs of health care providers and health plans or payers for identification. For example, a hospital may issue a card to identify a recurring patient. A plan may issue a card to identify an insurance plan and subscriber. A RHIO may issue a card to identify a patient's consolidated medical records.

2 Revision of INCITS 284 is expected 2nd or 3rd quarter 2008. This guide is premised on that revision.
This implementation guide specifies different types of health ID cards, including the following:

<table>
<thead>
<tr>
<th>Type of Card</th>
<th>Essential Required Information</th>
<th>Cardholder ID</th>
<th>Cardholder Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4.1 Provider-issued card for repeated admission or treatment.</td>
<td>Standard National Provider Identifier (NPI)*. Refer to 3.4.</td>
<td>Patient or Medical Record ID.</td>
<td>Name of Patient.</td>
</tr>
<tr>
<td>1.4.2 Health Benefit or Insurance ID card.</td>
<td>Standard PlanID* described in 3.4.</td>
<td>Subscriber ID or Member ID assigned by plan.</td>
<td>Name of Subscriber or Member; see 3.2.</td>
</tr>
<tr>
<td>1.4.3 Health ID &amp; Bank card.</td>
<td>Bank card with health ID card information added.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4.4 Other Health ID card.</td>
<td>Standard Trading4 Partner ID described in 3.4.</td>
<td>ID for person, record, or other object, assigned by issuer.</td>
<td>Name of cardholder, that is, person, record, or other object being identified.</td>
</tr>
<tr>
<td>1.4.5 Card Assigning ISO U.S. Healthcare ID such as for Atypical Provider</td>
<td>Standard ID for entity that is card issuer</td>
<td>Standard ID for cardholder such as an Atypical Provider</td>
<td>Name of cardholder such as an Atypical Provider</td>
</tr>
</tbody>
</table>

* This implementation guide specifies card issuer numbers to be ISO Standard U.S. Health Care Identifiers issued under authority of ISO Standard 7812. For example, the National Provider Identifier (NPI) is such a number. Refer to 3.4 for more complete description.

Illustrations are examples only. Illustrations in this implementation guide are examples of compliant cards. The guide’s requirements allow significant variation from these examples.

1.4.1 Provider-issued card for repeated admission or treatment (Refer to 3.0 and 8.0)

A typical provider-issued card is for identification of the patient who is admitted or treated repeatedly such as for rehabilitation or other treatment. On readmission, the patient presents the card so that completely accurate identification on the card allows the patient and provider to identify the patient’s medical records and to avoid a full admission process.

Essential information consists of (1) Patient Name, (2) Patient or Medical Record ID (either proprietary or standard), and (3) National Provider Identifier (NPI). Refer to 3.0 and 8.0.

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3 Essential Information is a defined term meaning Cardholder Name, Cardholder ID, and Card Issuer ID. Refer to 2.0.

4 A standard Trading Partner ID is an ISO Standard U.S. Healthcare Identifier for a clearinghouse, billing service, provider network, RHIO, public health reporting agency, or other entity that is not identified with an NPI or PlanID. Some health plans, while identified by PlanID, also use a Trading Partner ID to identify an EDI portal.
1.4.2 Health Benefit or Insurance Card (Refer to 3.0 and 5.0)

A health plan issues a health benefit ID card to a subscriber or a member, who presents the card to a health care provider to convey with accuracy and clarity the benefit identifying information that the provider needs in order to conduct transactions such as eligibility inquiry and claim submission. Refer to 3.0 and 5.0 for further detail.

Essential information consists of (1) Subscriber or Member Name, (2) Subscriber or Member ID, and (3) Standard Health Plan ID. Refer to 3.6 for placement options for essential information. The examples also illustrate some discretionary data elements in addition to the essential information.

1.4.3 Optional Health ID Card and Bank Card Combo (Refer to 3.0, 5.0, and 7.0)

This implementation guide permits, but does not require, a health identification card to be added on the same card to a standard credit or debit card. Essential information consists of standard bank card information plus health ID card information. The following is illustrative only. Refer to 3.0, 5.0, and 7.0 for detail.
1.4.4 Other Health ID Cards (Refer to 3.0 and 9.0)

Entities other than health care providers or health plans may issue health ID cards. For example, a Regional Health Information Organization (RHIO) may issue an ID card for access and maintenance of a patient’s consolidated medical records. Other examples include cards issued by health data banks, blood banks, American Red Cross, social services, and others. Essential information consists of (1) Patient Name, (2) Either proprietary or standard confidential patient record ID, (3) Standard card issuer ID such as a RHIO. The following is an example. Refer to 3.0 and 9.0 for detail.

**RHIO Logo & Name**

<table>
<thead>
<tr>
<th>Patient Record Identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issuer (80840)</td>
</tr>
<tr>
<td>9312 567 598</td>
</tr>
<tr>
<td>Patient ID</td>
</tr>
<tr>
<td>MRN 123456</td>
</tr>
<tr>
<td>Patient</td>
</tr>
<tr>
<td>SUSAN B JONES-SMITH</td>
</tr>
<tr>
<td>Date 11/14/1978</td>
</tr>
<tr>
<td>Issued 05/14/06</td>
</tr>
</tbody>
</table>

**RHIO Logo & Name**

<table>
<thead>
<tr>
<th>Confidential Patient ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
</tr>
<tr>
<td>SUSAN B JONES-SMITH</td>
</tr>
<tr>
<td>Confidential Patient ID</td>
</tr>
<tr>
<td>808400 123456 789012</td>
</tr>
<tr>
<td>Issuer (80840)</td>
</tr>
<tr>
<td>9312 567 598</td>
</tr>
<tr>
<td>Date 11/14/1978</td>
</tr>
<tr>
<td>Issued 05/14/06</td>
</tr>
</tbody>
</table>

Other Entity-Issued Card with a Proprietary Patient Record ID

1.4.5 Standard Health ID Card to Assign Standard Identifiers (Refer to 10.0)

When an ISO Standard U.S. Healthcare Identifier is issued to an entity, the most convenient means to convey this identifier may be an identification card. The following is an example in which a health plan arranges for a standard Atypical Provider Identifier (API) to be assigned to an Atypical Provider and a card to convey the API to that provider. Essential information consists of (1) Standard Card Issuer identifier of the entity arranging the assignment (e.g. the Medicaid state plan), (2) Standard ID being assigned to the Entity, and (3) the Entity Name. The card issuer is a health plan, provider, or other trading partner authorized to arrange assignment of standard IDs to Atypical Providers, bill reviewers, or others. Refer to 10.0.

**Logo of Plan Assigning APIs**

<table>
<thead>
<tr>
<th>Standard Atypical Provider ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use Your API Number on Healthcare Claims</td>
</tr>
<tr>
<td>Provider:</td>
</tr>
<tr>
<td>YELLOW CAB OF AUSTIN</td>
</tr>
<tr>
<td>Your API:</td>
</tr>
<tr>
<td>9312 567 598</td>
</tr>
<tr>
<td>(80840)</td>
</tr>
<tr>
<td>Issuer (80840)</td>
</tr>
<tr>
<td>9210 567 898</td>
</tr>
<tr>
<td>Issued 05/14/06</td>
</tr>
</tbody>
</table>

Card to Convey ISO Standard U.S. Healthcare Identifier
1.5 **Essential Information Common to All ID Cards**

Every ID card of any kind must convey two essential identifications:

1) **Card Issuer.** Identifies the authority or sponsor who is responsible for issuance of the card; in card language, this is called the *card issuer*. What is new for health cards, other than a BIN number identifying the benefit manager on drug benefit cards, is identifying the card issuer with a *standard ID* rather than text. This is the most important new element for standardization of a health ID card. Machine-readability requires it.

2) **Cardholder.** Identifies the person, family, record, bank account, or other object being identified; in card language, the object being identified is called the *cardholder*. The cardholder is identified with two data elements:
   
   - **Cardholder ID.** An identifier for the cardholder. This ID has meaning within the context of the card issuer.
   - **Cardholder Name.** The name for the cardholder. Must correspond to the Cardholder ID; both ID and Name must identify the same person or object.

Three examples showing card issuer and cardholder:

<table>
<thead>
<tr>
<th>Social Security Card</th>
<th>Bank Card</th>
<th>Minimum Health ID Card</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Social Security Card" /></td>
<td><img src="image" alt="Bank Card" /></td>
<td><img src="image" alt="Minimum Health ID Card" /></td>
</tr>
</tbody>
</table>

SSN Card Does Not Need Card Issuer ID

a) **Social Security Card.** A Social Security Card identifies the Social Security Administration with text and the person with an ID. But because SSN is so ubiquitous, a card issuer *identifier* for the Social Security Administration is not included nor warranted.

b) **Bank Card.** A bank card identifies both the bank and the account at the bank. The first six digits of the card number identify the bank using an ID assigned internationally under ISO Standard 7812, the same standard used for NPI and PlanID. Processing of bank cards is easily automated because the bank is identified by this ISO standard identifier.

c) **Health Identification Card.** Until now, health ID cards, other than drug benefit cards, identify the card issuer only with text, not with an identifier. As a result, processing of a health benefit ID card has required a person in the provider’s office to interpret the card, look up the health plan, and enter a code into the provider’s systems in order to instruct the provider’s systems who is the health plan and where to send transactions.

In this guide the Health Identification Card introduces a standard card issuer identifier, such as a NPI, PlanID, or trading partner identifier, which is assigned for U.S. health applications under authority of ISO Standard 7812.
1.6 Economic Benefits from a Machine-Readable Card with Standard Card Issuer ID

This section describes qualitative benefits that may be expected from machine-readable health identification cards as standardized in this implementation guide.

1) For providers. Machine-readable health identification cards (1) help to eliminate patient and insurance benefit identification errors, (2) reduce costs and aggravation of rejected claims, (3) reduce lengthy admission processes, and (4) contribute to smoother office procedures and patient satisfaction. (5) Significant reduction in claim errors will enhance provider relations with plans. (6) The costs of traditional photocopying the front and back of cards, manual lookup and key entry of card information, and filing paper copies can be eliminated over time. (7) When integrated with enhanced provider systems, machine-readable identification cards will facilitate immediate automatic transactions such as eligibility inquiries. (8) Even in phone conversations, the simplicity of needing only two identifiers aids both patient and provider to convey insurance benefit information or medical record identification quickly with complete accuracy.

2) For health plans and administrators. Patient and insurance benefit identification errors significantly increase processing and service costs for plans; they aggravate providers; and they contribute to member dissatisfaction. Elimination of patient identification errors will benefit health plans to: (1) improve subscriber or member satisfaction, (2) improve employer and plan sponsor satisfaction, (3) reduce cost to return and subsequently reconcile claims with errors, (4) reduce significantly the cost of both provider and member help desks and administrative record searches, and (5) improve plan-provider relations. (6) In addition, the universal health plan identifier conveyed by the card is one ingredient for improved coordination of benefits. (7) With multiple-benefit cards, administrators and medium sized payers are able more easily to provide a convenient range of benefit plans to meet the needs of employers.

3) For patients or consumers. (1) Elimination of patient and insurance identification errors significantly reduces the hassle factor and increases patient and subscriber satisfaction. (2) Consumers desire simplicity, and they want a single card for multiple benefits and functions. This implementation guide, using only two identifiers, enables multiple benefits on a single card. (3) Patients can more easily and accurately read the essential identifiers from a card to a provider over a telephone. (4) It also permits an option to combine an insurance card with a bank card on the same card.

4) For employers. (1) Employers desire to improve employer-employee satisfaction and reduce costs. Elimination of patient and insurance identification errors increases employee satisfaction with the company's benefit plans and reduces cost of helping employees resolve insurance benefit problems. (2) With a multiple-benefit card, employers are able more competitively to purchase multiple benefits using different administrators while presenting to an employee only a single, simple card.

5) For clearinghouses. (1) The standard health plan identifier conveyed by the card assists all-plan routing without requiring translation of trading-partner specific identifiers. (2) Reduction of errors will reduce expense and increase client satisfaction. (3) Multi-benefit cards enable clearinghouses to support increased value to providers.
1.7  Economic Strategy to Achieve Industry Implementation

In order for full value to be realized from cards specified in this implementation guide, three investments must be made:

1) For Card Issuers the investment is adoption of this implementation guide for cards when reissued, especially including the standard card issuer ID and machine-readable technology. A card issuer may need to issue standard cards in anticipation of future return. For a card issuer, the incremental investment at the time it is issuing cards anyway is only a marginal cost.

2) For Card Users the investment is primarily in the systems capability to process automatically the two identifiers on a standard card; so it is reasonable for a provider or other card user to desire a significant percentage of cards to be standard before justifying the investment. There are various potential levels of system capability that a provider may elect to install; for example:

   - The user may elect to defer any changes and operate the same as presently.
   - The user may use the two identifiers to populate Direct Data Entry screens.
   - The user’s system may accept and store the two identifiers for transactions.
   - The user’s system may machine-read the card information.
   - The user’s system may automatically generate standard transactions, such as eligibility inquiries and claims based on the two identifiers, which might be machine-read or entered manually (such as when received over the phone).

For a card user such as a provider, the investment in system enhancement may be significant such that, to be justified, there must be reasonably high frequency of use although a plan or other entity may elect to fund some of the user’s investment.

3) For Clearinghouses the investment is to use standard card issuer IDs and direct transactions to multiple payers and administrators.

When the card issuer is a provider, then the provider controls the environment for use of the cards and would determine ROI based on its own operations.

When the card issuer is a health plan or administrator, then:

   - Before providers implement machine-readability and integrate the card into their systems, providers and plan may obtain a good portion of the error reduction potential, realize more error-free telephone communication of identifiers between a consumer and provider, and be able to combine multiple benefits on a single card.

   - After providers implement machine-readability and integrate the card into their systems, the full return can be realized by plans, providers, employers, clearinghouses, and consumers described in 1.6.

   - The key to success is therefore for health plans, as cards are reissued, to adopt this implementation guide now—especially including the standard card issuer ID and machine-readability—to help build a large industry population of standard, machine-readable cards. Providers will enhance their systems to obtain the returns from card standardization as the population of standard cards increases.
1.8 Other Principles of this Implementation Guide

1) Simplicity and Permitting Maximum Card Issuer Discretion

The design philosophy of this implementation guide and the underlying standard is that only the most essential information and format should be required. It should require the least information necessary. In general, additional information is discretionary unless explicitly disallowed or discouraged. The simplicity design principle maximizes flexibility by maximizing card issuer options. The design philosophy's central premise is that a card issuer desires the best value for its card, and after meeting requirements, will effectively balance objectives of usefulness, simplicity, card life, and other factors. This guide encourages card issuers to accept the simplicity principle.

Important to simplicity for consumers, providers, plans, and other card users is uniformity and placement of information. For example, the two essential identifiers—card issuer and cardholder ID—should be adjacent to each other in predictable location as, for example, bank cards always place these two identifiers in the same location.

Simple Test of Simplicity. The simplicity test is the ease by which a consumer, coached by a provider over a telephone, is able easily and accurately to read the card’s printed information and convey the two essential identifiers and name to the provider.

2) Process Neutrality

The card should meet stakeholders’ needs. It should be neutral to the conduct of business. For example, it should permit but not require multi-functional cards. It should permit host and home plan structures, geographical or regional plan structures, provider networks, and any other such arrangement. It should support different types of benefit plans such as medical, dental, drug, vision, supplemental; and it should permit but not require combinations of benefit plans. It should have flexibility to permit new business structures and processes in the future, including potential financial transactions.

Its processes should be open, and supporting directories should be publicly accessible to responsible participants in healthcare electronic commerce.

3) Card Must be Effective for all User Environments

The card must work in all user environments regardless whether or not the user has system capability for machine readability.

4) This Implementation Guide and the Underlying Standard are Voluntary

The potential benefits to the health care industry—to patients, health care providers, and health plans—are very significant, especially from multiple functions, uniformity, efficiency, automation, and error elimination; however, implementation of this guide is voluntary.5

5 The authors recognize certain state regulations require the NCPDP Implementation Guide, which includes the underlying standard by reference, for prescription drug plan identification cards. Also, Medicare Part-D guidelines are based on the NCPDP implementation guide, this implementation guide, and the underlying standard. So it may happen that, while implementation of this implementation guide is voluntary, some states may decide to require all or part of it.
5) **Conformance**

A health identification card is in conformance with this Implementation Guide if it meets all requirements specified directly or by reference contained in this Implementation Guide and the underlying standard, INCITS 284 as revised. See 1.2. To this end, this implementation guide is designed to permit maximum user discretion within minimum requirements. Cards not conforming to all requirements are not in conformance.

6) **This Card is not a National Personal Identification Card**

This is not a national ID card. The individual, family, medical record, or other ID number on the card continues to be the same identifier that card issuers now put on their cards. Cardholder ID has meaning only in context with the card issuer identifier. This implementation guide does not require a national individual identifier.

7) **Limitations Imposed by this Implementation Guide**

The design philosophy in this implementation guide is to simplify; so this implementation guide requires a card to have only a single set of identifiers—one card issuer identifier, one cardholder identifier and name. With two exceptions described below, when a single card combines benefits, each benefit must employ the same set of identifiers (refer to Section 6.0 for exception for combined medical and drug benefit cards).

If the sets of identifiers for multiple benefits on a card cannot be the same for all benefits, this Implementation Guide requires the health plan to issue separate cards for each benefit plan, and it further recommends benefit plans explore means to employ only a single set of identifiers. This may be accomplished through coordination among the benefit plans to use the same identifiers, or through an electronic cross-walk or directory (refer to 3.4 and 5.3). Use of a single set of identifiers for a multi-benefit card conforms to the simplicity design principle that is central to the objectives of this guide.

However, there are two exceptions to the simplicity principle. A card may have additional identifiers in the following circumstances:

1. When a drug benefit card is combined on a single card with another benefit plan. Refer to Section 6 for specifications to align this guide with the NCPDP implementation guide.

2. When a commercial plan is combined on a single card with a Medicare plan, which employs a Medicare-assigned subscriber number for each member.

8) **Requirement for Machine-readability**

This implementation guide requires that a card include machine-readable technology, either 3-track magnetic stripe and/or PDF417 2-dimensional bar code, specified in 12.0 and 13.0.
9) Information and technology not Addressed in this Implementation Guide

In general, information and technology not addressed in this guide is additional to what is required and is at the discretion of the card issuer.

10) Information Sources Listed in Attachment A

Refer to Attachment A for sources of the INCITS 284 standard, other implementation guides, legacy formats, code values, and card issuer identifiers.
Project SwipeIT is an industry wide initiative launched by the Medical Group Management Association (MGMA) in January 2009 to advance the adoption of standardized patient health insurance identification (ID) cards containing machine-readable information. MGMA estimates that the health care industry wastes as much as $1 billion annually as a result of nonstandardized cards.

- Why are nonstandardized, nonmachine-readable cards so costly to the industry?
- Who benefits from standardized ID cards?
- Why is MGMA launching this campaign now?
- Are Medicare and Medicaid included in your initiative?
- What is the WEDI implementation guide for health insurance ID cards?
- Why haven’t health insurance ID card standards been widely accepted and implemented yet?
- Won’t it be costly for insurers to redesign and reissue cards to their beneficiaries?
- Why is Medicare/Medicaid not included in your initiative?
- You are asking stakeholders to pledge their support, but how will you ensure compliance?
- How much will adopting this technology cost your MGMA members?
- How does this initiative complement or contrast with the health system reform expected under the Obama administration?
- Are you calling for legislative action to standardize cards? When will standardized cards be fully implemented?
- Who needs to get involved and how can they take part in the project?
- Who can I contact for additional information?

Why are nonstandardized, nonmachine-readable cards so costly to the industry?

- Nonstandard appearance and content contribute to a higher error rate in manual transcription and entry of patient information. Many cards have photos, illustrations and dark colors that make accurate photocopying difficult.
- Lack of machine-readable data requires manual data entry with high labor cost and high potential for human error.
- Cost of making copies of patients’ ID cards (labor and materials).

All these factors lead to rework for providers and costly manual intervention for insurers.

Who benefits from standardized ID cards?

Everyone. Patients will have less hassle from denied claims. Providers will save money on labor and copying, and will get paid more quickly and accurately. Insurers will save by doing less manual work on rejected claims. Ultimately, employers should see savings from less growth in health care costs.

Why is MGMA launching this campaign now?

Because this is an area where a simple change can save immense amounts of money. Standards for patient health-insurance ID cards were developed in 1997, but have not yet been widely implemented.

Economic pressure – exacerbated by the nation’s credit crisis – squeezes our health care system to the breaking point. It’s time for the industry to look inward at the duplicative, wasteful and valueless processes that drive up health care costs for all stakeholders.

The time is very much past due. We are taking the lead to make it happen NOW.
Are Medicare and Medicaid included in your initiative?

Yes, absolutely. We have invited government insurers to be among the first to pledge to adopt standardized patient health-insurance ID cards.

What is the WEDI implementation guide for health insurance ID cards?

The Workgroup for Electronic Data Interchange (WEDI) developed an implementation guide to enable automated identification using standardized health-insurance ID cards. The guide standardizes present practices and brings uniformity of information, appearance and technology to the more than 100 million cards issued by health care providers, health plans, government programs and others.

Why haven’t health insurance ID card standards been widely accepted and implemented yet?

Primarily because of inertia. It is difficult for one insurer to make the change alone. The market requires a critical mass of companies to make it worthwhile for providers to use the new technology.

Won’t it be costly for insurers to redesign and reissue cards to their beneficiaries?

Estimates are that the cost of a WEDI-compliant, machine-readable card is 50 cents — only a fraction more than the nonstandardized, plastic or paper cards that most insurers use now. The savings that insurers will see from reduced claim denials, provider inquiries, re-work and labor will far exceed this cost.

You are asking stakeholders to pledge their support, but how will you ensure compliance?

In Phase 1 of the project, we are asking insurers to agree to issue WEDI-compliant, machine-readable cards by January 2010. In Phase 2, we will publicly recognize payers that have met their pledge and issued standardized, machine-readable health ID cards. We will publicly identify those that haven’t.

How much will adopting this technology cost your MGMA members?

A card reader costs less than $200. Practice management system (PMS) vendors tell us that connecting the reader to a PMS is a simple, inexpensive upgrade. We estimate that the current system costs providers as much as $1 billion in wasted administrative expenses each year. Eliminating that waste will make these small start-up costs pale in comparison.

How does this initiative complement or contrast with the health system reform expected under the Obama administration?

It is wholly consistent with the expected Obama effort to reduce administrative costs in our health care system. We’ve invited the secretary of the Department of Health and Human Services to take the lead by asking Medicare to be among the first to pledge to issue WEDI-compliant, machine-readable ID cards.

Are you calling for legislative action to standardize cards? When will standardized cards be fully implemented?
Some states have already mandated this change through legislation. We are urging the health insurance industry to adopt standardized cards voluntarily. We believe the logic is so compelling that legislation will not be required. However, if voluntary efforts don't succeed, legislation should be enacted to ensure that change occurs.

Who needs to get involved and how can they take part in the project?

Insurers, employers, practice management-system vendors, hospitals, medical practices, associations, medical societies and government should all be involved to ensure this effort succeeds.

- Insurers must pledge to issue new cards that are WEDI-compliant and machine-readable.
- PMS vendors must pledge to make inexpensive interfaces available between card readers and their PMS products.
- Employers – self-insured and fully insured – must demand that their health insurers or administrative services organizations issue WEDI-compliant, machine-readable cards.

Who can I contact for additional information?

MGMA is leading the charge for this effort. If you are an insurer, provider or vendor who wants to get involved, please e-mail us at swipeit@mgma.com.

Visit wesi.org for more information about the WEDI Implementation Guide.
In addition, the authors wish to credit many other individuals who worked to create the underlying standard in 1992-97, especially Tom Keane of Blue Cross Blue Shield of Florida, Joel Ackerman, the members of ASC INCITS B10, and Harvey Rosenfeld of ANSI.

### 14.3 Major Stakeholders Panel

The authors wish to credit the following individuals and organizations who contributed generously of their time and perspective as members of a special ad hoc panel of major stakeholders established to address data content, technology, financial card combination, and usage. Participation on the panel does not constitute endorsement of this guide.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Person</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Dental Association</td>
<td>David Preble, DDS</td>
<td><a href="mailto:prebled@ada.org">prebled@ada.org</a></td>
</tr>
<tr>
<td>American Express</td>
<td>Illene Dansie</td>
<td><a href="mailto:illene.j.dansie@aexp.com">illene.j.dansie@aexp.com</a></td>
</tr>
<tr>
<td>American Express</td>
<td>Sarah E. Harrison</td>
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</tr>
<tr>
<td>American Hospital Association</td>
<td>George Arges</td>
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<tr>
<td>American Medical Association</td>
<td>Cindy Penkala</td>
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<td>American Medical Association</td>
<td>Stephanie Stahl</td>
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<td>Availity</td>
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<td><a href="mailto:jduisberg@availity.com">jduisberg@availity.com</a></td>
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<td>Availity</td>
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</tr>
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<td>Blue Cross Blue Shield of North Carolina</td>
<td>Morgan Tackett</td>
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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 734
(A-09)

Introduced by: New York Delegation

Subject: National Practitioner Data Bank: Length of Time for Storing Medical Malpractice Data

Referred to: Reference Committee G
(J. Leonard Lichtenfeld, MD, Chair)

Whereas, The New York State Physician Profile lists all medical malpractice claims for a period of ten preceding years on its Website; and

Whereas, The New York State Office for Professional Medical Conduct lists all actions taken against a physician for a period of ten preceding years on its Website; and

Whereas, Likewise, credit bureau agencies have a time limit that issues remain on an individual’s credit report; and

Whereas, Likewise, the New York State Department of Motor Vehicles has a time limit for maintaining infractions on a driver license record; and

Whereas, The experience of practitioners increases over time, and the complexity of cases accepted by practitioners also changes over time; and

Whereas, Physicians may be discouraged from accepting patients with challenging complex medical issues in the climate of heightened medical malpractice concerns; and

Whereas, The National Practitioner Data Bank stores medical malpractice claims indefinitely with no time limit; and

Whereas, In some cases physicians may have settled claims that they may have won if the cases had gone to trial, yet settled claims appear in the National Practitioner Data Bank; therefore be it

RESOLVED, That our American Medical Association work with the National Practitioner Data Bank so that there is a time frame for storing all entries regarding physicians and that the time frame be limited to ten preceding years. (Directive to Take Action)

Fiscal Note:

Received: 05/14/09

H-355.999 Minimum Reporting Requirements to National Practitioner Data Bank
Our AMA believes that (1) the National Practitioner Data Bank requirements should be modified so that settlements and judgments of less than $30,000 are not reported or recorded; (2) reports, other than licensure revocation, in the Data Bank should be purged after five years; (3) proctoring of physicians for the purpose of investigation should not be reportable; (4) physicians should not be required to turn over copies of their Data Bank file to anyone not authorized direct access to the Data Bank; and (5) any
physician's statement included in the Data Bank file should automatically accompany any adverse report about that physician in distributions from the Data Bank. (Sub. Res. 80, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmation & Reaffirmed: Res. 216, A-01)

**H-355.995 National Practitioner Data Bank**

It is the policy of the AMA to (1) work with HHS to establish a mechanism to inform physicians when an inquiry to the Data Bank has been made; **(2) reaffirm its policy that reports, other than licensure revocation, in the Data Bank should be purged after five years;** and (3) support efforts to require the same Data Bank reporting requirements for physicians, dentists and other licensed health care practitioners. (Sub. Res. 41, I-90; Modified: Sunset Report, I-00)