

Reference Committee J

CMS Report(s)

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

Resolution(s)

- 801 Increasing Access to Medical Devices for Insulin-Dependent Diabetics
- 802 Eliminate "Fail First" Policy in Addiction Treatment
- 803 Reducing Perioperative Opioid Consumption
- 804 Parity in Reproductive Health Insurance Coverage for Same-Sex Couples
- 805 Health Insurance Companies Should Collect Deductible from Patients After Full Payments to Physicians
- 806 Pharmaceutical Industry Drug Pricing is a Public Health Emergency
- 807 Pharmacy Use of Medication Discontinuation Messaging Function
- 808 A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities
- 809 Addressing the Exploitation of Restricted Distribution Systems by Pharmaceutical Manufacturers
- 810 Medical Necessity of Breast Reconstruction and Reduction Surgeries
- 811 Opposition to CMS Mandating Treatment Expectations and Practicing Medicine
- 812 Enact Rules and Payment Mechanisms to Encourage Appropriate Hospice and Palliative Care Usage
- 813 Physician Payment for Information Technology Costs
- 814* Addressing Discriminatory Health Plan Exclusions or Problematic Benefit Substitutions for Essential Health Benefits Under the Affordable Care Act
- 815* Preservation of Physician-Patient Relationships and Promotion of Continuity of Patient Care
- 816* Support for Seamless Physician Continuity of Patient Care

* contained in Handbook Addendum

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-16

Subject: Infertility Benefits for Veterans
(Resolution 223-I-15)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 At the American Medical Association's (AMA) 2015 Interim Meeting, the House of Delegates
2 referred Resolution 223, "Infertility Benefits for Wounded Warriors," submitted by the Young
3 Physicians Section (YPS). The Board of Trustees referred this issue to the Council on Medical
4 Service for a report back to the House of Delegates at the 2016 Interim Meeting. Resolution
5 223-I-15 asked that our AMA:

6
7 (1) support lifting the congressional ban on the Department of Veterans Affairs (VA)
8 from covering in vitro fertilization (IVF) costs and (2) work with the American Society for
9 Reproductive Medicine (ASRM) and other interested organizations to encourage lifting the
10 congressional ban on the VA from covering IVF costs.

11
12 This report summarizes the increase in combat-related injuries that cause infertility; outlines
13 coverage of IVF benefits through the Department of Defense (DOD), the Veterans Health
14 Administration (VHA) and private health insurers; highlights the medical community's efforts to
15 provide IVF to veterans; summarizes AMA policy; discusses strategies to eliminate barriers to
16 accessing IVF for veterans; and presents policy recommendations.

17 18 BACKGROUND

19
20 Testimony on Resolution 223-I-15 expressed concern that there may be inconsistency in health
21 care coverage of IVF between TRICARE, the health care program through the DOD for active duty
22 service members, and the VHA, the health care program through the US Department of Veterans
23 Affairs for veterans. Testimony urged the AMA to address the lack of access to IVF for veterans,
24 review the categories of veterans who are entitled to IVF, consider advocating for parity between
25 private and VA health insurance coverage of IVF, and take into account the cost of such services.

26
27 The majority of active duty service members are of childbearing age. Approximately 65 percent of
28 enlisted personnel are younger than 30 years old and about 50 percent of all military officers are
29 between the ages of 26 and 35. About 50 percent of enlisted military members and 70 percent of all
30 officers are married. An estimated 84,000 marriages are unions between two members of the
31 military. Many service members and their partners make family planning decisions to
32 accommodate their military service duties.

1 COMBAT-RELATED INFERTILITY

2
3 Service members may be exposed to job-related risks that can result in injuries impacting their
4 fertility. In recent years, there has been an increased use of improvised explosive devices (IEDs),
5 which are homemade bombs that can be hidden on roads and walkways. A blast from an IED can
6 cause severe damage to the genitourinary system, which includes the kidneys, and reproductive and
7 urinary tract organs. Because of increased ground patrol in the Afghanistan War, the incidence of
8 service members sustaining genitourinary injuries is 350 percent higher than for those who served
9 in the Iraq War. Since 2001, IEDs have caused more US military casualties than traditional
10 weapons.

11
12 Gunshot wounds and exposure to hazardous materials are also common causes of infertility.
13 Approximately 1,400 service members returned from Iraq and Afghanistan with severe injuries to
14 their reproductive organs. It is estimated that thousands more sustained paralysis, brain injuries or
15 other conditions that make IVF their best option to conceive a child. Results from the National
16 Health Study for a New Generation of US Veterans indicated that about 16 percent of female
17 veterans and 14 percent of male veterans reported experiencing infertility.¹ According to the most
18 recent Centers for Disease Control and Prevention surveys, approximately 11 percent of female and
19 male civilians aged 15-44 experience infertility.^{2, 3}

20
21 ACCESS TO IN VITRO FERTILIZATION

22
23 *TRICARE*

24
25 Communication with the DOD's Defense Health Agency clarified that IVF is not included as a
26 TRICARE covered benefit for all active duty service members. By law TRICARE covers
27 medically necessary treatments and procedures that include infertility testing and correction of
28 physical causes of infertility. Assisted Reproductive Technologies (ART), such as IVF, are not
29 covered because they are not considered medically necessary treatments. However, section 1633 of
30 the National Defense Authorization Act for FY 2008 (HR 4986) allows for the provision of ART,
31 including IVF, for certain active duty service members. The limited IVF benefit was implemented
32 in 2012.

33
34 If health care providers who specialize in urogenital trauma and ART determine that a service
35 member and their spouse are good candidates for IVF they can request this benefit for their patients
36 who have sustained a serious or severe illness or injury while on active duty that led to the loss of
37 their natural procreative ability. To qualify as seriously ill or injured a service member must meet
38 the following criteria: (1) have a serious injury or illness; (2) be unlikely to return to duty within a
39 time specified by his or her military department; and (3) may be medically separated or retired
40 from the military. To qualify as severely ill or injured a service member must meet the following
41 criteria: (1) have a severe or catastrophic injury or illness; (2) be highly unlikely to return to duty;
42 and (3) will most likely be medically separated or retired from the military. By law, no other
43 TRICARE beneficiaries are eligible for this benefit.

44
45 Communication with the DOD's Defense Health Agency indicated that military providers are
46 aware of the DOD policy and make every effort to request the IVF benefit for those who qualify.
47 The most recent data available from the Office of the Secretary of Defense indicates that from
48 2012-2015, a total of 20 active duty service members met the criteria to receive the IVF benefit.
49 The DOD paid an average of \$5,000 for each IVF cycle.⁴ To date, a total of 26 service members
50 have qualified for the IVF benefit.

1 As part of the “Force of the Future” initiative, the DOD recently announced plans to implement a
2 two-year fertility preservation pilot program to provide sperm banking and egg freezing to active
3 duty service members.⁵ While the program is not available to current veterans, it is a proactive
4 approach to address potential infertility issues for active duty service members and future veterans.
5 The program will only cover fertility preservation, not the cost of IVF, which may pose a
6 significant financial barrier to the use of the benefit.

7

8 *Veterans Affairs*

9

10 The VA covers fertility assessments, counseling and some treatment, such as surgeries,
11 medications and intrauterine insemination, but has not been able to provide IVF benefits as
12 stipulated by the Veterans Health Care Act of 1992 (PL 102-585).⁶ When the law was enacted, IVF
13 was considered to be experimental, which is no longer the case. Providing IVF health care benefits
14 to veterans has been and still is controversial. Some individuals who are in the position to advocate
15 for changing the VA’s coverage policy on IVF are opposed to the treatment based on religious
16 grounds. However, in October 2016, the Military Construction, Veterans Affairs, and Related
17 Agencies Appropriations Bill for FY 2017 was signed into law, which allows the VA to cover IVF
18 costs for the next two years. While this is a step in the right direction, the legislation is temporary
19 and does not lift the ban on the VA from covering IVF.

20

21 Service members who complete a length of service in any branch of the armed forces are classified
22 as veterans as long as they were not dishonorably discharged. Retired veterans are service members
23 who remain on active duty or have served in the Army National Guard, Army Reserve, Navy
24 Reserve, Marine Corps Reserve, Air National Guard, Air Force Reserve or the Coast Guard
25 Reserve for a sufficient period of time, which is usually a minimum of 20 years. Veterans who are
26 not retired do not qualify for the TRICARE program, whereas retired veterans do qualify with the
27 stipulation that they are no longer eligible for the IVF benefit. Service members who become
28 disabled while on duty may be medically retired and receive a disability retirement before serving
29 20 years in the military. Most of the seriously or severely ill or injured service members are
30 medically retired before serving 20 years, receive the same benefits as other retirees, are eligible to
31 enroll in TRICARE and may qualify for IVF.

32

33 *Private Insurance*

34

35 The Affordable Care Act does not mandate coverage for infertility treatments as one of the 10
36 essential health benefits that must be included in all health plans sold through state health insurance
37 marketplaces. Most health insurance plans provide limited, if any, coverage for infertility
38 treatments according to the National Conference of State Legislatures. However, about a dozen
39 states have laws that require private insurers to cover infertility treatment, with eight of these states
40 having insurance mandates requiring qualified employers to include IVF coverage in the plans they
41 offer to their employees (AR, CT, HI, IL, MD, MA, NJ and RI).⁷ The infertility benefits these
42 states require from health insurers vary. Massachusetts requires insurance policies that provide
43 pregnancy-related benefits to also provide coverage for the diagnosis and treatment of infertility,
44 including IVF. Hawaii requires a one-time benefit for outpatient expenses related to IVF
45 procedures when a couple has a history of infertility for at least five years.^{8,9} In addition, the
46 federal government does not require coverage of infertility treatment for federally sponsored plans
47 through the Federal Employee Health Benefits Program.

1 MEDICAL ASSISTANCE FOR IN VITRO FERTILIZATION
2

3 In November 2015, the American Society for Reproductive Medicine (ASRM), along with the
4 Society for Assisted Reproductive Technology (SART), announced the "Serving Our Veterans"
5 program.¹⁰ Through the program, participating ASRM and SART members provide discounted IVF
6 treatments to veterans with service-related injuries that have caused infertility. The discount
7 amount is determined by each individual participating clinic, although ASRM and SART
8 recommend that each clinic follow the eligibility criteria established for active duty service
9 members by the DOD, which is a discount of at least 50 percent. In order to provide IVF treatments
10 to as many veterans as possible, the program allows for each clinic to cap the number of discounted
11 treatments it offers each individual. The program will expire when the ban on IVF is lifted or at the
12 end of the 2016 congressional calendar year.

13
14 RELEVANT AMA POLICY
15

16 AMA Policy H-185.990 encourages health insurers to provide benefits for the diagnosis and
17 treatment of male and female infertility; however, AMA Policy H-165.856 cautions that benefit
18 mandates should be minimized to allow markets to determine benefit packages and permit a wide
19 choice of coverage options. Consistent with the ASRM and SART "Serving Our Veterans"
20 program, AMA Policy H-510.986 urges all physicians to participate, when needed, in providing
21 health care to veterans. Policy further encourages state and local medical societies to create a
22 registry of physicians who are willing to provide health care to veterans in their community. The
23 AMA supports improved access to health care for veterans, including in the civilian sector, for
24 returning military personnel when their needs are not being met by locally available resources
25 through the DOD or the VA (Policies H-510.985, H-510.990, H-510.991 and D-510.994).

26
27 DISCUSSION
28

29 Proponents of lifting the congressional ban on the VA from covering IVF costs emphasize that the
30 VA provides comprehensive health care services for injuries sustained in the line of duty so that
31 veterans can live as normal of a life as possible. Veterans who have become infertile due to a
32 service-related injury may view access to IVF treatments as their only opportunity to conceive a
33 child, start a family and live a "normal life."

34
35 The Council notes that most private insurers do not offer IVF and state laws vary on whether
36 private health insurance companies must provide such coverage. Accordingly, due to the variation
37 in coverage of IVF among private health insurers, parity of IVF treatments between private and VA
38 health insurance is not recommended.

39
40 The Council believes that advocating for the VA to have the option to offer IVF is consistent with
41 AMA policy supporting access to health care for veterans while limiting benefit mandates. As
42 such, the Council suggests that our AMA support lifting the congressional ban on the VA from
43 covering IVF costs for veterans who have become infertile due to service-related injuries and
44 encourage interested stakeholders to collaborate in lifting the ban.

45
46 The potential for active duty service members to sustain injuries impacting their fertility has
47 increased in recent years and should be proactively addressed. The Council believes that service
48 members should be offered pre-deployment fertility counseling and information on the relevant
49 health care benefits provided through TRICARE and the VA before they are deployed and that the
50 same information be provided during the medical discharge process.

1 The DOD's new pilot program offering sperm freezing and egg harvesting to active duty service
2 members has been applauded by stakeholders as a step in the right direction to assist service
3 members with a fertility preservation option. The program was announced earlier this year, has yet
4 to be implemented and may have limited impact because it does not cover the cost of IVF.
5 Accordingly, the Council believes that the AMA should support efforts by the DOD and VA to
6 offer service members comprehensive health care services to preserve their ability to conceive a
7 child and offer treatment to address infertility due to service-related injuries.
8

9 **RECOMMENDATIONS**

10

11 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
12 223-I-15 and that the remainder of the report be filed:
13

14

- 15 1. That our American Medical Association (AMA) support lifting the congressional ban on the
16 Department of Veterans Affairs (VA) from covering in vitro fertilization (IVF) costs for
17 veterans who have become infertile due to service-related injuries. (New HOD Policy)
- 18 2. That our AMA encourage interested stakeholders to collaborate in lifting the congressional ban
19 on the VA from covering IVF costs for veterans who have become infertile due to service-
20 related injuries. (New HOD Policy)
- 21 3. That our AMA encourage the Department of Defense (DOD) to offer service members fertility
22 counseling and information on relevant health care benefits provided through TRICARE and
23 the VA at pre-deployment and during the medical discharge process. (New HOD Policy)
- 24 4. That our AMA support efforts by the DOD and VA to offer service members comprehensive
25 health care services to preserve their ability to conceive a child and provide treatment within
26 the standard of care to address infertility due to service-related injuries. (New HOD Policy)

27
28 Fiscal Note: Less than \$500.

REFERENCES

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³ Anjani Chandra, Casey Copen and Elizabeth Hervey Stephen. Centers for Disease Control and Prevention. National Center for Health Statistics Reports. Infertility and Impaired Fecundity in the United States, 1982-2010: Data From the National Survey of Family Growth. 2013. Available at: <http://www.cdc.gov/nchs/data/nhsr/nhsr067.pdf>

⁴ Report to Congress: Efforts to Treat Infertility of Military Families. Department of Defense. Office of the Secretary of Defense. December 2015. Available at: [file:///C:/Users/dberthma/Downloads/Report%20on%20Efforts%20to%20Treat%20Infertility%20of%20Military%20Families%20\(2\).pdf](file:///C:/Users/dberthma/Downloads/Report%20on%20Efforts%20to%20Treat%20Infertility%20of%20Military%20Families%20(2).pdf)

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⁸ National Conference of State Legislatures. State Laws Related to Insurance Coverage for infertility Treatment. 2014. Available at: <http://www.ncsl.org/research/health/insurance-coverage-for-infertility-laws.aspx>

⁹ Resolve: The National Infertility Association. Fast Facts about Infertility. 2015. Available at: <http://www.resolve.org/about/fast-facts-about-fertility.html>

¹⁰ American Society for Reproductive Medicine. Serving Our Veterans: Discounted Fertility Treatments for Wounded Warriors. 2015. Available at: https://www.asrm.org/IVF4VETS_Serving_Our_Veterans/

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-16

Subject: Health Care while Incarcerated
(Resolution 118-A-16)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 At the 2015 Interim Meeting, the House of Delegates adopted as amended Resolution 801 (Policy
2 D-430.994), which asked that the American Medical Association (AMA) study mental health and
3 health care for incarcerated juvenile and adult individuals and identify the best mental health and
4 health care models for local, state and federal facilities.

5
6 At the 2016 Annual Meeting, the House of Delegates referred Resolution 118, “Addressing the
7 Health and Health Care Access Issues of Incarcerated Individuals,” submitted by the Minority
8 Affairs Section. Resolution 118-A-16 asked that our AMA advocate for:

9
10 (1) an adequate number of health care providers to address the medical and mental health needs
11 of incarcerated individuals; and (2) an adequate number of primary care and mental health
12 personnel to provide adequate health care treatment to civilly committed (designated to
13 correctional institutions), incarcerated, or detained individuals; and (3) the reversal of the
14 “inmate exclusion clause” such that detainees and inmates who are eligible for state and
15 federally funded insurance programs in the community maintain their eligibility when they are
16 pre-trial, detained up to one year, and within one year of release to improve health outcomes in
17 this vulnerable population and decrease its burden of racial and ethnic health care disparities.
18

19 The Board of Trustees referred these items to the Council on Medical Service for a report back to
20 the House of Delegates at the 2016 Interim Meeting. This report provides background on the
21 criminal justice population; explains the role of the Affordable Care Act (ACA) Medicaid
22 expansion in accessing health care for the criminal justice population; highlights quality health care
23 and behavioral health care delivery models in the correctional system; summarizes AMA policy
24 and activity; discusses avenues to provide quality health care to the incarcerated population; and
25 presents policy recommendations.
26

27 BACKGROUND

28
29 Testimony on Resolution 118-A-16 urged the AMA to address barriers to health care access for the
30 incarcerated population and suggested that the requested study review the provision of behavioral
31 and physical health care throughout the full continuum of incarceration from intake to re-entry into
32 the community. Testimony also requested that the study address the training of correctional facility
33 staff on providing behavioral health care; the training of correctional facility staff on providing
34 prenatal care, delivery support and postpartum care; and the use and interoperability of electronic
35 health records (EHRs) in correctional facilities.

1 Approximately 2.3 million individuals are currently incarcerated, including 34,000 juveniles in the
2 juvenile justice system and 5,200 juveniles in adult prisons or jails.^{1, 2} An additional 4.7 million
3 individuals are on probation.³ The incarcerated population disproportionately consists of low-
4 income, uninsured, adult men of color.^{4, 5, 6} It is widely acknowledged that the incarcerated
5 population has a higher rate of chronic diseases, mental health conditions, substance use disorders
6 and contagious diseases than the general population.⁷ Juveniles may also have additional issues
7 impacting their health, such as more recent histories of physical abuse or assault, sexual abuse or
8 assault, victimization by sex trafficking, emotional abuse, neglect, domestic violence, traumatic
9 loss, community violence and school violence.⁸

10 In a 1976 landmark case, *Estelle v. Gamble*, the US Supreme Court established that the standard of
11 pleading required for a prisoner to assert a denial of access to health care constitutes “cruel and
12 unusual punishment,” which is in violation of the US Constitution.⁹ Nevertheless, not all
13 correctional systems comply with providing timely, comprehensive or high quality health care to
14 their inmates. Many studies analyzing health care provided in correctional institutions are limited
15 and outdated.

16
17 **AFFORDABLE CARE ACT MEDICAID EXPANSION**

18 Section 1905 of the Social Security Act prohibits the use of Medicaid funds for the cost of any
19 services provided to an “inmate of a public institution,” except when the individual is a “patient in
20 a medical institution.”^{10, 11} This policy is referred to as the “Medicaid Inmate Payment Exclusion.”
21 Given the historically low number of incarcerated individuals who qualified for Medicaid, some
22 states have not enrolled their inmates in the program.

23 The ACA has provided states with the opportunity to expand Medicaid eligibility to low-income
24 childless adults, which characterizes the majority of the incarcerated population. States that have
25 expanded Medicaid may now have the opportunity to enroll many of their inmates in Medicaid,
26 which pays for inpatient care if needed and may facilitate continuity of care upon release. Given
27 the increased number of inmates who could benefit from Medicaid coverage, many expansion
28 states are eager to enroll their detainees. However, some state laws prohibit the submission of
29 Medicaid applications during incarceration; whereas others permit submission, but no earlier than
30 30 days before release from custody.

31 An Illinois state law (HB 1046) was enacted in 2014 allowing individuals to apply for Medicaid
32 while incarcerated with coverage taking effect upon release. Cook County Jail in Chicago has
33 enrolled at least 11,000 inmates since the law went into effect. The state of New York has
34 submitted a waiver request to the Centers for Medicare & Medicaid Services (CMS) asking to use
35 Medicaid funding to pay for coordination of care services during the 30 days prior to an inmate’s
36 release. The status of the waiver is pending.

37 CMS has advised states to consider Medicaid as a valuable resource for their incarcerated
38 populations. In May 2004, CMS issued guidance to state Medicaid agencies to suspend, rather than
39 terminate, Medicaid enrollment when individuals become incarcerated in order to facilitate re-entry
40 into the community.¹² Not every state has followed this guidance, as the majority of states currently
41 terminate instead of suspend Medicaid eligibility upon intake into a correctional system.¹³

42 In April 2016, CMS issued a letter to state health officials providing guidance on facilitating
43 successful re-entry for individuals transitioning from incarceration into their communities.¹⁴ The
44 guidance specified that individuals on probation, parole or community release pending trial are

1 eligible for Medicaid as are individuals residing in corrections-related, supervised community
2 residential facilities.

3

4 **HEALTH CARE MODELS**

5

6 Policy D-430.994 requested that the AMA identify the best mental health and health care models
7 for local, state and federal correctional facilities. The National Commission on Correctional Health
8 Care (NCCHC) has developed standards for how health care services should be delivered in jails,
9 prisons, and juvenile facilities as well as for mental health services and opioid treatment programs.
10 Implementing the standards and becoming accredited ensures that systems, policies and procedures
11 are in place to provide quality delivery models for jails, prisons, and juvenile facilities as well as
12 for mental health services and opioid treatment programs. Following are examples of NCCHC
13 accredited health care delivery models on the local and federal levels.

14

15 *Local: Maricopa County Jail System, Phoenix, AZ*

16

17 Maricopa County Jail System received the NCCHC's "Facility of the Year" award in 2015 for its
18 efficiency, coordination, information-sharing and provision of quality team-based health care.
19 Inmates are considered patients and receive a comprehensive health screening during the intake
20 process to allow staff to provide continuity of care and make necessary referrals for mental health,
21 substance use or acute care services. Each of the six NCCHC accredited jails in the system include
22 an outpatient clinic staffed by board-certified physicians, psychiatrists and mental health
23 professionals providing medical care and mental health services. An EHR system facilitates
24 coordination of health care services. The correctional system provides classes for inmates on
25 substance use, mental health coping strategies, health care, education, parenting and transitioning
26 into the community.¹⁵ Assistance is provided with enrolling in health care coverage through
27 Medicaid or the federal marketplace.^{16, 17, 18}

28

29 *Federal: Federal Bureau of Prisons*

30

31 The Federal Bureau of Prisons (FBP) is the nation's largest correctional system with 121
32 institutions housing approximately 200,000 inmates. The FBP is overseen by a national health care
33 governing board and mental health clinical care committee and uses a primary care team-based
34 model to ensure continuity of health care. Comprehensive clinical practice guidelines have been
35 developed that define the scope of health care services for federal inmates, which the FBP has
36 published for other correctional systems to emulate.¹⁹ The FBP includes centers of excellence, a
37 system-wide infection control program, inmate access to organ transplants, a preventive health care
38 program, an EHR system, telehealth and telepsychiatry.²⁰

39

40 **BEHAVIORAL HEALTH CARE**

41

42 In the vast majority (44) of states, more seriously mentally ill individuals are incarcerated than are
43 receiving treatment in psychiatric hospitals.^{21, 22} The health care professionals and services
44 necessary to address these inmates' behavioral health care needs are often lacking with many
45 inmates not receiving adequate care. Cook County Jail in Chicago has developed a program to
46 provide quality behavioral health care to its inmates.

47

48 *Cook County Jail, Chicago, IL*

49

50 Chicago's Cook County Jail is often referred to as the nation's largest mental health facility with
51 approximately 30 percent of the 9,000 daily detainees having a serious mental health diagnosis.

1 The executive director of the jail is a clinical psychologist. The correctional facility includes a
2 mental health transition center that provides mental health care, psychoeducation, peer support and
3 re-entry services. Ongoing treatment at the center is available once an inmate is released.²³ The
4 Cook County Circuit Court has a countywide network of specialty courts that includes mental
5 health and drug treatment courts to assist individuals who have committed non-violent, nonsexual
6 felonies, and are more in need of health care treatment than incarceration. A team of professionals
7 coordinate efforts between members of the court system and outside organizations to guarantee that
8 participants receive intensive treatment, interventions and supervision. The program has succeeded
9 in significantly reducing its participants' recidivism rates.

10
11 **RELEVANT AMA POLICY**
12

13 Notably, Council on Science and Public Health Report 8-A-16, "Juvenile Justice System Reform,"
14 established Policy H-60.919, which comprehensively outlines ways to transform the juvenile
15 justice system to focus on preventing delinquency, rehabilitating justice-involved youth, providing
16 access to health care, ensuring a safe environment and prohibiting discrimination. Of note, Policy
17 H-60.919[7] encourages states to suspend rather than terminate Medicaid coverage following arrest
18 and detention.

19
20 AMA policy supports access to mental health services, including an adequate supply of
21 psychiatrists, appropriate payment for all services provided and adequate funding levels for public
22 sector mental health services (Policies H-345.981, D-345.997, D-345.998, H-345.976 and
23 H-345.980). AMA Policy H-345.981 further advocates that the diagnosis and treatment of mental
24 illnesses should be tailored to age, gender, race, culture and other characteristics that shape a
25 person's identity. The AMA encourages physicians to become more involved in pre-crisis
26 intervention, treatment and integration of chronic mentally ill patients into the community in order
27 to prevent unnecessary jail confinement (Policies H-345.995 and H-95.931).

28
29 The AMA urges state and local health departments to foster closer working relations between the
30 criminal justice, medical, and public health systems to ensure continuity of health care services
31 (Policies H-430.989 and H-60.919). The AMA believes that correctional and detention facilities
32 should provide medical, psychiatric and substance use treatment that meets prevailing community
33 standards, including appropriate referrals for ongoing care upon release from the correctional
34 facility in order to prevent recidivism (Policies H-430.997, H-430.987, H-430.988, H-440.931 and
35 H-430.994). The AMA advocates for the maintenance of essential mental health services at the
36 state level to identify and refer individuals with significant mental illnesses for treatment in order to
37 avoid repeated interactions with the law primarily as a result of untreated mental health conditions
38 (Policy H-345.975). The AMA supports the accreditation standards developed by the National
39 Commission on Correctional Health Care (NCCCHC) to improve the quality of physical and
40 behavioral health care services to the incarcerated population and encourages all correctional
41 systems to support NCCCHC accreditation (Policy D-430.997).

42
43 As outlined in Policy H-60.986, the AMA encourages state and county medical societies to become
44 involved in the provision of adolescent health care within correctional facilities and to work to
45 ensure that these facilities meet minimum national accreditation standards for health care as
46 established by the NCCCHC. The AMA opposes the use of solitary confinement in juvenile
47 correctional facilities (Policy H-60.922), advocates that juveniles receive comprehensive screening
48 and treatment for sexually transmitted infections and sexual abuse (Policy D-60.994), and that
49 safeguards be in place to protect prisoners from sexual misconduct and assault (Policy D-430.999).

1 A correctional facility should use the least restrictive restraints necessary for pregnant inmates. No
2 restraints of any kind should be used when an inmate is in labor, delivering her baby or
3 recuperating from the delivery unless the inmate poses a serious threat of harm to herself or others
4 and cannot be reasonably contained by other means (Policy H-420.957).

5
6 **AMA ACTIVITY**
7

8 The AMA, as a supporting organization of the NCCHC, has a physician member as a liaison to the
9 NCCHC. The NCCHC maintains standards on how to manage the delivery of behavioral and
10 physical health care in correctional systems. The standards are the foundation of NCCHCs
11 voluntary accreditation program for correctional facilities to demonstrate a commitment to
12 delivering high quality health care. The NCCHC also offers a correctional health professional
13 program, which certifies individuals working in the correctional system who demonstrate mastery
14 of national standards. Advanced certifications can be obtained by behavioral health practitioners,
15 physicians and registered nurses. In addition, the AMA has developed model state legislation
16 advocating for states to study the physical and mental health care needs of detained and
17 incarcerated youth, and prohibiting the shackling of pregnant prisoners.

18
19 **DISCUSSION**
20

21 The Council has highlighted local and federal examples of correctional systems that have been
22 accredited by the NCCHC to serve as models for other systems to emulate. The Council
23 recommends the reaffirmation of Policy D-430.997, which supports the accreditation standards
24 developed by the NCCHC to improve the quality of physical and behavioral health care services to
25 incarcerated individuals and encourages all correctional systems to support NCCHC accreditation.

26 The majority of individuals in the correctional system are low-income, uninsured and have multiple
27 health conditions. The Council believes that access to and continuity of care is a priority for this
28 population and recommends that our AMA advocate for adequate payment to health care providers,
29 including primary care and mental health professionals, to encourage improved access to
30 comprehensive physical and behavioral health care services to juveniles and adults throughout the
31 incarceration process from intake to re-entry into the community.

32 In order to facilitate continuity of care for individuals transitioning between the correctional system
33 and the community, the Council suggests that the AMA support partnerships and information
34 sharing between correctional systems, community health systems and state insurance programs to
35 provide access to a continuum of health care services for individuals in the correctional system. An
36 avenue to share information could be the implementation of EHRs in correctional facilities.

37 The majority of inmates struggle with mental health conditions and substance use disorders.^{24, 25}
38 Some may be incarcerated due to crimes committed because of their illnesses and are in need of
39 consistent health care rather than time in correctional facilities. Some may never have had health
40 care except for while they were incarcerated. The Council suggests that the AMA encourage state
41 Medicaid agencies to accept and process Medicaid applications from individuals who are
42 incarcerated. State Medicaid agencies should work with their local departments of corrections,
43 prisons, and jails to assist incarcerated individuals who may not have been enrolled in Medicaid at
44 the time of their incarceration to apply and receive an eligibility determination for Medicaid.

45
46 Resolution 118-A-16 requested that our AMA advocate for the reversal of the “Medicaid Inmate
47 Payment Exclusion” so that detainees can retain their Medicaid eligibility throughout the
48 incarceration process. The Council cautions that advocating for the elimination of the exclusion

1 necessitates the redistribution of Medicaid funding and could have unintended consequences
2 regarding the provision of care and payment to physicians. AMA Policy H-60.919[7] addresses
3 continuity of Medicaid eligibility by encouraging states to suspend rather than terminate Medicaid
4 coverage for juveniles following arrest and detention. Consistent with Policy H-60.919[7], which
5 was adopted at the 2016 Annual Meeting, the Council believes that Medicaid eligibility for both
6 juveniles and adults should be suspended rather than terminated during the entire incarceration
7 process and that coverage should be reinstated when the individual transitions back into the
8 community.

9
10 The Council recommends that Policy D-430.994 be rescinded, which requested the study that this
11 report has accomplished.

12
13 RECOMMENDATIONS

14
15 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
16 118-A-16 and that the remainder of the report be filed:

17
18 1. That our American Medical Association (AMA) reaffirm Policy D-430.997, which supports
19 the accreditation standards developed by the National Commission on Correctional Heath Care
20 (NCCHC) to improve the quality of physical and behavioral health care services to
21 incarcerated individuals and encourages all correctional systems to support NCCHC
22 accreditation. (Reaffirm HOD Policy)

23
24 2. That our AMA advocate for adequate payment to health care providers, including primary care
25 and mental health professionals, to encourage improved access to comprehensive physical and
26 behavioral health care services to juveniles and adults throughout the incarceration process
27 from intake to re-entry into the community. (New HOD Policy)

28
29 3. That our AMA support partnerships and information sharing between correctional systems,
30 community health systems and state insurance programs to provide access to a continuum of
31 health care services for individuals in the correctional system. (New HOD Policy)

32
33 4. That our AMA encourage state Medicaid agencies to accept and process Medicaid applications
34 from individuals who are incarcerated. (New HOD Policy)

35
36 5. That our AMA encourage state Medicaid agencies to work with their local departments of
37 corrections, prisons, and jails to assist incarcerated individuals who may not have been enrolled
38 in Medicaid at the time of their incarceration to apply and receive an eligibility determination
39 for Medicaid. (New HOD Policy)

40
41 6. That our AMA encourage states to suspend rather than terminate an individual's Medicaid
42 eligibility upon intake into the criminal justice system and throughout the incarceration
43 process, and to reinstate coverage when the individual transitions back into the community.
44 (New HOD Policy)

45
46 7. That our AMA rescind Policy D-430.994, which requested the study accomplished by this
47 report. (Rescind HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-16

Subject: Providers and the Annual Wellness Visit
(Resolution 824-I-15)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 At the American Medical Association's (AMA) 2015 Interim Meeting, the House of Delegates
2 referred Resolution 824, "Defining the Annual Wellness Visit as Provided by Community-Based
3 Primary Care Physicians." The Board of Trustees referred this issue to the Council on Medical Service
4 for a report back to the House at the 2016 Interim Meeting. Introduced by the Pennsylvania
5 Delegation, Resolution 824-I-15 asked:

6
7 That our AMA advocate for clear definition of the Centers for Medicare & Medicaid Services'
8 Medicare Annual Wellness Visit as one that is provided only by physicians or members of a
9 community-based, physician-led team that will provide continuity of care to those patients.

10 This report discusses the history and components of Medicare's Annual Wellness Visit (AWV),
11 including its purpose; explains the role of continuity of care in the AWV; outlines the role of
12 commercial entities; and recommends policy recognizing the importance of the physician-led health
13 care team and the promotion of continuity of care.

14 BACKGROUND

15 The Affordable Care Act expanded Medicare preventive services coverage and in particular created
16 the AWV as a new Medicare benefit. The AWV benefit is available to beneficiaries who have had
17 Medicare Part B for longer than 12 months and have not had an AWV in the last 12 months.¹

18 The purpose of the AWV is to develop or update a personalized prevention plan based on current
19 health and risk factors. It aims to keep Medicare beneficiaries healthy by promoting positive health
20 habits.² The AWV may include the following elements: review of medical and family history; a list of
21 current providers and prescriptions; height, weight, blood pressure, and other routine measurements; a
22 screening schedule for appropriate services; and a list of risk factors and treatment options. It is
23 important to note that the AWV was meant to provide more comprehensive preventive services to
24 Medicare beneficiaries but does not replace the annual physical, which is a more extensive
25 examination.³ Further, if a patient is experiencing physical symptoms or complaints, it is suggested
26 that a patient schedule a problem-oriented visit separate from the AWV. In addition, during both the
27 initial AWV and any subsequent visits, the health professional performing the visit is statutorily
28 required to establish and update a list of current providers and suppliers that are regularly involved in
29 providing medical care to the beneficiary.^{4, 5}

1 There is no deductible or copayment for the AWV.⁶ However, if during the AWV it is discovered that
2 a patient has a particular medical condition that requires further evaluation or treatment, pursuant to
3 Medicare rules, the additional time or treatment would be billed separately with Medicare paying 80
4 percent of the allowed charges and the patient paying the remaining 20 percent.

5
6 The relevant legislation and Centers for Medicare & Medicaid Services (CMS) regulations list who is
7 eligible to provide the AWV. The list of eligible providers includes: a physician; physician assistant,
8 nurse practitioner, or clinical nurse specialist; or a medical professional or a team of medical
9 professionals working under the supervision of a physician.^{7,8} Neither the legislation nor the
10 regulations expressly define a “medical professional” eligible for providing the AWV working under
11 the supervision of a physician or otherwise address the issue of physician-led team-based care.

12
13 CMS does not assign particular AWV tasks or restrictions for particular members of the team because
14 the concept of team-based care should enable the supervising physician to assign the professionals best
15 suited to provide a portion of the AWV based on individual patient needs.⁹ Physicians leading these
16 teams are empowered to determine the coordination of various team members during the AWV.

17 18 CONTINUITY OF CARE

19
20 Although the AWV is not a thorough preventive visit or examination, the AWV encourages Medicare
21 beneficiaries to engage with their primary care physician or usual source of care on an annual basis for
22 prevention and early detection of illness, the treatment of which that usual source of care could provide
23 or manage. The AWV facilitates an ongoing relationship between the provider of the AWV and the
24 beneficiary. Consistent with the tenets of continuity of care, the patient and physician are
25 cooperatively involved in ongoing health care management toward the goal of high quality and cost
26 effective care. Continuity of care is rooted in a long-term patient-provider partnership in which the
27 provider knows the patient’s history and can integrate new information, such as that obtained during
28 the AWV, and share in medical decision-making from a whole-patient perspective.

29 30 NON-PHYSICIAN COMMERCIAL ENTITIES PROVIDING THE ANNUAL WELLNESS VISIT

31
32 Non-physician commercial entities such as retail and mobile health clinics have entered the
33 marketplace to provide the AWV and bill the code to CMS, which potentially precludes the patient
34 from the benefits of the AWV with a regular source of care.¹⁰ These commercial entities often have no
35 prior relationship with the patient and have no intention of caring for the patient after the AWV.¹¹
36 Commercial encounters can therefore lead to fragmented and duplicative care if the information
37 gathered at the AWV is never communicated to the patient’s physician. Because of potentially
38 disjointed care, there is concern that these commercial entities are subverting the intended benefit of
39 the AWV and may be misleading patients. The presence of commercial entities may interfere with
40 both the provider-patient relationship and appropriate continuity of care.

41 42 RELEVANT AMA POLICY

43
44 Policy H-425.994 supports the premise of the AWV stating that the evaluation of healthy person by a
45 physician can serve as a convenient reference point for preventive services and for counseling about
46 healthful living and known risk factors. Policy H-425.994 also states that the testing of individuals
47 should be pursued only when adequate treatment and follow-up can be arranged for the abnormal
48 conditions and risk factors identified.

49
50 Policy H-425.997 addresses preventive services and encourages the development of policies and
51 mechanisms to assure the continuity, coordination, and continuous availability of patient care,

1 including preventive care and early-detection screening services. Policy H-425.997 states further that
2 preventive care should ideally be coordinated by a patient's physician. To promote continuity of care,
3 Policy H-160.921 states that store-based health clinics must establish protocols for ensuring continuity
4 of care with practicing physicians within the local community and should be encouraged to use
5 electronic health records as a means of communicating patient information and facilitating continuity
6 of care. Further, Policy H-160.921 states that store-based health clinics should encourage patients to
7 establish care with a primary care physician to ensure continuity of care.

8
9 Policy D-35.985 recognizes non-physician providers as valuable components of the physician-led
10 health care team. With respect to the health care team, Policy H-275.976 states that the health
11 professional who coordinates an individual's health care has an ethical responsibility to ensure that the
12 services rendered are provided by those whose competence and performance are suited to render those
13 services safely and effectively.

14
15 **AMA ACTIVITY**

16
17 Consistent with Resolution 824-I-15, the AMA and several medical specialty societies, whose
18 members often provide the AWV, sent a joint letter to Acting Administrator of CMS expressing
19 concern about potential misuse of the AWV by commercial entities on April 30, 2015. The letter noted
20 that provision of the AWV from a source other than the patient's primary care physician or other usual
21 source of care inhibits the provision of preventive services through the patient's usual source of care
22 and disrupts the continuity of care important for both the physician-patient relationship and the
23 patient's health. The AMA also met with senior CMS officials following the agency's receipt of the
24 letter, and CMS staff expressed appreciation to the physician community for bringing this issue to their
25 attention. CMS indicated that it shares these concerns, particularly for Medicare patients who have
26 regular sources of care that also provide their annual visits.

27
28 **DISCUSSION**

29
30 Continuity of care is a bedrock principle of the physician-patient relationship and is a fundamental
31 feature of high-quality health care.^{12, 13} It is the process by which the patient and the physician-led
32 health care team are cooperatively involved in ongoing health care management with the shared goal
33 of high quality, cost-effective care. The Council recognizes continuity of care as a hallmark and
34 primary objective of medicine and believes it is consistent with quality patient care provided through a
35 patient-centered medical home. Continuity of care is rooted in the long-term physician-patient
36 relationship in which the physician knows the patient's information from experience and can integrate
37 new information and decisions from a holistic standpoint.

38
39 A physician-led, team-based approach to health care facilitates continuity of care which in turn,
40 reduces fragmentation and thus improves patient safety and quality of care. It ensures salient issues
41 and markers are tracked consistently to further the goal of high quality care.¹⁴ To that end, the Council
42 recommends reaffirming Policy H-425.997 encouraging continuity of care and supporting the
43 principle that preventive care should be coordinated by the patient's physician.

44
45 Retail clinics and other non-physician facilities may provide a limited scope of services to patients that
46 may seem to be timely and convenient. However, these clinics can ultimately lead to fragmentation if
47 not properly coordinated with the patient's primary physician's office or usual source of care. This
48 fragmentation compromises patient care and health care quality and cost. Using a retail health clinic
49 for the AWV may result in a missed opportunity to address more complex patient needs. Care
50 delivered in retail clinics and other non-physician facilities must work in coordination with the
51 patient's current and regular sources of care to mitigate the effects of fragmentation. Fragmentation

1 and unaccountable silos of care are in direct opposition to achieving continuous whole-person care
2 with improved health outcomes.¹⁵ Accordingly, while there is no statutory authority to require that one
3 must be physician or member of a physician-led health care team to provide the AWV, it is crucial to
4 note that the AWV is most appropriately provided by a physician or member of a physician-led health
5 care team to promote efficient, quality care that either establishes or continues to provide ongoing
6 continuity of care. Further, the Council recommends reaffirming Policy H-160.921 on protocols for
7 store-based health clinics to ensure and promote continuity of care. Notably, the Council will be
8 preparing an updated report on retail health clinics for the 2017 Annual meeting. Additionally, the
9 Council recommends that any clinic performing the AWV enumerate all relevant findings and make
10 provisions for all appropriate follow-up care. The Council believes this recommendation will more
11 explicitly hold other clinicians to a reasonable reporting and follow-up standard.

12
13 Physicians often do not know whether a patient has received the AWV in the past 12 months until
14 after the physician's claim is denied. Therefore, the Council recommends that CMS promote a
15 mechanism to ensure that physicians have a way to determine whether Medicare has already paid for
16 an AWV for a patient in the past 12 months, thereby ensuring that physicians are paid appropriately
17 for the health care services they provide. Additionally, the Council notes the importance of educating
18 patients on the AWV and continuity of care and believes CMS should have the responsibility for
19 educating beneficiaries. Accordingly, the Council recommends that CMS communicate to Medicare
20 enrollees that, in choosing their primary care physician, they are encouraged to make their AWV
21 appointments with this physician in order to facilitate continuity and coordination of care.

22
23 **RECOMMENDATIONS**

24
25 The Council on Medical Service recommends that the following be adopted in lieu of Resolution 824-
26 I-15 and that the remainder of the report be filed:

27
28 1. That our American Medical Association (AMA) reaffirm Policy H-425.997 encouraging
29 continuity of care and supporting the principles that preventive care should be coordinated by the
30 patient's physician. (Reaffirm HOD Policy)

31
32 2. That our AMA reaffirm Policy H-160.921 on protocols for store-based health clinics to ensure
33 continuity of care. (Reaffirm HOD Policy)

34
35 3. That our AMA support that the Medicare Annual Wellness Visit (AWV) is a benefit most
36 appropriately provided by a physician or a member of a physician-led health care team that
37 establishes or continues to provide ongoing continuity of care. (New HOD Policy)

38
39 4. That our AMA support that, at a minimum, any clinician performing the AWV must enumerate all
40 relevant findings from the visit and make provisions for all appropriate follow-up care. (New
41 HOD Policy)

42
43 5. That our AMA support that the Centers for Medicare & Medicaid Services (CMS) provide a
44 means for physicians to determine whether or not Medicare has already paid for an AWV for a
45 patient in the past 12 months. (New HOD Policy)

46
47 6. That our AMA encourage CMS to educate Medicare enrollees, that, in choosing their primary care
48 physician, they are encouraged to make their AWVs with their primary care physician in order to
49 facilitate continuity and coordination of their care. (New HOD Policy)

Fiscal Note: Less than \$500.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-16

Subject: Concurrent Hospice and Curative Care
(Resolution 804-I-15)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 At the 2015 Interim Meeting, the House of Delegates referred Resolution 804, which was
2 sponsored by the Medical Student Section. Resolution 804-I-15 asked the American Medical
3 Association (AMA) to amend Policy H-85.955, "Hospice Care" to read as follows:

4
5 H-85.955, "Hospice Care"
6 Our AMA: (1) approves of the physician-directed hospice concept to enable the terminally ill
7 to die in a more homelike environment than the usual hospital; and urges that this position be
8 widely publicized in order to encourage extension and third party coverage of this provision for
9 terminal care; (2) encourages physicians to be knowledgeable of patient eligibility criteria for
10 hospice benefits and, realizing that prognostication is inexact, to make referrals based on their
11 best clinical judgment; (3) supports modification of hospice regulations so that it will be
12 reasonable for organizations to qualify as hospice programs under Medicare; (4) believes that
13 each patient admitted to a hospice program should have his or her designated attending
14 physician who, in order to provide continuity and quality patient care, is allowed and
15 encouraged to continue to guide the care of the patient in the hospice program; (5) supports
16 changes in Medicaid regulation and reimbursement of palliative care and hospice services to
17 broaden eligibility criteria concerning the length of expected survival for pediatric patients and
18 others, to allow provision of concurrent life-prolonging and palliative care, and to provide
19 respite care for family care givers; and (6) seeks amendment of the Medicare law to eliminate
20 the six-month prognosis under the Medicare Hospice benefit and support identification of
21 alternative criteria, meanwhile supporting extension of the prognosis requirement from 6 to 12
22 months as an interim measure; and (7) supports changes in Medicare regulation to allow
23 provision of concurrent curative and hospice care. (Modify AMA Policy)
24

25 The Board of Trustees assigned this report to the Council on Medical Service for a report back to
26 the House of Delegates at the 2016 Interim Meeting. This report provides background on hospice,
27 palliative and curative care; describes Medicare's hospice benefit and the Medicare Care Choices
28 Model (MCCM); summarizes relevant AMA policy; and makes policy recommendations.
29

30 BACKGROUND

31
32 The American Academy of Hospice and Palliative Medicine (AAHPM) defines palliative care as
33 that which relieves suffering and improves quality of life for people with serious illnesses, no
34 matter whether they can be cured. Hospice is a specific type of palliative care for people who likely
35 have six or fewer months to live. Not all palliative care is hospice, although hospice care is always
36 palliative. Hospice is a distinct delivery system for which eligibility is usually defined by public

1 and private insurers offering the benefit. Curative care under the Medicare program refers to health
2 care practices that treat patients with the intent of curing them or modifying their underlying
3 disease as opposed to managing symptoms such as pain or stress.

4

5 *Medicare's Hospice Benefit*

6

7 Medicare is the largest insurer of end-of-life medical care, with spending on patients during their
8 last year of life making up 25 percent of total Medicare spending on patients 65 years of age and
9 older.¹ Predictably, Medicare is also the largest payer of hospice care, most frequently in patients'
10 homes but also at Medicare-certified hospices, hospitals and skilled nursing facilities. In 2014,
11 more than 1.3 million people received Medicare hospice services from 4,100 certified for-profit
12 and non-profit providers at a cost of \$15.1 billion. Average length of stay was about 88 days;
13 however, median length of stay was only 17 days. Spending on Medicare's hospice benefit has
14 doubled since 2000 but held steady between 2012 and 2014.²

15

16 The literature on hospice costs to the Medicare program has produced mixed results, with some
17 studies showing large cost savings among hospice patients and others pointing to higher costs of
18 care, particularly for long-term enrollees. A recent MedPAC analysis suggests that hospice on
19 average produces no savings and may modestly increase end-of-life costs.³ Benefits to patients and
20 their families—which are not taken into account in cost analyses—have been identified in separate
21 studies. Although there is evidence that early hospice referral reduces hospitalizations and high-
22 cost procedures, further research is needed.

23

24 The hospice benefit was introduced to the Medicare program in 1983 to provide interdisciplinary,
25 team-based services including: nursing care; physicians' services; social worker services;
26 counseling; short-term inpatient hospice care; medical appliances and supplies; drugs and biologics
27 for pain relief and symptom control; home health or hospice aid services; physical, occupational
28 and speech therapy; bereavement support and other services.⁴ To be eligible to elect hospice care
29 under Medicare, patients must be certified as having a life expectancy of six months or less if the
30 terminal illness runs its normal course. Eligible Medicare patients can file an election statement
31 with a particular hospice. The statement must include a number of elements, including the patient's
32 acknowledgement that he or she: 1) has been given a full understanding of the palliative rather than
33 curative nature of hospice care; and 2) waives all rights to Medicare payments for services related
34 to the treatment of the terminal illness and related conditions.⁵ Patients can revoke their election to
35 hospice care at any time and return to standard Medicare coverage.

36

37 Medicare pays for hospice care using per diem payment categories encompassing four levels of
38 care: (1) routine home care, for which Medicare pays \$187 per day for the first 60 days and \$147
39 per day thereafter; (2) general inpatient care, paid \$720 per day; (3) continuous home care, paid at a
40 rate of \$39 per hour; and (4) inpatient respite care, for which Medicare pays \$167 per day (payment
41 rates are for fiscal year 2016).⁶ Service intensity add-on payments are also made when hospice
42 provides direct patient care by a registered nurse or social worker during patients' last seven days
43 of life. In keeping with the hospice philosophy, routine home care accounts for the large majority
44 of hospice payments.

45

46 Despite growth in hospice utilization, fewer than half of Medicare patients (47.8 percent in 2014)
47 elect hospice services, and more than a quarter do not enroll until their final week of life.⁷ In
48 addition to late enrollments, there are concerns about extremely long hospice stays and
49 disenrollments prior to death.⁸ Utilization of hospice care is lower among racial and ethnic
50 minorities.⁹

1 The requirement that patients waive Medicare coverage for services related to the treatment of their
2 terminal illness compels Medicare patients to choose between continuing these treatments and
3 enrolling in hospice care. Reluctance among patients to stop expensive treatments, that may either
4 prolong their lives or improve their functional status and quality of life, is believed to contribute to
5 underutilization of the benefit, as is increased availability of palliative care options outside of
6 hospice.¹⁰ It is important to point out that Medicare-certified hospices are not prohibited from
7 providing treatments that may be life-prolonging or curative, and some hospices have done so
8 under “open access” policies. However, it is generally not financially viable for hospices to provide
9 curative treatments since they receive no additional payments for the significantly higher costs they
10 incur.

11
12 Restricted access policies among hospices are far more common than “open access” policies and
13 may also impact hospice utilization. Findings from a national survey of hospice providers suggest
14 wide variation among hospice enrollment policies, but found that 78 percent of the surveyed
15 providers had at least one restrictive enrollment policy. More than 60 percent of the surveyed
16 hospices will not enroll patients receiving chemotherapy; over half will not accept patients
17 receiving parenteral nutrition; and 40 percent will not take patients who receive transfusions.¹¹

18
19 *Palliative Care*
20

21 The philosophies underlying hospice and palliative care are similar; however, care location, timing
22 and eligibility often differ. At its core, palliative care is designed to assess, prevent and manage
23 physical and psychological symptoms, address spiritual concerns, and focus on communications
24 that establish patient goals of care and assist patients with medical decision-making about treatment
25 options. Whereas services provided by hospice are most commonly provided to patients in their
26 homes, non-hospice palliative care is frequently provided in hospitals or community settings such
27 as cancer centers, clinics and nursing homes, although palliative care can also be provided in-home.
28 Patients can receive palliative care while continuing curative treatment at any stage of their
29 illnesses, and many studies have shown that early palliative care interventions improve quality of
30 life and increase patient and family satisfaction.¹² Palliative care providers—either primary
31 physicians who have the skills and competencies to care for the seriously ill, or physicians with
32 specialty training and certification in palliative medicine—may also help patients who wish to
33 discontinue life-prolonging care to transition to hospice or end-of-life care. Since palliative care is
34 most commonly provided by hospitals, palliative specialists or other physicians, many of these
35 services are covered by public and private insurance.

36
37 *Concurrent Curative Care*
38

39 Some stakeholders question whether Medicare’s requirement that patients forego curative care in
40 order to elect the hospice benefit still makes sense in today’s health care environment.
41 Chemotherapy, radiation and blood transfusions are routinely provided to seriously and terminally
42 ill patients, and the distinction between what constitutes life-prolonging and end-of-life treatment is
43 significantly less clear than it once was. For example, chemotherapy or radiation treatment of
44 certain metastases can be provided to alleviate pain and/or prolong life, and may be considered
45 palliative and/or curative, depending on patient circumstances.

46
47 A provision in the Affordable Care Act stipulated that terminally ill children enrolled in hospice
48 under a state’s Medicaid or Children’s Health Insurance Program be permitted to receive
49 concurrent curative care; however, implementation of this change has proven exceedingly
50 challenging and is not working effectively in most states.

1 *Medicare Care Choices Model*

2
3 In January 2016, the Center for Medicare and Medicaid Innovation (CMMI) launched a concurrent
4 care demonstration project called the Medicare Care Choices Model (MCCM). According to the
5 CMMI, this pilot will test the impact of patient access to concurrent hospice and curative care on
6 quality of care and patient and family satisfaction.¹³

7
8 To participate in the model, Medicare patients diagnosed with certain terminal illnesses must meet
9 the program's hospice eligibility requirements; must not have elected hospice within the last 30
10 days; must receive services from one of about 140 Medicare-certified hospices selected by the
11 CMMI to participate in the model; must have been hospitalized twice in the last year; and must live
12 at home. Eligible patients can receive services from a hospice while continuing to receive curative
13 or disease modifying care from other providers. The model will last five years and target 150,000
14 eligible Medicare patients diagnosed with advanced cancers, chronic obstructive pulmonary
15 disease, congestive heart failure or human immunodeficiency virus/acquired immune deficiency
16 syndrome.¹⁴ Phase 1 hospices began delivering services on January 1, 2016, and Phase 2 will begin
17 on January 1, 2018.

18
19 Under the MCCM, the non-hospice treating physician is the referring physician and is responsible
20 for directing patient care. The role of the hospice under the MCCM is to provide supportive care
21 and to integrate that care with that of the treating physician through case management, care
22 coordination, shared decision-making and other specified services. Participating hospices are paid
23 \$400 per month per MCCM enrollee, which is substantially less than daily rates paid under the
24 traditional Medicare hospice benefit.¹⁵ Some have questioned whether hospice payments under the
25 MCCM are sufficient to deliver true hospice services. The AAHPM maintains, and the Council
26 agrees, that a true concurrent care model should include the full scope of hospice care, services and
27 resources to be successful.

28
29 AMA POLICY

30
31 The AMA has longstanding policy on hospice and palliative care. Policy H-85.966 maintains that
32 the use of hospice care should provide the patient and family with appropriate support, but not
33 preclude or prevent the use of appropriate palliative therapies to continue to treat the underlying
34 disease. Under Policy D-140.962, the AMA recognizes the benefits of hospice, and reaffirms that
35 physicians: (a) have a responsibility to see that hospice services are authorized in appropriate
36 circumstances and settings, and (b) should be allowed and encouraged to remain actively involved
37 in managing their patients' hospice care. Policy D-140.962 also asks the AMA to call on the
38 Centers for Medicare & Medicaid Services (CMS) to thoroughly study Medicare's hospice benefit.

39
40 Policy H-85.955 supports changes to the Medicaid program to allow provision of concurrent life-
41 prolonging and palliative care, and also broadening eligibility beyond six-month prognoses under
42 Medicaid and Medicare hospice benefits. Policy H-85.955 also encourages physicians to be
43 knowledgeable of patient eligibility for hospice benefits and maintains that designated attending
44 physicians should be allowed to guide the care of hospice patients. Policy H-70.915 supports
45 improved payments for health care practices caring for dying patients, and encourages research into
46 the needs of dying patients and how they could be better served by the health care system.

47
48 DISCUSSION

49
50 A 2014 report from the Institute of Medicine (IOM), *Dying in America*, found that "improving the
51 quality and availability of medical and social services for patients and their families could not only

1 enhance quality of life through the end of life, but may also contribute to a more sustainable care
2 system." The IOM panel further recommended "a major reorientation of payment systems to
3 incentivize the integration of medical and social services, the coordination of care across multiple
4 care settings, and the use of advance care planning and shared decision making to better align the
5 services patients receive with their care goals and preferences."¹⁶ The Council found these
6 recommendations sensible and worthy of consideration during its discussions. The Council
7 reviewed the literature on hospice and palliative care and will monitor evaluations of the MCCM as
8 they become available, revisiting hospice payment and coverage issues as needed. Valuable
9 feedback was also solicited and received from the AAHPM.

10

11 The Council wishes to clarify that the Medicare program does not require patients to discontinue
12 life-prolonging treatments in order to enroll in hospice, but Medicare will not pay separately for
13 treatments for one's terminal illness which are considered to be curative. The Council also clarifies
14 that the policy modification requested by Resolution 804-I-15 would require the AMA to support a
15 legislative rather than regulatory change, given that eligibility for election of Medicare's hospice
16 benefit is defined in the Social Security Act.

17

18 The Council understands that Medicare's existing eligibility criteria compel most patients to either
19 pursue curative treatments or enroll in hospice care. The Council concurs with the authors of
20 Resolution 804-I-15 that underutilization of Medicare's hospice benefit is due in part to reluctance
21 among patients to abandon life-prolonging treatments. The Council further agrees that hospice care
22 should not preclude the use of appropriate palliative therapies to treat underlying disease, which is
23 the essence of Policy H-85.966. Accordingly, the Council recommends that Policy H-85.966 be
24 reaffirmed.

25

26 The Council believes that in the future, thoughtfully designed, financially sustainable concurrent
27 hospice/curative care models have tremendous potential to improve the quality of life and
28 satisfaction of some of Medicare's sickest patients and their families. However, the evidence base
29 does not yet exist to determine the most effective model for providing and paying for concurrent
30 care. The "open access" hospice model is not financially sustainable for most hospices, and there
31 are questions as to whether the MCCM is too limited to deliver its intended value. The Council has
32 similar misgivings about the MCCM and believes that, as designed, the pilot program may not
33 produce meaningful data on true concurrent care. The Council is equally troubled by the low
34 payment rates under the MCCM, which are not adequate to provide true, interdisciplinary,
35 physician-involved hospice care.

36

37 Additionally, the Council feels strongly that implementation issues associated with concurrent
38 hospice/curative care models must be resolved before the AMA can credibly support a major
39 legislative change to the Medicare statute. For example, it is unclear how life expectancy would be
40 quantified under these models given that life-prolonging care could extend patients' prognoses
41 beyond six months, thereby affecting their eligibility for hospice. Because there is still so much
42 work to be done, the Council believes it is premature to modify Policy H-85.955 as requested by
43 Resolution 804-I-15. Instead, the Council recommends that the AMA support continued study and
44 pilot testing by CMS of a variety of models for providing and paying for concurrent hospice,
45 palliative and curative care.

46

47 Numerous studies have shown that palliative care improves pain and symptom control, increases
48 satisfaction with care among seriously ill patients and reduces costs. The Council underscores the
49 AMA's support for palliative care services, and recommends that the AMA encourage CMS to
50 identify ways to optimize patient access to palliative care, which relieves suffering and improves

1 quality of life for people with serious illnesses regardless of whether they can be cured, and to
2 provide appropriate coverage and payment for these services.

3
4 Because many seriously and terminally ill patients and their families may be unaware of the
5 benefits of hospice and palliative care, or available resources in their communities, the Council
6 hopes physicians will learn more about local resources. Patients and physicians can search for
7 hospices and palliative care providers at <http://www.nhpco.org/find-hospice>. The Council
8 recommends that the AMA encourage physicians to be familiar with local hospice and palliative
9 care resources and their benefit structures, and to refer seriously ill patients accordingly.

10
11 RECOMMENDATIONS
12

13 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
14 804-I-15 and the remainder of the report be filed:

15
16 1. That our American Medical Association (AMA) reaffirm Policy H-85.966, which maintains
17 that hospice care should provide the patient and family with appropriate physical and
18 emotional support, but not preclude the use of appropriate palliative therapies to continue to
19 treat underlying disease. (Reaffirm HOD Policy)

20
21 2. That our AMA support continued study and pilot testing by the Centers for Medicare &
22 Medicaid Services (CMS) of a variety of models for providing and paying for concurrent
23 hospice, palliative and curative care. (New HOD Policy)

24
25 3. That our AMA encourage CMS to identify ways to optimize patient access to palliative care,
26 which relieves suffering and improves quality of life for people with serious illnesses,
27 regardless of whether they can be cured, and to provide appropriate coverage and payment for
28 these services. (New HOD Policy)

29
30 4. That our AMA encourage physicians to be familiar with local hospice and palliative care
31 resources and their benefit structures, and to refer seriously ill patients accordingly. (New HOD
32 Policy)

Fiscal Note: Less than \$500.

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REPORT 5 OF THE COUNCIL ON MEDICAL SERVICE (I-16)
Incorporating Value into Pharmaceutical Pricing
(Resolution 712-A-16)
(Reference Committee J)

EXECUTIVE SUMMARY

Following the adoption of the recommendations of Council on Medical Service Report 2-I-15, “Pharmaceutical Costs,” the Council spent the past year reviewing the substantial body of American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing in the context of rising concerns about pharmaceutical spending. The Council concluded that additional AMA policy is needed to respond to innovative proposals addressing pharmaceutical pricing that could potentially be included in future legislation and regulations, including those that call for value-based pricing of pharmaceuticals. In addition, at the 2016 Annual Meeting, the House of Delegates referred Resolution 712, which asked that our AMA “advocate with Congress and federal agencies, for any necessary combination of legislation, regulation, negotiation with the pharmaceutical industry, and federal subsidies, to lower the cost of treatment for all Americans infected with Hepatitis C virus using highly effective oral medications, to a price level that would make treatment affordable and accessible.”

The integration of value into pharmaceutical pricing builds upon long-standing AMA policy that supports market-driven mechanisms to control pharmaceutical costs, as well as recognizes that improvements need to be made to ensure that the pharmaceutical marketplace operates efficiently and effectively. Importantly, value-based pricing of pharmaceuticals does not require the establishment of price controls or other mandates that may stifle innovation in the pharmaceutical industry. However, pricing pharmaceuticals based on their value should aim to improve affordability for patients and limit system-wide budgetary impact. As policymakers, insurers and other stakeholders move forward with efforts to integrate value into pharmaceutical pricing, the Council has proposed principles to guide AMA advocacy in this arena, which state that initiatives to determine value-based pricing for pharmaceuticals should aim to ensure patient access to necessary prescription drugs, allow for patient variation and physician discretion, limit administrative burdens on physician practices and patients, and be evidence-based, transparent, objective and involve the input of practicing physicians and researchers.

The Council notes that there continues to be a lack of high-quality data on the cost and value of interventions using pharmaceuticals in practice. Increased comparative effectiveness research on pharmaceuticals is imperative so patients, physicians and other stakeholders are aware of differences between the prescription drugs available within the same category or class. However, in order to be truly effective, the cost of alternatives, as well as cost-effectiveness analysis, should be included in comparative effectiveness research endeavors.

The Council believes that pharmaceutical pricing mechanisms need to take into account a drug’s public health value. For pharmaceuticals that are used to treat or cure diseases that pose unique public health threats, including hepatitis C, the Council supports the use of direct purchasing mechanisms to assure patient access to the treatments they need. Direct purchase arrangements will guarantee prices for prescription drugs as well as volume for manufacturers. As such, lower prices can be achieved in exchange for a larger, guaranteed market for a drug.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 5-I-16

Subject: Incorporating Value into Pharmaceutical Pricing
(Resolution 712-A-16)

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Following the adoption of the recommendations of Council on Medical Service Report 2-I-15,
2 “Pharmaceutical Costs,” the Council spent the past year reviewing the substantial body of
3 American Medical Association (AMA) policy pertaining to pharmaceutical costs and pricing, and
4 determining whether additional policy was needed to guide future AMA advocacy efforts. In its
5 review, the Council concluded that additional AMA policy is needed to respond to innovative
6 proposals addressing pharmaceutical pricing that could potentially be included in future legislation
7 and regulations, including those that call for value-based pricing of pharmaceuticals.
8

9 At the 2016 Annual Meeting, the House of Delegates referred Resolution 712, “Remove Pricing
10 Barriers to Treatment for Hepatitis C (HCV),” which was introduced by the New Mexico
11 Delegation and assigned to the Council for study. Resolution 712-A-16 asked:

12 That our American Medical Association advocate with Congress and federal agencies, for any
13 necessary combination of legislation, regulation, negotiation with the pharmaceutical industry,
14 and federal subsidies, to lower the cost of treatment for all Americans infected with Hepatitis C
15 virus using highly effective oral medications, to a price level that would make treatment
16 affordable and accessible.
17

18 This report provides background on prescription drug spending and pricing; summarizes relevant
19 AMA policy; highlights potential mechanisms to determine the value of pharmaceuticals; assesses
20 the impact of Medicare drug price negotiation and associated AMA policy; and presents policy
21 recommendations.
22

23 BACKGROUND

24 According to the Assistant Secretary for Planning and Evaluation of the US Department of Health
25 and Human Services (HHS), prescription drug spending was \$457 billion in 2015, accounting for
26 16.7 percent of spending on personal health care services. Of this amount, \$328 billion (71.9
27 percent) was for retail drugs (at outlets that directly serve patients), and \$128 billion (28.1 percent)
28 was for non-retail drugs (by medical providers for drugs they provide directly to patients).¹
29

30 Prescription drug spending increased by 12.6 percent in 2014, with a higher rate of spending
31 growth also estimated for 2015. From 2013 to 2018, prescription drug spending is projected to
32 increase by an average of 7.3 percent per year.¹ Leading contributors to the growth in prescription
33 drug spending in the US include the prices and uptake of brand-name drugs and biologics new to
34 the market, the prices of protected brands, the lessening impact of major patent expirations, invoice
35

1 price increases of brand-name drugs, biologics and generic drugs, and increases in the number of
2 prescriptions per person.^{1,2} The prices of new treatments for multiple sclerosis, HIV, hepatitis C,
3 oncology and autoimmune conditions have contributed to new brand spending growth, as well as
4 specialty drugs making up 36 percent of drug spending in 2015. At the same time, the uptake levels
5 of specialty drugs have contributed to the growth rate in pharmaceutical spending. For example,
6 approximately 250,000 new patients received treatment for hepatitis C in 2015, with over 400,000
7 patients having been treated with at least one of the six drugs brought to the market in the past two
8 years. In addition, there has been a rapid uptake in the use of PD-1 inhibitors, new immuno-
9 oncology drugs.²

10
11 In 2013, the average annual increase in retail prices for 622 brand name and generic versions of
12 traditional and specialty prescription drugs widely used by older Americans, including Medicare
13 beneficiaries, was 9.4 percent.³ Invoice (list) prices for brand-name prescription drugs and
14 biologics already on the market increased 12.4 percent in 2015, while the average net price for the
15 drugs—i.e., adjusted for rebates and other price concessions by pharmaceutical companies—
16 increased by 2.8 percent.² Cumulatively, between 2008 and 2015, the average price for the most
17 commonly used brand-name prescription drugs, as defined by the Express Scripts Prescription
18 Price Index, increased by 164 percent.⁴ Price increases for older generic drugs moderated in 2015
19 when compared to 2013 and 2014, contributing \$0.5 billion versus more than \$3 billion in spending
20 growth. However, the invoice prices of branded generics notably increased.²

21
22 The level at which drugs are priced impacts health plans, payers, pharmacy benefit managers,
23 employers, physicians and patients. Medicare, Medicaid, employer-sponsored health plans and
24 plans offered in health insurance exchanges have had to make adjustments in response to the higher
25 costs of prescription drugs. Prescription drug prices have been frequently cited as a main
26 justification for higher health insurance premiums, higher prescription drug cost-sharing, additional
27 prescription drug tiers and use of utilization management techniques.

28
29 Approximately 4.4 billion outpatient prescriptions were dispensed in the US in 2015.² In 2013, the
30 average annual retail cost of drug therapy for a prescription drug, based on 477 widely used
31 prescription drugs by older Americans indicated for treating chronic conditions, which include
32 generic, brand and specialty drug products, was \$11,341. The average annual cost of therapy for
33 widely used generic drugs by older Americans was \$283 in 2013, while the average cost of therapy
34 was \$2,960 for widely used brand-name drugs and \$53,384 for widely used specialty drugs.³ The
35 cost of drug therapies impacts patient cost-sharing responsibilities. In 2015, stand-alone Part D
36 prescription drug plans (PDPs) had median cost sharing of \$38 for preferred brand-name drugs,
37 \$80 for non-preferred brand-name drugs, and \$1 for preferred generic drugs. Median cost-sharing
38 in Medicare Advantage prescription drug plans (MA-PDPs) was \$45 for preferred brand-name
39 drugs, \$95 for non-preferred brand-name drugs and \$3 for preferred generic drugs. In 2015, 48
40 percent of enrollees in PDPs with a specialty drug tier and approximately three-quarters of MA-PD
41 enrollees in plans with specialty drug tiers were in plans that required 33 percent coinsurance for
42 specialty drugs.⁵ In commercial plans overall, the average patient cost exposure for a brand
43 prescription filled was \$44 in 2015. The percentage of brand prescriptions with patient cost
44 exposure over \$50 increased to 17 percent in 2015, while the percentage with \$0 patient cost
45 exposure increased to 24 percent. The average patient cost exposure for generic drugs was
46 approximately \$8 in 2015.²

47
48 AMA POLICY ADDRESSING PHARMACEUTICAL PRICING AND VALUE
49
50 Council on Medical Service Report 2-I-15, which established Policy H-110.987, stipulates that our
51 AMA:

- Encourage Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
- Encourage Congress, the FTC and HHS to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
- Monitor the impact of mergers and acquisitions in the pharmaceutical industry.
- Continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
- Encourage prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
- Support legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
- Support legislation to shorten the exclusivity period for biologics.
- Convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
- Generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and will report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.

As outlined in Board of Trustees Report 10-I-16, "AMA Initiatives on Pharmaceutical Costs," the AMA convened a Task Force on Pharmaceutical Costs pursuant to Policy H-110.987, which met four times to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs. The Task Force reviewed the substantial body of AMA policy addressing pharmaceutical costs and pricing, and discussed potential issues and issue combinations to feature in an AMA grassroots campaign, including pharmaceutical cost and price transparency, Medicare drug price negotiation, banning direct-to-consumer advertising and prescription drug reimportation. The Task Force agreed that banning direct-to-consumer advertising and prescription drug reimportation should not be pursued as part of the grassroots campaign at this time, after considering several factors, including political feasibility, as well as the thresholds for AMA support for prescription drug reimportation outlined in Policy D-100.983. The Task Force agreed that increasing transparency among pharmaceutical companies, health plans and PBMs should be the focus of Phase I of the grassroots campaign (remainder of 2016), with the specifics of Phase II of the grassroots campaign (2017) to be determined after the 2016 presidential and congressional elections and after any additional policy is established by the House of Delegates. However, the Task Force agreed that strong consideration should be given to including Medicare drug price negotiation in Phase II of the campaign. Resulting from the work of the Task Force, the AMA launched a grassroots campaign on increasing pharmaceutical cost and price transparency among pharmaceutical companies, health plans and pharmacy benefit managers.

Previously, at the 2015 Annual Meeting, the House of Delegates adopted Policy H-110.988, which states that the AMA will:

- Work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the US Food and Drug Administration, the FTC, and the Generic

1 Pharmaceutical Association) to identify and promote adoption of policies to address the already
2 high and escalating costs of generic prescription drugs;

3 • Advocate with interested parties to support legislation to ensure fair and appropriate pricing of
4 generic medications, and educate Congress about the adverse impact of generic prescription
5 drug price increases on the health of our patients;
6 • Encourage the development of methods that increase choice and competition in the
7 development and pricing of generic prescription drugs; and
8 • Support measures that increase price transparency for generic prescription drugs.

9
10 Addressing the integration of value in the health care system, Policy H-460.909 outlines principles
11 for creating a centralized comparative effectiveness research entity, including a principle that states
12 that the comparative effectiveness research entity must not have a role in making or recommending
13 coverage or payment decisions for payers. Of note, the Patient-Centered Outcomes Research
14 Institute (PCORI), which sunsets in 2019, does not fund studies conducting formal cost-
15 effectiveness analyses or directly comparing the costs of care between two or more alternative
16 approaches to providing care due to restrictions outlined in the Affordable Care Act.

17
18 Policy H-155.960 advocates that sources of medical research funding give priority to studies that
19 collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well
20 as clinical outcomes; and translate research findings into useable information on the relative cost-
21 effectiveness of alternative diagnostic services and treatments. The policy also advocates that
22 health information systems be designed to provide physicians and other health care decision-
23 makers with relevant, timely, actionable information, automatically at the point of care, including
24 relative cost-effectiveness of alternative diagnostic services and treatments. This information would
25 help fulfill the intent of Policy H-450.938, which outlines principles to guide physician value-based
26 decision-making. Policy H-155.960 encourages third-party payers to use targeted benefit design,
27 whereby patient cost-sharing requirements are determined based on the clinical value of a health
28 care service or treatment. Likewise, Policy H-185.939 supports flexibility in the design and
29 implementation of value-based insurance design programs, consistent with outlined principles.
30 Policy H-185.935 supports the appropriate use of reference pricing as a possible method of
31 providing health insurance coverage of specific procedures, products or services, consistent with
32 outlined principles.

33
34 Policy H-450.933 encourages multi-stakeholder efforts to develop and fund clinical data registries
35 for the purpose of facilitating quality improvements and research that result in better health care,
36 improved population health, and lower costs. The policy also encourages national medical specialty
37 societies, state medical associations, and other physician groups to join the National Quality
38 Registry Network and to participate in efforts to advance the development and use of clinical data
39 registries. Finally, the policy supports flexibility in the development and implementation of clinical
40 data registries, and outlines guidelines to help maximize opportunities for clinical data registries to
41 enhance the quality of care provided to patients.

42
43 **POTENTIAL MECHANISMS TO DETERMINE THE VALUE OF PHARMACEUTICALS**
44

45 During its review of AMA policy addressing pharmaceutical pricing, as well as responses to
46 address the high costs of pharmaceuticals, the Council determined that policy had a noteworthy gap
47 with respect to value-based pricing—an approach that has the potential to impact the prices of drugs
48 across the health care system. Policy H-460.909 defines value as “the best balance between
49 benefits and costs, and better value as improved clinical outcomes, quality, and/or patient
50 satisfaction per dollar spent. Improving value in the US health care system will require both
51 clinical and cost information.” However, the pricing of prescription drugs, which is market-based

1 in nature, is often not clearly commensurate with the drug's clinical outcomes, and reductions in
2 morbidity and mortality.

3
4 Various public and private payers have moved forward in implementing initiatives to tie drug
5 prices to outcomes. In addition, value frameworks exist to support a transition to basing
6 prescription drug pricing on a balance of value and health outcomes—converting evidence based on
7 patient health outcomes to a price. Two of the value frameworks outlined below provide value-
8 based prices for drugs, while others could be used to measure a drug's value as part of the shared
9 decision-making process between patients and their physicians. The strength and accuracy of any
10 framework to support value-based pricing of prescription drugs depends on the validity, reliability
11 and comprehensiveness of necessary inputs and data, which could come from clinical trials, clinical
12 data registries and comparative effectiveness research, as well as an integrated information
13 infrastructure.

14
15 *Outcomes-Based Pricing Initiatives*
16

17 Public and private payers have moved forward with initiatives that would tie how much they pay
18 for drugs to patient health outcomes. Cigna entered into value-based contracts with both Amgen
19 and Sanofi/Regeneron for their PCSK9 inhibitors, Repatha and Praluent, which reduce the amount
20 of harmful LDL cholesterol circulating in the bloodstream. Under the agreement, if Cigna enrollees
21 who take the drugs do not achieve reductions in their LDL-C levels as was experienced in clinical
22 trials, the two pharmaceutical companies would give Cigna discounts on the original negotiated
23 price. If the drugs meet or exceed the expected LDL-C reduction target, the original negotiated
24 price remains in place.⁶ Express Scripts has launched its Oncology Care Value Program, which is
25 aiming to align the cost of cancer treatment with its outcomes. This year, the program is focusing
26 on prostate cancer, lung cancer, and renal cell carcinoma.⁴ In addition, the Centers for Medicare &
27 Medicaid Services (CMS) released a proposed rule that put forward a two-phase drug payment
28 model under Medicare Part B, the second phase of which includes a proposal to allow CMS to
29 enter into voluntary agreements with manufacturers to link health care outcomes to payment. As
30 outlined in the proposed rule, these outcomes-based risk-sharing agreements “tie the final price of a
31 drug to results achieved by specific patients rather than using a predetermined price based on
32 historical population data. Manufacturers agree to provide rebates, refunds, or price adjustments if
33 the product does not meet targeted outcomes.” CMS proposed that value would be measured
34 “through data collection likely, though not necessarily, provided by the prescriber,” intended to
35 address factors such as long-term safety and outcomes, effects on individual patients, patient
36 adherence, or impact on utilization and costs.⁷

37
38 *Institute for Clinical and Economic Review (ICER)*
39

40 The Value Assessment Framework developed by ICER includes two components: a drug's long-
41 term care value and the potential short-term budget impact following a drug's introduction to the
42 marketplace. ICER determines care value by evaluating a drug's comparative clinical effectiveness,
43 incremental costs per outcomes achieved, other benefits or disadvantages (e.g., methods of
44 administration, public health benefit) and contextual considerations (e.g., future competition in the
45 marketplace). In measuring incremental costs per outcomes achieved, ICER uses quality-adjusted
46 life years (QALYs) and sets thresholds of reasonable ratios of cost-effectiveness at \$100,000 (high
47 care value) to \$150,000 (intermediate care value) per QALY. ICER measures provisional health
48 system value to assess the short-term budget impact of a drug in comparison with its long-term care
49 value. To measure the short-term budget impact of a drug, ICER estimates the net change in total
50 health care costs during the five years following the launch of a new drug into the marketplace.
51 ICER developed an affordability threshold of a drug's short-term budgetary impact to serve as an

1 “alarm bell” to indicate whether additional responses may be needed due to a drug’s short-term
2 budgetary impact. The short-term affordability threshold represents the contribution of a new drug
3 to the growth in overall health care spending of no more than the anticipated growth in national
4 gross domestic product plus one percent. Therefore, ICER calculates its value-based price
5 benchmark using long-term cost-effectiveness as well as potential short-term budget impact,
6 developing prices to achieve cost-effectiveness thresholds of \$100,000 per QALY and \$150,000
7 per QALY, as well as a maximum price using its affordability threshold. For example, in its review
8 of PCSK9 drugs, which have a list price of \$14,350, ICER concluded that the drugs would have to
9 be priced at \$5,404 to achieve a cost-effectiveness ratio of \$100,000 per QALY; \$7,735 to achieve
10 a cost-effectiveness ratio of \$150,000 per QALY; and \$2,177 to meet its affordability threshold. In
11 its review of Entresto, which has a list price of \$4,560, ICER determined that the drug would have
12 to be priced at \$9,480 to achieve a cost-effectiveness ratio of \$100,000 per QALY; \$14,472 to
13 achieve a cost-effectiveness ratio of \$150,000 per QALY; and \$4,168 to meet its affordability
14 threshold.⁸

15

16 *DrugAbacus, Memorial Sloan Kettering Cancer Center*

17

18 DrugAbacus is a tool that could potentially be used to help stakeholders determine value-based
19 prices for 52 cancer drugs approved between 2001 and 2015. The DrugAbacus price, which is
20 relevant for a typical treatment period, is calculated using a formula that uses eight domains as
21 inputs: efficacy, tolerability, novelty, research and development costs, rarity, population burden,
22 unmet need, and prognosis. Users of the tool determine the weight (i.e., value) to be given to each
23 domain, which results in a value-based price. Again, the value-based price is dependent on user
24 inputs and determinations of value. Of note, DrugAbacus includes an indication-specific pricing
25 feature, which allows users to compare the actual and DrugAbacus price of different indications for
26 four drugs: Abraxane, Avastin, Nexavar, and Tarceva.⁹

27

28 *National Comprehensive Cancer Network (NCCN) Evidence Blocks*

29

30 NCCN Evidence Blocks provide five key value measures of systemic cancer therapy, meant to be
31 used in shared decision-making between patients and their physicians. The five value measures—
32 efficacy, safety, quality of evidence, consistency of evidence, and affordability—are each rated on a
33 scale of one to five. The value measures provide additional information about specific NCCN
34 guideline recommendations, and allow physicians and patients to be able to visually compare the
35 values of available therapies and make their own assessments of value. As of the drafting of this
36 report, NCCN Evidence Blocks are available for breast cancer; breast cancer risk reduction; central
37 nervous system cancers gliomas; chronic myelogenous leukemia; colon cancer; head and neck
38 cancers—very advanced head and neck cancer; hepatobiliary cancers; kidney cancer; malignant
39 pleural mesothelioma; melanoma; multiple myeloma; non-Hodgkin’s lymphomas—diffuse large
40 B-cell lymphoma; non-small cell lung cancer; ovarian cancer; penile cancer; prostate cancer; rectal
41 cancer; testicular cancer; and thymomas and thymic carcinomas.¹⁰

42

43 *American College of Cardiology/American Heart Association (ACC/AHA)*

44

45 The ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and
46 Performance Measures provides a value framework for practice guideline and performance
47 measurement development that establishes the benefit of diagnostic approaches and treatment
48 compared with risk (COR), assesses the level/quality of evidence, and gives each
49 approach/treatment a level of value. CORs can range from class I (highest) to III (lowest). The
50 level/quality of evidence underlying a diagnostic approach and treatment would be given a value of

1 A, B or C. In addition, the approach or treatment would be given a value level of high,
2 intermediate, low or uncertain, or value not assessed, based on QALYs gained.¹¹

3

4 *American Society of Clinical Oncology (ASCO)*

5

6 In June 2015, ASCO released a conceptual framework to assess the value of cancer treatment
7 options to be used in shared decision-making. Two versions of the framework were developed: one
8 for advanced cancer and one for potentially curative treatment.¹² ASCO then opened up the
9 conceptual value framework to a 60-day public comment period; more than 400 comments were
10 received. Based on the input and feedback received, ASCO released revised versions of the
11 framework for advance disease and adjuvant settings in May 2016. In both frameworks, points are
12 awarded based on clinical benefit and toxicity, and bonus points can also be applied. Overall, both
13 versions of the framework use points to determine the net health benefit, and have the net health
14 benefit and the cost of the regimen side by side in order to assist physicians and patients to assess
15 value at the point of care. ASCO plans to launch the framework in a software application, which
16 would allow for the modification of the weight attributed to the elements included in the net health
17 benefit based on patient preferences and circumstances.¹³

18

19 *Public Health Approaches to Drug Pricing*

20

21 The Council notes that Resolution 712-A-16 was focused on lowering the cost of treatments for
22 hepatitis C, a disease with an incidence rate of 0.7 cases per 100,000 population in 2014 in the US.
23 Approximately 30,500 acute hepatitis C cases occurred in 2014, with an estimated 2.7-3.9 million
24 individuals in the US with chronic hepatitis C.¹⁴ The Council notes that different approaches have
25 been used to directly purchase drugs and vaccines that have been determined to have a high value
26 in terms of protecting public health. Preventing the spread of infectious diseases, such as hepatitis
27 C, as well as the occurrence of vaccine-preventable diseases, impacts the treatment burden of these
28 diseases, in terms of number of individuals affected, and total treatment costs. The Vaccines for
29 Children (VFC) program is used to provide federally purchased vaccines to children who are
30 uninsured, underinsured, Medicaid-eligible or Native Americans at no cost. Purchasing vaccines
31 through VFC ensures access to lower prices for vaccines; the Centers for Disease Control and
32 Prevention purchases vaccines at a discount, and distributes the vaccines to grantees (i.e., state
33 health departments and local public health agencies), which in turn distribute them at no charge to
34 participating public and private VFC providers.¹⁵

35

36 In addition, the AIDS Drug Assistance Program (ADAP), authorized under Part B of the Ryan
37 White HIV/AIDS Treatment Extension Act of 2009, is a federally funded, but state-administered
38 program that provides FDA-approved HIV medications to uninsured or underinsured low-income
39 individuals living with HIV. ADAPs are required to purchase drugs in the most economic manner
40 feasible, which can either be 340B pricing or otherwise showing that they pay no more than 340B
41 prices for drugs covered under ADAP formularies. In June 2015, 197,117 individuals were enrolled
42 in ADAPs.¹⁶

43

44 **ANALYZING THE IMPACT OF MEDICARE DRUG PRICE NEGOTIATION**

45

46 In addition to reviewing and analyzing approaches to value-based pricing of prescription drugs, the
47 Council, based on feedback received from the Task Force on Pharmaceutical Costs, reviewed
48 policy addressing Medicare drug price negotiation, and analyzed whether additional changes
49 should be made to increase the policy's ability to achieve cost savings and political feasibility.
50 Policy D-330.954 states that our AMA will support federal legislation which gives the Secretary of

1 HHS the authority to negotiate contracts with manufacturers of covered Part D drugs, and will
2 work toward eliminating Medicare prohibition on drug price negotiation.

3
4 Policy D-330.954 responds to the “noninterference clause” in the Medicare Modernization Act of
5 2003 (MMA), which states that the Secretary of HHS “may not interfere with the negotiations
6 between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may
7 not require a particular formulary or institute a price structure for the reimbursement of covered
8 part D drugs.” Instead, participating Part D plans compete with each other based on plan premiums,
9 cost-sharing and other features, which provides an incentive to contain prescription drug spending.
10 To contain spending, Part D plans not only establish formularies, implement utilization
11 management measures and encourage beneficiaries to use generic and less-expensive brand-name
12 drugs, but are required under the MMA to provide plan enrollees access to negotiated drug prices.
13 These prices are achieved through direct negotiation with pharmaceutical companies to obtain
14 rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.
15

16 *Lack of Bipartisan Support*

17
18 The scope and approach of federal legislation introduced to date that would grant the Secretary of
19 HHS the authority to negotiate contracts with manufacturers of Part D drugs vary. The Council
20 notes that, at the time this report was written, none of the bills introduced that would allow the
21 Secretary of HHS to negotiate drug prices in Part D included any Republican sponsors or
22 cosponsors. As such, achieving legislative success in this arena considering the current political
23 atmosphere is unlikely.¹⁷ S. 31/H.R. 3061, the Medicare Prescription Drug Price Negotiation Act of
24 2015, and S. 2023/H.R. 3513, the Prescription Drug Affordability Act, include language that
25 authorizes the HHS Secretary to negotiate Part D drug discounts and prohibits the Secretary from
26 imposing a national formulary. H.R. 4207, the Medicare Fair Drug Pricing Act of 2015, contains a
27 provision allowing for an exception to Medicare Part D’s “noninterference clause” for specified
28 covered part D drugs, which are defined as either sole source drugs or biologics and are not
29 manufactured by more than two drug manufacturers, or other covered drugs for which there is a
30 limited ability for Medicare Part D and Medicare Advantage plans to negotiate rebates that have a
31 significant fiscal impact on Medicare Part D. If the Secretary and the applicable drug
32 manufacturers are not able to agree on a negotiated price for these specified drugs, the legislation
33 grants the Secretary the authority to determine the price of the drug based on certain factors,
34 including the VA price of the drug (if applicable) and what price would ensure affordability and
35 accessibility. Part D plans could still negotiate for lower prices than the one determined by the
36 Secretary. The legislation also prohibits the Secretary from establishing or requiring a particular
37 formulary.

38
39 An alternative to simply allowing the Secretary of HHS to negotiate drug prices in Part D is to
40 establish a “public option” in Part D, an approach included in S. 1884/H.R. 3261, the Medicare
41 Prescription Drug Savings and Choice Act. The legislation would establish a Medicare operated
42 Medicare prescription drug plan option – a public option. The legislation would authorize the use
43 of a formulary for this public option, but would not establish a national formulary for all Part D
44 plans. This public Part D plan would operate nationwide, but would not alter the private insurance
45 plan administered Part D program.

46
47 *Limited Ability to Achieve Savings Without Additional Negotiating Leverage*

48
49 In addition, questions have been raised whether HHS could achieve much greater savings than
50 what is currently achieved by health plans and pharmacy benefit managers in Part D. The
51 Congressional Budget Office (CBO), as well as CMS actuaries, have estimated that providing the

1 Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations
2 taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by
3 Part D.^{18,19} Therefore, it is projected that legislation granting the Secretary of HHS broad authority
4 to negotiate drug prices would likely have a negligible effect on federal spending.

5
6 If the Secretary of HHS were granted the authority to negotiate prices for unique covered Part D
7 drugs that lack competitor products or therapeutic alternatives, the CBO has stated that there may
8 be potential savings.¹⁶ However, neither the CBO or the Office of Management and Budget (OMB)
9 has scored any savings associated with providing the Secretary of HHS the authority to negotiate
10 drug prices for biologics and high-cost drugs in Medicare Part D, an option which was included in
11 the Obama administration's fiscal year 2016 and 2017 budget proposals.^{20,21,22,23}

12
13 Perhaps of most concern, CBO has acknowledged that, in order for the Secretary to have the ability
14 to obtain significant discounts in negotiations with drug manufacturers, the Secretary would also
15 need the "authority to establish a formulary, set prices administratively, or take other regulatory
16 actions against firms failing to offer price reductions. In the absence of such authority, the
17 Secretary's ability to issue credible threats or take other actions in an effort to obtain significant
18 discounts would be limited."¹⁸ CMS actuaries have concurred, stating "the inability to drive market
19 share via the establishment of a formulary or development of a preferred tier significantly
20 undermines the effectiveness of this negotiation. Manufacturers would have little to gain by
21 offering rebates that are not linked to a preferred position of their products, and we assume that
22 they will be unwilling to do so."¹⁹

23

24 Any Positive Impact Primarily Limited to Medicare Part D Beneficiaries

25

26 The Council notes that, if allowing for Medicare drug price negotiation would achieve any savings,
27 the primary impact would be to reduce the cost-sharing of patients enrolled in Medicare Part D
28 plans, versus patients insured in both private and public plans. At the same time, pharmaceutical
29 companies could potentially shift costs to commercial health plans, as Medicaid programs already
30 have access to lower prescription drug prices resulting from existing rebates and other measures. If
31 Medicare drug price negotiation does indeed cause pharmaceutical manufacturers to shift their
32 costs to commercial health plans, that may cause plans offered in the exchanges and by employers
33 to raise their premiums and cost-sharing, which could negatively impact patient access and
34 adherence.

35

36 Unintended Consequences of Amending Policy

37

38 Accordingly, the Council believes that amending Policy D-330.954 to increase the likelihood for
39 cost savings associated with allowing the Secretary of HHS to negotiate drug prices in Medicare
40 Part D would entail supporting authority for the Secretary to establish a Part D formulary or
41 develop a preferred tier in Part D. The Council does not support amending the policy in this
42 fashion, due to its expected impact on patient choice of Part D plans, and patient access to the
43 prescription drugs they need. If the Secretary were given the authority to establish a Part D
44 formulary, any drug not on the formulary or at a high tier on the formulary would require an
45 exception request/appeal by the patient. In addition, formularies include prior authorization
46 requirements, quantity limits and step therapy requirements. Importantly, expanding the Secretary's
47 authority in this fashion may further reduce the political feasibility of the policy. Overall, the
48 Council believes that value-based pricing may serve as a more politically viable, cost-saving,
49 choice-saving and fair alternative to the Secretary of HHS negotiating drug prices in Medicare Part
50 D. In addition, value-based pricing has the potential to impact the prescription drug cost-sharing of
51 all patients, not just those enrolled in Medicare Part D plans.

1 DISCUSSION
2

3 The integration of value into pharmaceutical pricing has the potential to build off of long-standing
4 AMA policy that supports market-driven mechanisms to control pharmaceutical costs, as well as
5 recognizes that improvements need to be made to ensure that the pharmaceutical marketplace
6 operates efficiently and effectively. Importantly, value-based pricing of pharmaceuticals does not
7 require the establishment of price controls or other mandates that may stifle innovation in the
8 pharmaceutical industry. However, pricing pharmaceuticals based on their value should aim to
9 improve affordability for patients and limit system-wide budgetary impact. As policymakers,
10 insurers and other stakeholders move forward with efforts to integrate value into pharmaceutical
11 pricing, the Council believes that the establishment of principles are necessary to guide AMA
12 advocacy. Initiatives to determine value-based pricing for pharmaceuticals should aim to ensure
13 patient access to necessary prescription drugs and allow for patient variation and physician
14 discretion. In addition, such initiatives should limit administrative burdens on physician practices
15 and patients. The Council is concerned that some value-based pricing approaches, by being
16 dependent on the tracking and reporting of outcomes, have the potential to impose administrative
17 burdens on physicians and patients.

18 Processes that determine value-based prices of pharmaceuticals need to be evidence-based,
19 transparent, and objective, and involve the input of practicing physicians and researchers. The
20 Council notes that the strength and accuracy of any framework to support value-based pricing of
21 pharmaceuticals depends on the validity, reliability and comprehensiveness of necessary inputs and
22 data, which could come from clinical trials, clinical data registries and comparative effectiveness
23 research, as well as an integrated information infrastructure. The Council notes that there continues
24 to be a lack of high-quality data on the cost and value of interventions using pharmaceuticals in
25 practice. Increased comparative effectiveness research in the pharmaceutical arena is imperative so
26 patients, physicians and other stakeholders are aware of differences between the prescription drugs
27 available within the same category or class. The Council believes that the AMA must continue to
28 advocate for adequate investment in comparative effectiveness research, as called for in Policies
29 H-460.909 and D-390.961. However, in order to be truly effective, the cost of alternatives, as well
30 as cost-effectiveness analysis, should be included in comparative effectiveness research endeavors.
31 In addition, your Council recognizes that clinical data registries, as addressed in Policy H-450.933,
32 may be useful in measuring and tracking short- and long-term clinical outcomes of
33 pharmaceuticals.

35 Value-based pharmaceutical pricing can also be incorporated into health insurance benefit design,
36 to limit patient cost-sharing for pharmaceuticals that have a high clinical benefit. Policies
37 H-155.960 and H-185.939, which are also relevant to alternative payment models, support the use
38 of value-based insurance design, determining patient cost-sharing requirements based on the
39 clinical value of a health care service or treatment. Policy also states that consideration should be
40 given to further tailoring cost-sharing requirements to patient income and other factors known to
41 impact compliance. Importantly, Policy H-185.939 states that value-based plan designs that include
42 higher cost-sharing or other disincentives to obtaining services designated as low-value must
43 include an appeals process to enable patients to secure care recommended by their physicians,
44 without incurring cost-sharing penalties.

46 With respect to Resolution 712-A-16, the Council believes that pharmaceutical pricing mechanisms
47 need to take into account a drug's public health value. For pharmaceuticals that are used to treat or
48 cure diseases that pose unique public health threats, including hepatitis C, the Council supports the
49 use of direct purchasing mechanisms to assure patient access to the treatments they need, which
50 will impact disease transmission rates as well as overall treatment costs. Existing models, including

1 the VFC program and the AIDS Drug Assistance Program, show the potential for using the direct
2 purchasing approach for other drugs. The Council notes that direct purchase arrangements will
3 guarantee prices for prescription drugs as well as volume for manufacturers. As such, lower prices
4 can be achieved in exchange for a larger, guaranteed market for a drug.

5
6 RECOMMENDATIONS
7

8 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
9 712-A-16, and that the remainder of the report be filed.

10

- 11 1. That our American Medical Association (AMA) reaffirm Policies H-155.960 and H-185.939,
12 which support the use of value-based insurance design, determining patient cost-sharing
13 requirements based on the clinical value of a treatment. (Reaffirm HOD Policy)
- 14 2. That our AMA reaffirm Policy H-450.933, which establishes guidelines to help maximize
15 opportunities for clinical data registries to enhance the quality of care provided to patients.
16 (Reaffirm HOD Policy)
- 17 3. That our AMA reaffirm Policies H-460.909 and D-390.961 in support of adequate investments
18 in comparative effectiveness research. (Reaffirm HOD Policy)
- 19 4. That our AMA support value-based pricing programs, initiatives and mechanisms for
20 pharmaceuticals that are guided by the following principles:
21
- 22 a) Value-based prices of pharmaceuticals should be determined by objective, independent
23 entities;
- 24 b) Value-based prices of pharmaceuticals should be evidence-based and be the result of valid
25 and reliable inputs and data that incorporate rigorous scientific methods, including clinical
26 trials, clinical data registries, comparative effectiveness research, and robust outcome
27 measures that capture short- and long-term clinical outcomes;
- 28 c) Processes to determine value-based prices of pharmaceuticals must be transparent, easily
29 accessible to physicians and patients, and provide practicing physicians and researchers a
30 central and significant role;
- 31 d) Processes to determine value-based prices of pharmaceuticals should limit administrative
32 burdens on physicians and patients;
- 33 e) Processes to determine value-based prices of pharmaceuticals should incorporate
34 affordability criteria to help assure patient affordability as well as limit system-wide
35 budgetary impact; and
- 36 f) Value-based pricing of pharmaceuticals should allow for patient variation and physician
37 discretion. (New HOD Policy)
- 38
- 39 5. That our AMA support the inclusion of the cost of alternatives and cost-effectiveness analysis
40 in comparative effectiveness research. (New HOD Policy)
- 41
- 42 6. That our AMA support direct purchasing of pharmaceuticals used to treat or cure diseases that
43 pose unique public health threats, including hepatitis C, in which lower drug prices are assured
44 in exchange for a guaranteed market size. (New HOD Policy)
- 45
- 46
- 47

Fiscal Note: Less than \$500.

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REPORT 6 OF THE COUNCIL ON MEDICAL SERVICE (I-16)
Integration of Mobile Health Applications and Devices into Practice
(Reference Committee J)

EXECUTIVE SUMMARY

Digital health, including the utilization of mobile health applications (mHealth apps) and devices, has the potential to be integrated into everyday practice in order to promote improved patient health outcomes, support care coordination and improve communication. The Council initiated this report to address the need to balance these innovations with appropriate industry standards for mHealth apps and US Food and Drug Administration (FDA) regulation of mobile medical devices. For those mHealth apps and mobile medical devices that are subject to FDA review and approval, FDA resources need to be sufficient to respond to the number of mHealth products under its jurisdiction.

While some mobile apps and devices are subject to FDA regulation, others are not, and do not undergo rigorous evaluation before deployment for general use, which raises quality and patient safety concerns. However, without ensuring that there is strong and sufficient evidence that provides clinical validation to mHealth apps and associated devices, trackers and sensors, the Council recognizes that physicians will not fully integrate mHealth apps into their practices. More investment is needed in expanding the evidence base necessary to show the accuracy, effectiveness, safety and security of mHealth apps.

The Council proposes principles to guide health plan coverage and payment decisions, employer wellness program inclusions and flexible spending account eligibility determinations concerning mHealth apps and associated devices, in order to protect the patient-physician relationship, support care delivery that is patient-centered, promote care coordination and facilitate team-based communication. Overall, coverage of and payment for mHealth apps and associated devices should be contingent upon a clinical evidence base to support their use in order to ensure app safety and effectiveness. In addition, interoperability between a patient's mobile technology and electronic health records will be an asset, as physicians must be able to meaningfully use the volumes of data mHealth apps and devices create. It is also essential for mHealth apps to follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care and positive health outcomes. National medical specialty societies have a key role in developing guidelines for the integration of mHealth apps and associated devices into care delivery.

Patient privacy and data security need to be a priority in digital health, because mobile apps and devices can be subject to privacy and data breaches. Patients must also be aware of the level at which their information and data is protected by mHealth apps. Overall, mHealth apps and associated devices, trackers and sensors need to abide by applicable laws addressing the privacy and security of patients' medical information. If physicians are unsure of whether mHealth apps meet Health Insurance Portability and Accountability Act's standards, they should consult with qualified legal counsel and inquire about any applicable state privacy and security laws. Given the lack of regulation of mHealth apps, regardless of whether an mHealth device is encrypted, physicians should alert patients to the potential privacy and security risks of any mHealth apps that he or she prescribes or recommends, and document the patient's understanding of such risks. Questions remain regarding liability risks to physicians who use, recommend or prescribe mHealth apps. Accordingly, the Council believes that the AMA should assess the potential liability risks to physicians for using, recommending, or prescribing mHealth apps, including risk under federal and state medical liability, privacy, and security laws.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 6-I-16

Subject: Integration of Mobile Health Applications and Devices into Practice

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 The use of digital and mobile health technologies and tools is increasing among patients and
2 physicians, with the potential to play a significant role in new payment and care delivery models.
3 The evolution of digital and mobile health technologies, including mobile applications (apps) and
4 devices, impacts all three strategic focus areas of the American Medical Association (AMA):
5 improving health outcomes, creating the medical school of the future, and creating thriving
6 physician practices. This Council-initiated report provides background on the number, use,
7 effectiveness and safety of mobile health applications (mHealth apps) and medical devices;
8 outlines relevant regulatory and legislative activity; provides a snapshot of the current coverage and
9 payment environment for mobile health apps and devices; summarizes relevant AMA policy and
10 advocacy; and presents policy recommendations.

11
12 **BACKGROUND**
13

14 Mobile health apps and medical devices are continuously being introduced into the marketplace to
15 assist patients in managing their health and wellness, with some having the capacity to support the
16 ability of physicians to monitor the health status and indicators of patients. Mobile health apps that
17 facilitate chronic disease management and patient engagement have the potential to serve as tools
18 to manage the care of patients with comorbidities, as well as patients who incur high health care
19 costs. There are distinct definitions that can be applied to the range of mobile apps and devices
20 available for use by patients and physicians:

21

- 22 • Mobile applications (mobile apps): A software application that can be run on a mobile
23 product such as a mobile phone, smartphone, or tablet (with or without wireless
24 connectivity) or a web-based software application run on a server, but meant to be used
25 through a mobile product (such as a smartphone).
- 26 • Mobile health applications (also referred to as mobile health or mHealth apps): A mobile
27 app that delivers health-related services using a mobile phone, smartphone or tablet. These
28 apps cover a wide spectrum of functions to support health and fitness, as well as disease
29 management.
- 30 • Mobile medical device applications: A mobile app that meets the definition of a device in
31 the Federal Food, Drug, and Cosmetic Act is considered by the US Food and Drug
32 Administration (FDA) to be a medical device, subject to risk-based oversight and
33 regulation. A mobile medical device app could be considered a regulated subset of
34 mHealth apps.

1 Approximately two-thirds of Americans own smartphones, including 27 percent of individuals 65
2 and older and half of those with incomes under \$30,000 per year¹—populations that may be key
3 targets for mobile health interventions. In addition, an increasing number of patients are taking
4 advantage of mHealth apps, as well as wearable sensor technologies to allow for real-time
5 monitoring and tracking of important health information.

6
7 There are more than 165,000 mHealth apps available to consumers. The number of mHealth apps
8 available in the marketplace has been increasing at a significant rate—from 2013 to 2015, the
9 number of mHealth apps on the iOS platform rose from 43,689 to 90,088—a 106 percent increase.²
10 While patient-facing health apps may track personal fitness and nutrition, provide medication
11 reminders, provide health-related information and display personal health records, physicians and
12 other health care providers can use mobile health apps to track patient vital signs and other health
13 indicators, and as diagnostic tools. Two-thirds of consumer mHealth apps are focused on wellness
14 (e.g., fitness, diet, nutrition and lifestyle), with approximately one-quarter of mHealth apps
15 targeting disease and treatment management.²

16
17 Mobile health apps vary greatly in their functionality, accuracy, safety and effectiveness. Most
18 mHealth apps have limited functionality, with many solely providing information without
19 additional capabilities. In fact, providing information is the most common capability of mHealth
20 apps. On the other hand, most apps lack the ability to communicate or connect with the systems of
21 physicians and other health care providers. While the percentage of mHealth apps with the capacity
22 to output user data increased between 2013 and 2015, the ability of mHealth apps to communicate
23 externally, including with patients’ treating physicians, remained the same. Approximately 10
24 percent of mHealth apps have the ability to connect to a device, which not only include fitness
25 apps, but also disease management apps that monitor blood pressure and blood glucose levels.²

26
27 The Commonwealth Fund conducted a search of the iOS and Android app stores for patient-facing
28 health apps for a broad set of medical conditions. Notably, upon evaluating the 1,046 apps related
29 to health care that were patient-facing based on criteria related to patient engagement, quality and
30 safety, 43 percent of iOS apps and 27 percent of Android apps appeared to be useful.³ Although the
31 Commonwealth Fund evaluated the health apps selected for this study for quality and safety, the
32 Council notes that its evaluation process was limited to analyses under its purview, and additional
33 efforts by industry to develop standards addressing the quality and safety of mHealth apps are
34 needed moving forward. Overall, while recent studies show promise in using mHealth apps for
35 patient engagement and treatment adherence, studies have also raised concerns regarding mHealth
36 app content and accuracy, which can pose threats to the health and safety of patients.^{2,4,5,6} The
37 nature of threats to patient safety differ based on what mHealth apps and associated devices
38 measure. For example, while apps that measure steps taken or calories consumed would be
39 considered to be lower-risk in nature, mHealth apps that are inaccurate in their blood pressure and
40 blood sugar readings, miscalculate insulin doses or misdiagnose skin cancer raise significant and
41 serious patient safety concerns.

42
43 **REGULATORY AND LEGISLATIVE ACTIVITY**

44
45 The Council notes that most mHealth apps available to consumers have not received clearance or
46 approval by the FDA. In 2015, the FDA released guidance on mobile medical applications for
47 industry and FDA staff.⁷ The guidance reiterated that the focus of FDA oversight of mobile health
48 apps is on those meeting the statutory definition of a medical device; either are intended to be used
49 as an accessory to a regulated medical device, or convert a mobile platform into a regulated
50 medical device; and pose a risk to patient safety if they do not function as intended. Accordingly,
51 the FDA regulates mobile health apps that use a mobile platform’s built-in features (light,

1 vibrations, camera, etc.) to perform medical device functions. In addition, the FDA regulates
2 mobile health apps that control the operation or function of an implantable or body worn medical
3 device. Finally, the FDA regulates mobile health apps that are used in active patient monitoring.⁸
4

5 The FDA has stated that it intends to exercise enforcement discretion for a subset of mobile health
6 apps that meet the definition of a medical device, but pose a low risk to the consumer. Therefore,
7 for these apps, the FDA's current guidance provides it does not intend to enforce requirements of
8 the Federal Food, Drug, and Cosmetic Act for this subset of mobile health apps that are medical
9 devices at this time. For example, mobile apps that fall into this category include those that assist
10 patients in managing their disease or conditions without providing specific treatment or treatment
11 suggestions, or provide patients with tools to organize and track their health information. In
12 addition, there are mobile health apps that are not considered medical devices, so the FDA does not
13 regulate them.
14

15 There is a noteworthy gap in ensuring the quality, safety, accuracy, effectiveness, and security of
16 mHealth apps, in part, due to the FDA's decision to exercise enforcement discretion with regard to
17 a broad category of medical devices apps coupled with the proliferation of mobile health apps that
18 do not meet the definition of medical device and, by law, are not subject to the FDA's jurisdiction.
19 As a result, several entities, including PatientView, Wellocracy and IMS Health's Appscript, are
20 moving forward with efforts to rate, evaluate and/or certify health apps.
21

22 In addition, the Federal Trade Commission (FTC), in cooperation with the FDA, the US
23 Department of Health and Human Services' Office for Civil Rights and Office of National
24 Coordinator for Health Information Technology (ONC), has developed the Mobile Health Apps
25 Interactive Tool to assist health app developers in ascertaining which federal laws apply to the
26 health app(s) they are developing, ranging from the Health Insurance Portability and
27 Accountability Act (HIPAA) to the FTC's Health Breach Notification Rule.⁹ In addition, the FTC
28 has offered best practices for mobile health app developers to build privacy and security into their
29 apps, as well as comply with the FTC Act, which prohibits deceptive or unfair acts or practices in
30 or affecting commerce, including those relating to privacy and data security, and those involving
31 false or misleading claims about apps' safety or performance.¹⁰
32

33 In addition to supporting health information technology (health IT) policy, ONC is charged with
34 establishing the certification and testing criteria for health IT products required by Centers for
35 Medicare & Medicaid Services (CMS) reporting programs. These programs, including the
36 electronic health records (EHR) incentive, or "Meaningful Use" program, require eligible
37 physicians to adopt and use health IT specifically designed to accommodate CMS objectives and
38 measures. While some base-level EHR functionality requirements can benefit physicians and
39 patients, CMS places additional requirements on the use of those functions – influencing the design
40 of the software. With the release of ONC's 2015 Edition Health IT Certification requirements, by
41 2018 many physicians participating in CMS reporting programs must use EHRs that include
42 application programming interfaces (API). These APIs will allow an app to access patient
43 information stored in the EHR.
44

45 Addressing health information privacy, the HIPAA Privacy, Security and Breach Notification
46 Rules apply only to covered entities, which include health plans, health care clearinghouses, and
47 health care providers, and their business associates. HIPAA generally does not apply to mHealth
48 apps, even if they handle or store an individual's health information. As such, mHealth apps are not
49 required to protect the privacy and security of an individual's health information in the same way
50 that a physician must because mHealth apps are not directly subject to HIPAA regulations.

1 Although HIPAA does not directly apply to mHealth apps, the HIPAA Security Rule sets out a
2 framework for safeguarding the content of transfers of protected health information. HIPAA
3 requires covered entities to consider encryption as an appropriate method of safeguarding protected
4 health information (PHI) and to encrypt electronic PHI if such a practice is considered a
5 “reasonable and appropriate” method of safeguarding PHI from environmental security threats.
6 Encryption offers the additional benefit of alleviating the physician from breach notification in the
7 event of impermissible use or disclosure. If the covered entity does not deem encryption to be a
8 reasonable and appropriate method of safeguarding PHI, then it must document the reasons for its
9 decision and adopt an equivalent alternative method for protecting PHI as necessary.
10

11 Legislation has been introduced in Congress in an effort to modify the FDA’s regulatory authority
12 and role in this space. Representative Marsha Blackburn (R-TX) introduced H.R. 2396, the
13 Sensible Oversight for Technology which Advances Regulatory Efficiency Act or the SOFTWARE
14 Act. An amended version of the legislation was passed by the US House of Representatives as part
15 of the 21st Century Cures Act. The SOFTWARE Act provides new statutory definitions and
16 categories of apps that would exempt health software from FDA regulation, including as a medical
17 device, with the exception of software that provides patient-specific recommendations and poses a
18 significant risk to patient safety. In addition, Senator Michael Bennet (D-CO) has introduced S.
19 1101, the Medical Electronic Data Technology Enhancement for Consumers’ Health Act or the
20 MEDTECH Act, which would exempt additional medical device software and mobile medical
21 devices from FDA regulation, and provide limitations on the software that would be regulated by
22 the FDA to protect patients.
23

24 COVERAGE AND PAYMENT OF MOBILE HEALTH APPS AND MEDICAL DEVICES 25

26 As payment models evolve, with payments to physicians and other health care entities being tied to
27 outcomes, digital and mobile health technologies are being increasingly used to manage patient
28 populations, improve patient access and engagement, and potentially control costs. Due to the wide
29 range of mHealth apps in the marketplace, the level of integration of applications into practice is
30 based on several factors, including whether or not the app and/or associated device are FDA-
31 cleared or approved; the demonstrated health benefit of the app and/or associated device; the
32 strength of research and data supporting the use of the health app and/or associated device; the
33 interoperability with EHR systems; outreach to physicians and patients; and patient and physician
34 out-of-pocket costs.
35

36 Typically, medical devices are covered by health insurance, conditioned on their FDA clearance
37 and approval, which can limit patient out-of-pocket costs. However, as most mHealth apps
38 currently will not be subject to clearance or approval by the FDA, the Council notes that health
39 insurance coverage of mHealth apps is likely to be an underutilized avenue to limit patient cost
40 exposure in this area in the near term. However, other financial incentives exist to spur patient
41 uptake of mHealth apps and associated devices, including eligibility for flexible spending account
42 (FSA) reimbursement and use in employee wellness programs, which could lead to a reduction in
43 employee health insurance premiums. Without mechanisms to limit patient cost exposure, patient
44 uptake of many mHealth apps and associated devices, trackers and sensors will depend on their
45 prices. This will be especially critical for low-income and elderly individuals, who could
46 potentially benefit from these digital health interventions.
47

48 There is a wide variation of how mobile apps are priced; pricing can include the initial purchase
49 price, in-app purchases and annual subscription costs. In addition, the functionality of some mobile
50 apps are dependent upon the purchase of an associated device, sensor or tracker. Increasingly,
51 sensors and trackers are increasingly built into the mobile device itself. One-third of apps studied

1 by IMS Institute for Healthcare Informatics in 2015 required a paid sensor for operation. More than
2 90 percent of mHealth apps are available to consumers at no cost.² The Council notes that mHealth
3 app costs can be hidden due to in-app techniques for purchasing and advertising. For those apps
4 that have a cost, the average price of an mHealth app doubled from \$1 to \$2 between 2013 and
5 2015. In this time period, there was also a four percent decrease in the percentage of mHealth apps
6 costing less than \$3 and an increase in the cost for apps over \$10. A significant proportion of the
7 most expensive mHealth apps available, the cost of which all exceed \$150, target therapeutic areas,
8 including for autism and augmentative and alternative communication.²

9
10 More than a third of US physicians have recommended an mHealth app to patients.² A noteworthy
11 barrier to physician adoption of mHealth apps is the lack of evidence demonstrating the
12 effectiveness, safety, and security of mHealth apps. In addition, within the fee-for-service payment
13 environment, there are insufficient pathways to incentivize physicians and other providers to
14 implement systems that use mobile apps and devices. Notably, the integration of mobile
15 applications and devices into practice is directly related to the ability of physicians to analyze and
16 interpret their data. Overall, payment mechanisms are necessary for physicians to allocate their
17 time to provide services including, but not limited to, the review, analysis and follow-up of
18 synthesized mHealth app data.

19
20 RELEVANT AMA POLICY AND ACTIVITIES

21
22 Policy H-480.946 outlines principles to guide the appropriate coverage of and payment for
23 telemedicine services, encourages additional research to develop a stronger evidence base for
24 telemedicine and supports pilot programs and demonstration projects to enable coverage of
25 telemedicine services and address how telemedicine can be integrated into new payment and
26 delivery models. Policy H-480.974 states that the AMA will work with CMS and other payers to
27 develop and test appropriate payment mechanisms for telemedicine through demonstration projects
28 aimed at evaluating the effect of care delivered by physicians using telemedicine-related
29 technology on costs, quality, and the patient-physician relationship. The policy also encourages
30 development of a code change application for Current Procedural Terminology (CPT) codes or
31 modifiers for telemedical services, to be submitted pursuant to CPT processes.

32
33 Addressing mobile applications and devices specifically, Policy D-480.972 states that our AMA
34 will monitor market developments in mHealth, including the development and uptake of mHealth
35 apps, in order to identify developing consensus that provides opportunities for AMA involvement.
36 The policy also states that our AMA will continue to engage with stakeholders to identify relevant
37 guiding principles to promote a vibrant, useful and trustworthy mHealth market. Important for the
38 integration of mHealth apps in medical practice, the policy states that our AMA will make an effort
39 to educate physicians on mHealth apps that can be used to facilitate patient communication, advice,
40 and clinical decision support, as well as resources that can assist physicians in becoming familiar
41 with mHealth apps that are clinically useful and evidence-based. Finally, the policy states that our
42 AMA will develop and publically disseminate a list of best practices guiding the development and
43 use of mobile medical applications.

44
45 Policy H-450.949 encourages physicians to become familiar with and capitalize on opportunities to
46 use technology to ensure patient safety in prescribing medications and medical devices. Policy
47 H-480.972 stresses that manufacturers are ultimately responsible for conducting the necessary
48 testing, research and clinical investigation to establish the safety and efficacy of medical devices
49 requiring FDA approval.

1 The AMA has been engaged in legislative and regulatory advocacy concerning mHealth apps and
2 coverage of telemedicine services, including remote patient monitoring. Federal and state advocacy
3 efforts have been focused on streamlining and updating regulatory oversight and expanding private
4 and public payer coverage. In addition, the AMA submitted comments for the record to the
5 Subcommittee on Commerce, Manufacturing and Trade of the House Energy and Commerce
6 Committee addressing health care apps.

7
8 The AMA also has hosted regular meetings with national medical specialty societies to encourage
9 the development of objectives and initiatives to support digital medicine adoption, including the
10 use of telemedicine and mobile medical apps. The AMA is a member of Health Level Seven
11 International (HL7), a not-for-profit, standards developing organization accredited by the American
12 National Standards Institute (ANSI), with its current Fast Healthcare Interoperability Resources
13 (FHIR) standard being recognized as having the capacity to facilitate interoperability in the
14 mHealth space. The AMA is working with others to develop an industry collaborative representing
15 diverse stakeholder perspectives whose objective is to develop guidance for the mHealth
16 community that focuses on issues of importance to physicians and their patients, to be used in the
17 development and evaluation of digital health tools. This activity and forthcoming guidance will
18 fulfill the intent of Policy D-480.972, which calls for the AMA to develop and publically
19 disseminate a list of best practices guiding the development and use of mobile medical
20 applications.

21
22 The AMA is a founding partner of Health2047, an integrated health care innovation company that
23 is working to develop and make available system-level solutions that enhance care delivery and
24 practice of medicine. One of the purposes of Health2047 is to catalyze collaboration across a
25 network of partners including technology firms, product companies, physicians and payers to drive
26 rapid and responsive change that makes new solutions possible. Health2047 incorporates physician
27 perspectives to inform every step – from the design process, to testing prototypes, early access to
28 solutions, and the ability to submit ideas of their own – so that health technology solutions work
29 well in the practice setting and benefit physicians and patients.

30
31 Another partnership includes the AMA at MATTER, an effort to support ideation and collaboration
32 with hundreds of entrepreneurs to ensure the physician perspective is included in the development
33 of new tools and innovative solutions from the outset, and includes an interaction studio so
34 entrepreneurs are able to test their solutions in a simulated clinical and non-clinical environment
35 and collaborate with physicians virtually. Since the partnership was established in 2015, hundreds
36 of physicians have visited MATTER or offered insight and feedback to entrepreneurs working on
37 early stage technologies and solutions. Additionally, the AMA at MATTER partnership has
38 brought physicians and entrepreneurs together for a variety of educational workshops, interactive
39 simulations, and collaboration events focused on optimizing health care.

40
41 Furthermore, since 2014, the AMA has been an active participant and board member of the
42 Substitutable Medical Applications & Reusable Technology Platforms project. This initiative with
43 Boston Children's Hospital and Harvard University's Medical School is working to use a mobile
44 app infrastructure to improve existing EHR technology and enhance interoperability. The project
45 also promotes the development and use of mobile health apps with the goal of making such
46 applications widely available to practicing physicians and patients.

47
48 The AMA conducted a survey of 1,300 physicians during the summer of 2016, which focused on
49 physicians' understanding digital health and their attitudes regarding adoption. The survey covered
50 a broad range of digital health tools, including telemedicine and telehealth, mobile health apps,
51 wearables and remote patient monitoring technologies. The purpose of the survey was to obtain a

1 summary view of physicians' thoughts regarding digital health, to understand what motivates them
2 to want to use various emerging digital tools, and what their requirements are for successfully
3 integrating them into patient care and their practices. The survey results and report were released at
4 the end of September, and can be accessed at ama-assn.org/ama/pub/news/news/2016/2016-09-26-digital-health-innovation_page. Survey results show that in order to spur physician adoption of
5 digital health technologies, including mobile health apps, physicians require such tools to fit within
6 their existing systems and practices, including being linked to and working within their EHRs. The
7 survey found that physicians need experts to ensure the data privacy and security of such tools.
8 Results also indicated that physicians need digital health tools to be covered by liability insurance
9 and linked to appropriate physician payment. In addition, as part of its work to bridge and increase
10 interactions between physicians and digital health stakeholders, the AMA has plans to pilot the
11 AMA Physician Innovation Network, which will connect physicians and health technology
12 entrepreneurs and industry for interaction and feedback. The AMA continues to monitor the
13 evolution of the digital health sector.
14

15

16

DISCUSSION

17

18 The Council believes that digital health, including the utilization of mobile health apps and devices,
19 has the potential to be integrated into everyday practice in order to promote improved patient health
20 outcomes, support care coordination and improve communication. The Council believes that,
21 moving forward, there needs to be a balance between innovation and appropriate industry standards
22 for mHealth apps and FDA regulation of mobile medical devices. For those mHealth apps and
23 mobile medical devices that are subject to FDA review and approval, FDA resources need to be
24 sufficient to respond to the number of mHealth products under its jurisdiction. Policy H-100.980
25 supports a strong and adequately funded FDA to ensure that safe and effective medical products are
26 made available to the American public as efficiently as possible.

27

28 While some mobile apps and devices are subject to FDA regulation, others are not, and do not
29 undergo rigorous evaluation before deployment for general use, which raises quality and patient
30 safety concerns. However, without ensuring that there is strong and sufficient evidence that
31 provides clinical validation to mHealth apps and associated devices, trackers and sensors, the
32 Council recognizes that physicians will not fully integrate mHealth apps into their practices. In
33 addition, health insurers will not be as likely to consider payment for interventions stemming from
34 mHealth apps, and employers will not be as likely to incorporate mHealth apps in their wellness
35 programs. As such, the Council believes more investment is needed in expanding the evidence base
36 necessary to show the accuracy, effectiveness, safety and security of mHealth apps, and believes
37 that research should also focus on showing the impact of mHealth apps on costs, practice
38 efficiencies and improvement in outcomes to facilitate mHealth app uptake and integration in
39 alternative payment models. Overall, coverage of and payment for mHealth apps and associated
40 devices should be contingent upon a clinical evidence base to support their use in order to ensure
41 app safety and effectiveness.

42

43 It is also essential for mHealth apps to follow evidence-based practice guidelines, to the degree
44 they are available, to ensure patient safety, quality of care and positive health outcomes. The
45 Council believes that national medical specialty societies have a key role in developing guidelines
46 for the integration of mHealth apps and associated devices into care delivery.

47

48 Other obstacles to the acceptance and widespread utilization of mHealth technologies include the
49 current drivers of physician payment, as well as health insurance coverage and other mechanisms
50 to limit patient cost exposure or provide financial incentives to patients. While the shift to
51 alternative payment models is propelling the increased use of digital and mobile health tools, the

1 lack of insurance payment for related services remains an obstacle. Health insurance payment for
2 mobile apps and associated devices has the potential to serve as a pathway to assist patients and
3 physicians in monitoring patient health indicators, as well as improve medication and treatment
4 adherence. For any mHealth app or device that facilitates the delivery of any telemedicine service,
5 the Council stresses that Policy H-480.946, which guides the appropriate coverage of and payment
6 for telemedicine services, must be followed. In addition, the Council believes that additional
7 principles are necessary to guide health plan coverage and payment decisions, employer wellness
8 program inclusions and FSA eligibility determinations concerning mHealth apps and associated
9 devices, in order to protect the patient-physician relationship, support care delivery that is patient-
10 centered, promote care coordination and facilitate team-based communication.

11
12 The Council believes that prescriptive requirements on the use of EHRs have negatively affected
13 the usability of these tools. Many health information technology (health IT) developers are forced
14 to prioritize the design of their products to meet ONC and CMS demands, contributing to physician
15 dissatisfaction and burnout. The Council is concerned that, while new certification requirements
16 can improve data access for physicians and patients through the use of APIs and apps, many
17 developers will limit software functionality to that of federal requirements. This, coupled with
18 continued interoperability issues, may detract from app uptake, and could taint the rapidly maturing
19 mHealth industry. The Council believes that CMS, ONC, and other federal agencies must
20 acknowledge the history of EHR development, the unintended consequences of the Meaningful
21 Use program, and allow new payment models and user demand to shape health IT functionality
22 going forward. Furthermore, mHealth app developers should strive to incorporate physician and
23 patient input early in the development of their products and allocate resources to ensure design
24 reflects user needs.

25
26 The Council recognizes that physicians can contribute to increases in patient retention rates for
27 mHealth apps. Before prescribing any mHealth app or associated device, the usability of data from
28 mobile apps and devices will remain a priority for physicians and their patients, as the success of
29 mHealth apps in the long term will depend on the level and quality of connectivity between
30 patients, apps and devices, and physicians and other health care providers. Overall, interoperability
31 between a patient's mobile technology and EHRs will be an asset, as physicians must be able to
32 meaningfully use the volumes of data mHealth apps and devices create. As such, EHRs must have
33 the capacity to download and synthesize data from such mobile technologies. In addition, there
34 must be mechanisms for physician payment to allow for the review, analysis and follow-up of
35 synthesized mHealth app data.

36
37 Patient privacy and data security need to be a priority in the digital health space, as mobile apps
38 and devices can be subject to privacy and data breaches. Accordingly, the Council recommends
39 that mHealth apps and associated devices, trackers and sensors must abide by applicable laws
40 addressing the privacy and security of patients' medical information. In addition, physicians should
41 consider whether the mHealth apps they wish to use offer encryption, and whether the level of
42 encryption satisfies HIPAA's standards. Mobile health app developers may not readily disclose
43 whether their apps are encrypted, and the level of encryption may be unclear. If the physician is
44 unsure of whether the mHealth app meets HIPAA's standards, he or she should consult with
45 qualified legal counsel; the physician should also inquire about any applicable state privacy and
46 security laws. Given the lack of regulation of mHealth apps, regardless of whether an mHealth
47 device is encrypted, physicians should alert patients to the potential privacy and security risks of
48 any mHealth apps that he or she prescribes or recommends, and document the patient's
49 understanding of such risks. The Council recognizes that questions remain regarding liability risks
50 to physicians who use, recommend or prescribe mHealth apps. As such, the Council believes that
51 the AMA should assess the potential liability risks to physicians for using, recommending, or

1 prescribing mHealth apps, including risk under federal and state medical liability, privacy, and
2 security laws.

3
4 Patients must also be aware of the level at which their information and data are protected by
5 mHealth apps. For apps that collect, store and/or transmit protected health information, the Council
6 believes that a standard privacy notice should be provided to patients. To the extent a physician, as
7 a HIPAA-covered entity, incorporates an app into his or her practice, HIPAA is implicated and
8 physicians should revisit their HIPAA Notice of Privacy Practices to ensure apps are appropriately
9 addressed and secured. Overall, there is a need for the mobile app industry and other relevant
10 stakeholders to conduct industry-wide outreach and provide necessary educational materials to
11 patients to promote increased awareness of the varying levels of privacy and security of their data
12 in mHealth apps, and how their information and data can potentially be collected and used.

13
14 RECOMMENDATIONS

15
16 The Council on Medical Service recommends that the following be adopted and the remainder of
17 the report be filed:

18
19 1. That our American Medical Association (AMA) reaffirm Policy H-480.946, which outlines
20 principles to guide the appropriate coverage of and payment for telemedicine services.
21 (Reaffirm HOD Policy)

22
23 2. That our AMA reaffirm Policy H-100.980, which supports a strong and adequately funded US
24 Food and Drug Administration to ensure that safe and effective medical products are made
25 available to the American public as efficiently as possible. (Reaffirm HOD Policy)

26
27 3. That our AMA support the establishment of coverage, payment and financial incentive
28 mechanisms to support the use of mobile health applications (mHealth apps) and associated
29 devices, trackers and sensors by patients, physicians and other providers that:
30
31 a) support the establishment or continuation of a valid patient-physician relationship;
32 b) have a clinical evidence base to support their use in order to ensure mHealth app safety and
33 effectiveness;
34 c) follow evidence-based practice guidelines, to the degree they are available, to ensure
35 patient safety, quality of care and positive health outcomes;
36 d) support care delivery that is patient-centered, promotes care coordination and facilitates
37 team-based communication;
38 e) support data portability and interoperability in order to promote care coordination through
39 medical home and accountable care models;
40 f) abide by state licensure laws and state medical practice laws and requirements in the state
41 in which the patient receives services facilitated by the app;
42 g) require that physicians and other health practitioners delivering services through the app be
43 licensed in the state where the patient receives services, or be providing these services as
44 otherwise authorized by that state's medical board; and
45 h) ensure that the delivery of any services via the app be consistent with state scope of
46 practice laws. (New HOD Policy)

47
48 4. That our AMA support that mHealth apps and associated devices, trackers and sensors must
49 abide by applicable laws addressing the privacy and security of patients' medical information.
50 (New HOD Policy)

- 1 5. That our AMA encourage the mobile app industry and other relevant stakeholders to conduct
- 2 industry-wide outreach and provide necessary educational materials to patients to promote
- 3 increased awareness of the varying levels of privacy and security of their information and data
- 4 afforded by mHealth apps, and how their information and data can potentially be collected and
- 5 used. (New HOD Policy)
- 6
- 7 6. That our AMA encourage the mHealth app community to work with the AMA, national
- 8 medical specialty societies, and other interested physician groups to develop app transparency
- 9 principles, including the provision of a standard privacy notice to patients if apps collect, store
- 10 and/or transmit protected health information. (New HOD Policy)
- 11
- 12 7. That our AMA encourage physicians to consult with qualified legal counsel if unsure of
- 13 whether an mHealth app meets Health Insurance Portability and Accountability Act standards
- 14 and also inquire about any applicable state privacy and security laws. (New HOD Policy)
- 15
- 16 8. That our AMA encourage physicians to alert patients to the potential privacy and security risks
- 17 of any mHealth apps that he or she prescribes or recommends, and document the patient's
- 18 understanding of such risks. (New HOD Policy)
- 19
- 20 9. That our AMA assess the potential liability risks to physicians for using, recommending, or
- 21 prescribing mHealth apps, including risk under federal and state medical liability, privacy, and
- 22 security laws. (Directive to Take Action)
- 23
- 24 10. That our AMA support further development of research and evidence regarding the impact that
- 25 mHealth apps have on quality, costs, patient safety and patient privacy. (New HOD Policy)
- 26
- 27 11. That our AMA encourage national medical specialty societies to develop guidelines for the
- 28 integration of mHealth apps and associated devices into care delivery. (New HOD Policy)

Fiscal Note: Less than \$5,000.

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 7-I-16

Subject: Hospital Discharge Communications

Presented by: Peter S. Lund, MD, Chair

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 At the 2016 Annual Meeting, the House of Delegates adopted the recommendations of Council on
2 Medical Service Report 6, which addressed communication and care coordination between
3 hospital physicians and their community counterparts during patient hospitalizations (see Policy
4 H-225.946). While developing that report, the Council agreed that communications during the
5 hospital discharge process, which can be a confusing and potentially dangerous time for patients,
6 should be examined in a separate report.

7
8 This report, initiated by the Council, provides background on communications during the hospital
9 discharge process, summarizes relevant AMA policy and principles, and makes recommendations
10 for new policy to help safeguard patients as they transition home from hospitals or to continuing
11 care facilities.

12 BACKGROUND 13

14 Suboptimal or delayed communication between hospital and community physicians, and between
15 physicians and patients, can lead to serious and costly post-discharge problems, including adverse
16 events and hospital readmissions. Conversely, effective communication during the discharge period
17 results in more seamless and safe care during this critical transition. An estimated 19 to 23 percent
18 of patients experience an adverse event in the period following hospital discharge,¹ costing the
19 health care system an estimated \$12 - \$44 billion per year.² Twenty percent of Medicare patients
20 are readmitted to hospitals within 30 days of discharge, and approximately one-third of these
21 readmissions could be avoided with improved transitional care.³ Notably, more than one-third of
22 post-discharge follow-up testing is never completed.⁴ Hospitals are penalized financially for excess
23 readmissions associated with certain conditions and, this year, Medicare's readmission penalties
24 have reached a new high.

25
26 At the time of discharge, hospital-based physicians—generally hospitalists or proceduralists—hand
27 over clinical responsibility for patients to primary care or other community physicians, or post-
28 acute care facilities. The discharge summary is typically used during discharge transitions to
29 document diagnostic findings and plans for post-discharge follow-up care. The Joint Commission
30 stipulates that discharge summaries include the following elements: the reason for the
31 hospitalization; significant findings; procedures and treatments provided; the patient's condition at
32 discharge; instructions for patients and families, including necessary follow-up, medication
33 changes and dietary needs; and the attending physician's signature. Notwithstanding these
34 standards, hospital discharge summaries vary in terms of content, quality and relevancy. Discharge
35 summaries may be incomplete or lack salient patient information such as pending diagnostic or
36 laboratory tests. Transmittal of discharge summaries to outpatient physicians may be delayed or
37

1 never reach the appropriate treating physicians. Patients and/or their families may not fully
2 understand discharge instructions and the importance of follow-up appointments and treatment.
3

4 Evidence in the literature has identified widespread deficits in communication at the time of
5 discharge⁵ between physicians overseeing hospital care and community physicians. Many errors
6 and adverse patient events during this time period are the result of communication failures,⁶ with
7 the majority of post-discharge problems related to medications. A recent meta-analysis of
8 interventions to improve care transitions for adults with chronic illnesses suggests that high
9 intensity interventions may be needed to prevent hospital readmissions in the early time period
10 following hospitalization.⁷ This study found an association between reduced 30-day hospital
11 readmission rates and interventions consisting of communication between the hospital and primary
12 care provider, care coordination by a nurse, and a home visit by a nurse within three days of
13 discharge.

14

15 Quality improvement projects that have demonstrated reductions in hospital readmissions by
16 improving hospital discharge processes are numerous and varied. Examples of effective,
17 multifaceted interventions include the SafeMed care transitions model, Project BOOST (Better
18 Outcomes for Older Adults through Safe Transitions), and Project RED (Re-Engineered
19 Discharge). SafeMed uses intensive medication reconciliation, home visits and telephone follow-up
20 to manage high-risk/high needs patients as they transition from the hospital to outpatient setting. As
21 part of its *STEPS Forward*TM initiative, the AMA developed a module for implementing the
22 SafeMed model within primary care practices. Project BOOST is the Society of Hospital
23 Medicine's signature mentoring program for improving the care of patients as they transition home
24 from the hospital or to other care facilities. Project RED, developed by Boston University Medical
25 Center, is a multilayered intervention that includes dedicated discharge advocates, improved
26 medication reconciliation and enhanced discharge instructions.

27

28 *Patient/Family Engagement*

29

30 Communication between physicians and patients and those persons who will be caring for patients
31 post-discharge is an important component of successful care transitions, and a review of the
32 literature has found deficits in this area as well.⁸ Failure to adequately educate patients about health
33 care decisions and follow-up care; lower levels of health literacy among some patients; and time
34 constraints have been found to contribute to suboptimal care transitions.⁹ Patients with limited
35 education and non-English speakers are less likely to have adequate discharge understanding and
36 more likely to be re-hospitalized. Shared decision-making and patient-centered discharge planning
37 are two factors identified as countering barriers to patient engagement.

38

39 A proposed rule by the Centers for Medicare & Medicaid Services (CMS), in the fall of 2015
40 highlighted the importance of focusing on patients' goals and preferences during the hospital
41 discharge process, and also better preparing patients and their families/caregivers to be active
42 partners in post-discharge care. The proposed rule implements the requirements of the Improving
43 Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. It proposed modifying hospital
44 Conditions of Participation by requiring all hospital inpatients, as well as many outpatients—
45 including those receiving observation care or undergoing same-day procedures that require
46 sedation—to be evaluated for their discharge needs and have a written plan developed. Discharge
47 plans would need to be developed within 24 hours of admission, completed before the patient is
48 discharged, and sent to the physician responsible for follow-up care within 48 hours of discharge.
49 The proposed rule would also require a medication reconciliation process and a post-discharge
50 follow-up process. Hospitals would be required to provide detailed discharge instructions to

1 patients going home and to continuing care facilities for patients being discharged to these settings.
2 A post-discharge follow-up process to check on patients who return home would also be required.¹⁰
3

4 *Physician Payment*
5

6 Current Procedural Terminology (CPT) Codes 99238 and 99239 can be used by hospital-based
7 physicians to bill for a hospital discharge day management service if there is a face-to-face
8 encounter between the patient and attending physician. Medicare also pays for transitional care
9 management (TCM), or services delivered during the 30 days after hospital discharge. TCM
10 services must be furnished to patients who have medical and/or psychosocial problems that require
11 moderate or high complexity medical decision-making.¹¹ Providers are required to contact patients
12 within two business days by telephone or e-mail, or meet them face-to-face. Face-to-face visits are
13 required within seven to 14 days, depending on whether the moderate complexity code (CPT
14 99494) or the high complexity code (CPT 99496) is used.

15
16 **AMA POLICY**
17

18 The AMA has extensive policy on care transitions, including hospital discharge. Policy H-160.942
19 established comprehensive, evidence-based principles addressing discharge criteria, teamwork
20 involved in discharge planning, contingency plans for adverse events, and communication. Policy
21 H-160.942 makes clear that responsibility and accountability for patients transitioning care settings
22 rests with attending physicians, who are responsible for ensuring that physicians and facilities
23 providing care in new settings are fully informed about the patient. Policy H-160.942 also
24 maintains that the transfer of all pertinent information about the patient, and the discharge
25 summary, should be completed before or at the time the patient is transferred to another setting.
26 Policy H-160.942 in its entirety is appended to this report.

27
28 AMA policy recognizes the importance of effective communication between hospital-based and
29 primary care physicians. Policy D-160.945 directs the AMA to advocate for timely and consistent
30 inpatient and outpatient communications among hospital-based physicians and the patient's
31 primary care referring physician to decrease gaps that may occur in the coordination of care
32 process. Policy D-160.945 directs the AMA to explore new mechanisms to facilitate and
33 incentivize this communication and the transmission of important data. Policy H-155.994
34 encourages the sharing of patients' diagnostic findings and urges hospitals to return information to
35 attending physicians at patient discharge.

36
37 Policy D-120.965 supports medication reconciliation as a means to improve patient safety, and
38 calls for systems to support physicians in medication reconciliation. The AMA has numerous
39 policies on usability and interoperability of electronic health records (EHRs), including Policy
40 D-478.995 on health information technology (health IT).

41
42 **DISCUSSION**
43

44 The Council recognizes that the health care landscape is evolving in terms of care delivery models
45 and improvements in health IT, and that implementation of a single hospital discharge standard
46 across diverse clinical practice settings is impractical at this time. Improved EHR capabilities,
47 which will enable more widespread use of direct messaging (e.g., admit/discharge/transfer
48 messaging) and standardized electronic forms (e.g., the Continuity of Care Document), have the
49 potential to enhance communication and the timely exchange of patient information among
50 providers across multiple care settings. The Council recognizes that the AMA continues to engage
51 in extensive advocacy to improve EHRs and address technology barriers that impede the exchange

1 of meaningful patient information during care transitions, and that numerous AMA policies guide
2 this work. The Council recommends reaffirming Policy D-478.995, which directs the AMA to
3 continue its advocacy to expedite interoperability of EHR systems, standardize key EHR elements,
4 and engage the vendor community to promote improvements in EHR usability.

5
6 After reviewing the literature and extensive AMA policy on care transitions, the Council
7 appreciates the need for a more refined discharge process that improves the quality and safety of
8 patient care and reduces the incidence of adverse events and hospital readmissions. Recognizing
9 that multi-component interventions are more likely to reduce readmissions, the Council has
10 identified several critical elements that can be adapted locally.

11
12 The Council further recognizes that consistent physician-to-physician communication across care
13 settings is integral to achieving an efficient, patient-centered discharge process. Because
14 community physicians who are knowledgeable of their patients' hospitalizations are better prepared
15 to provide appropriate discharge follow-up, Council on Medical Service Report 6-A-16
16 recommended prompt notification to community physicians of patient hospitalizations, and also the
17 timely exchange of relevant patient information. Communication between hospital and community
18 physicians at the time of discharge, and the timely transfer of patient information between hospitals
19 and providers responsible for patients' follow-up care, are also addressed in Policies H-160.942
20 and D-160.945. The Council believes that the comprehensive, evidence-based discharge principles
21 and criteria outlined in Policy H-160.942 remain relevant and recommends that this policy be
22 reaffirmed. The Council further recommends reaffirmation of Policy D-160.945, which supports
23 timely and consistent communication between physicians in inpatient and outpatient care settings.
24 AMA policies recommended for reaffirmation are appended to this report.

25
26 The Council discussed timing of discharge planning and completion of discharge summaries and
27 points to existing policy stating that discharge summaries should be completed before or at the time
28 of patient transfer, and discouraging discharge timing requirements by Congress for specific
29 treatments or procedures (Policy H-160.942). The Council believes engagement of patients and
30 their families/caregivers at the time of hospital admission, and before hospitalization for surgical
31 patients, will lead to greater patient self-management and participation in their care, especially
32 during brief hospitalizations. Accordingly, the Council recommends that the AMA encourage the
33 initiation of the discharge planning process, whenever possible, at the time patients are admitted for
34 inpatient or observation services and before patients scheduled for surgery are hospitalized.

35
36 The Council recognizes the frustration with lengthy discharge documents that do not highlight key
37 points, often requiring physicians to sift through numerous pages of patient information.
38 Accordingly, the Council recommends that the AMA encourage the development of discharge
39 summaries that are presented to physicians in a meaningful format that prominently highlights
40 salient patient information, such as the discharging physician's narrative and recommendations for
41 ongoing care.

42
43 The Council discussed the importance of engaging patients and their families/caregivers in the
44 discharge process to increase patient involvement in discharge planning and encourage self-
45 management of care after hospitalizations. Communication with patients, and those persons who
46 will be caring for patients post-discharge, is critical to improving patient outcomes and preventing
47 re-hospitalizations and emergency department visits. The Council believes it is good clinical
48 practice to not only provide detailed discharge instructions and education, but also to confirm
49 understanding of this information by patients and their families/caregivers. Accordingly, the
50 Council recommends new AMA policy that encourages active engagement of patients and their
51 families/caregivers in the discharge process, and offers guidelines to ensure that patient needs,

1 including communication needs, are taken into account and that discharge instructions are fully
2 understood.

3
4 In its review of the literature, the Council found that medication reconciliation is an effective
5 strategy for preventing adverse patient events in the post-discharge period. Medication
6 reconciliation is the process of creating the most accurate list of medications a patient is taking, and
7 comparing that list against the medications included in the physician's discharge summary. The
8 Council recommends that the AMA encourage implementation of medication reconciliation as part
9 of the hospital discharge process, and outlines strategies to help ensure that patients take their
10 medications correctly post-hospitalization.

11
12 The Council also found that successful discharge interventions often include protocols for post-
13 discharge follow-up. Communicating with patients post hospitalization—in their homes or
14 continuing care facilities, or by telephone or e-mail—helps ensure adherence to discharge
15 instructions and may also uncover symptoms that need attention. Accordingly, the Council
16 recommends that our AMA encourage follow-up in the early time period after discharge as part of
17 the hospital discharge process, particularly for medically complex patients who are at high risk of
18 re-hospitalization.

19
20 Finally, the Council maintains that hospitals should evaluate their discharge processes on a regular
21 basis to ensure that they incorporate patients' post-discharge needs. The Council therefore
22 recommends that the AMA encourage hospitals to review early readmissions and modify their
23 discharge processes accordingly. Taken together, the Council is optimistic that these
24 recommendations will be an impactful addition to existing AMA policy on care transitions,
25 including the discharge period.

26
27 **RECOMMENDATIONS**
28

29 The Council on Medical Service recommends that the following be adopted and the remainder of
30 the report be filed:

31
32 1. That our American Medical Association (AMA) reaffirm Policy D-478.995, which directs the
33 AMA to continue its extensive advocacy to expedite interoperability of electronic health record
34 (EHR) systems, standardize key EHR elements, and engage the vendor community to promote
35 improvements in EHR usability. (Reaffirm HOD Policy)

36
37 2. That our AMA reaffirm Policy H-160.942, which outlines evidence-based discharge criteria
38 and principles regarding discharge planning, teamwork, communication, responsibility/
39 accountability among attending physicians and continuing care providers, as well as the
40 transfer of pertinent patient information and the discharge summary. (Reaffirm HOD Policy)

41
42 3. That our AMA reaffirm Policy D-160.945, which directs the AMA to advocate for timely and
43 consistent communication between physicians in inpatient and outpatient care settings to
44 decrease gaps in care coordination and improve quality and patient safety, and to explore new
45 mechanisms to facilitate and incentivize this communication. (Reaffirm HOD Policy)

46
47 4. That our AMA encourage the initiation of the discharge planning process, whenever possible,
48 at the time patients are admitted for inpatient or observation services and, for surgical patients,
49 prior to hospitalization. (New HOD Policy)

- 1 5. That our AMA encourage the development of discharge summaries that are presented to
- 2 physicians in a meaningful format that prominently highlight salient patient information, such
- 3 as the discharging physician's narrative and recommendations for ongoing care. (New HOD
- 4 Policy)
- 5
- 6 6. That our AMA encourage hospital engagement of patients and their families/caregivers in the
- 7 discharge process, using the following guidelines:
- 8
- 9 a. Information from patients and families/caregivers is solicited during discharge
- 10 planning, so that discharge plans are tailored to each patient's needs, goals of care and
- 11 treatment preferences.
- 12 b. Patient language proficiency, literacy levels, cognitive abilities and communication
- 13 impairments (e.g., hearing loss) are assessed during discharge planning. Particular
- 14 attention is paid to the abilities and limitations of patients and their families/caregivers.
- 15 c. Specific discharge instructions are provided to patients and families or others
- 16 responsible for providing continuing care both verbally and in writing. Instructions are
- 17 provided to patients in layman's terms, and whenever possible, using the patient's
- 18 preferred language.
- 19 d. Key discharge instructions are highlighted for patients to maximize compliance with
- 20 the most critical orders.
- 21 e. Understanding of discharge instructions and post-discharge care, including warning
- 22 signs and symptoms to look for and when to seek follow-up care, is confirmed with
- 23 patients and their families/caregiver(s) prior to discharge from the hospital. (New HOD
- 24 Policy)
- 25
- 26 7. That our AMA support implementation of medication reconciliation as part of the hospital
- 27 discharge process. The following strategies are suggested to optimize medication reconciliation
- 28 and help ensure that patients take medications correctly after they are discharged:
- 29
- 30 a. All discharge medications, including prescribed and over-the-counter medications,
- 31 should be reconciled with medications taken pre-hospitalization.
- 32 b. An accurate list of medications, including those to be discontinued as well as
- 33 medications to be taken after hospital discharge, and the dosage and duration of each
- 34 drug, should be communicated to patients.
- 35 c. Medication instructions should be communicated to patients and their
- 36 families/caregivers verbally and in writing.
- 37 d. For patients with complex medication schedules, the involvement of physician-led
- 38 multidisciplinary teams in medication reconciliation including, where feasible,
- 39 pharmacists should be encouraged. (New HOD Policy)
- 40
- 41 8. That our AMA encourage patient follow-up in the early time period after discharge as part of
- 42 the hospital discharge process, particularly for medically complex patients who are at high-risk
- 43 of re-hospitalization. (New HOD Policy)
- 44
- 45 9. That our AMA encourage hospitals to review early readmissions and modify their discharge
- 46 processes accordingly. (New HOD Policy)

Fiscal Note: Less than \$500.

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Appendix

H-160.942 Evidence-Based Principles of Discharge and Discharge Criteria

- (1) The AMA defines discharge criteria as organized, evidence-based guidelines that protect patients' interests in the discharge process by following the principle that the needs of patients must be matched to settings with the ability to meet those needs.
- (2) The AMA calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients and that are flexible to meet advances in medical and surgical therapies and adapt to local and regional variations in health care settings and services.
- (3) The AMA encourages incorporation of discharge criteria into practice parameters, clinical guidelines, and critical pathways that involve hospitalization.
- (4) The AMA promotes the local development, adaption and implementation of discharge criteria.
- (5) The AMA promotes training in the use of discharge criteria to assist in planning for patient care at all levels of medical education. Use of discharge criteria will improve understanding of the pathophysiology of disease processes, the continuum of care and therapeutic interventions, the use of health care resources and alternative sites of care, the importance of patient education, safety, outcomes measurements, and collaboration with allied health professionals.
- (6) The AMA encourages research in the following areas: clinical outcomes after care in different health care settings; the utilization of resources in different care settings; the actual costs of care from onset of illness to recovery; and reliable and valid ways of assessing the discharge needs of patients.
- (7) The AMA endorses the following principles in the development of evidence-based discharge criteria and an organized discharge process:
 - (a) As tools for planning patients' transition from one care setting to another and for determining whether patients are ready for the transition, discharge criteria are intended to match patients' care needs to the setting in which their needs can best be met.
 - (b) Discharge criteria consist of, but are not limited to:
 - (i) Objective and subjective assessments of physiologic and symptomatic stability that are matched to the ability of the discharge setting to monitor and provide care.
 - (ii) The patient's care needs that are matched with the patient's, family's, or caregiving staff's independent understanding, willingness, and demonstrated performance prior to discharge of processes and procedures of self care, patient care, or care of dependents.
 - (iii) The patient's functional status and impairments that are matched with the ability of the care givers and setting to adequately supplement the patients' function.
 - (iv) The needs for medical follow-up that are matched with the likelihood that the patient will participate in the follow-up. Follow-up is time-, setting-, and service-dependent. Special considerations must be taken to ensure follow-up in vulnerable populations whose access to health care is limited.
 - (c) The discharge process includes, but is not limited to:
 - (i) Planning: Planning for transition/discharge must be based on a comprehensive assessment of the patient's physiological, psychological, social, and functional needs. The discharge planning process should begin early in the course of treatment for illness or injury (prehospitalization for elective cases) with involvement of patient, family and physician from the beginning.
 - (ii) Teamwork: Discharge planning can best be done with a team consisting of the patient, the family, the physician with primary responsibility for continuing care of the patient, and other appropriate health care professionals as needed.

- (iii) Contingency Plans/Access to Medical Care: Contingency plans for unexpected adverse events must be in place before transition to settings with more limited resources. Patients and caregivers must be aware of signs and symptoms to report and have a clearly defined pathway to get information directly to the physician, and to receive instructions from the physician in a timely fashion.
- (iv) Responsibility/Accountability: Responsibility/accountability for an appropriate transition from one setting to another rests with the attending physician. If that physician will not be following the patient in the new setting, he or she is responsible for contacting the physician who will be accepting the care of the patient before transfer and ensuring that the new physician is fully informed about the patient's illness, course, prognosis, and needs for continuing care. If there is no physician able and willing to care for the patient in the new setting, the patient should not be discharged. Notwithstanding the attending physician's responsibility for continuity of patient care, the health care setting in which the patient is receiving care is also responsible for evaluating the patient's needs and assuring that those needs can be met in the setting to which the patient is to be transferred.
- (v) Communication: Transfer of all pertinent information about the patient (such as the history and physical, record of course of treatment in hospital, laboratory tests, medication lists, advanced directives, functional, psychological, social, and other assessments), and the discharge summary should be completed before or at the time of transfer of the patient to another setting. Patients should not be accepted by the new setting without a copy of this patient information and complete instructions for continued care.

(8) The AMA supports the position that the care of the patient treated and discharged from a treating facility is done through mutual consent of the patient and the physician; and

(9) Policy programs by Congress regarding patient discharge timing for specific types of treatment or procedures be discouraged. (CSA Rep. 4, A-96; Reaffirmation I-96; Modified by Res. 216, A-97; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed: BOT Rep. 1, A-08)

D-160.945 Communication Between Hospitals and Primary Care Referring Physicians

Our AMA: (1) advocates for continued Physician Consortium for Performance Improvement® (PCPI) participation in the American College of Physicians (ACP), the Society of General Internal Medicine (SGIM), and the Society of Hospital Medicine (SHM) work to develop principles and standards for care transitions that occur between the inpatient and outpatient settings; (2) advocates for timely and consistent inpatient and outpatient communications to occur among the hospital and hospital-based providers and physicians and the patient's primary care referring physician; including the physician of record, admitting physician, and physician-to-physician, to decrease gaps that may occur in the coordination of care process and improve quality and patient safety; (3) will continue its participation with the Health Information Technology Standards Panel (HITSP) and provide input on the standards harmonization and development process; (4) continues its efforts with The Joint Commission, the Centers for Medicare & Medicaid Services, and state survey and accreditation agencies to develop accreditation standards that improve patient safety and quality; and (5) will explore new mechanisms to facilitate and incentivize communication and transmission of data for timely coordination of care (via telephone, fax, e-mail, or face-to-face communication) between the hospital-based physician and the primary physician. (BOT Rep. 1, A-08; Reaffirmed in lieu of Res. 731, A-09; Appended: Res. 722, A-11; Reaffirmed: CMS Rep. 3, I-12)

D-478.995 National Health Information Technology

1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden

to the physician and maintaining the art of medicine without compromising patient care. 2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C) advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care.; and (D) advocates for more research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems. 3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians' practices; and (B) develop minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs. 4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery. 5. Our AMA will seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology's (ONC) certification process. 6. Our AMA will collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability. 7. Our AMA will directly engage the EHR vendor community to promote improvements in EHR usability. (Res. 730, I-04 Reaffirmed in lieu of Res. 818, I-07 Reaffirmed in lieu of Res. 726, A-08 Reaffirmation A-10 Reaffirmed: BOT Rep. 16, A-11 Modified: BOT Rep. 16, A-11 Modified: BOT Rep. 17, A-12 Reaffirmed in lieu of Res. 714, A-12 Reaffirmed in lieu of Res. 715, A-12 Reaffirmed: BOT Rep. 24, A-13 Reaffirmed in lieu of Res. 724, A-13 Appended: Res. 720, A-13 Appended: Sub. Res. 721, A-13 Reaffirmed: CMS Rep. 4, I-13 Reaffirmation I-13 Appended: BOT Rep. 18, A-14 Appended: BOT Rep. 20, A-14 Reaffirmation A-14 Reaffirmed: BOT Rep. 17, A-15 Reaffirmed in lieu of Res. 208, A-15 Reaffirmed in lieu of Res. 223, A-15 Reaffirmation I-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 801
(I-16)

Introduced by: Medical Student Section

Subject: Increasing Access to Medical Devices for Insulin-Dependent Diabetics

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, The average list price of an insulin pump for Type 1 and Type 2 Diabetes Mellitus
2 (T1DM and T2DM) is between \$4,995 and \$6,500, and pump supplies (infusion pump
3 cartridges, glucose meter test strips, lancets, batteries, and syringes) can cost an additional
4 \$250 per month;^{1,2} and

5
6 Whereas, Under Medicare Part B, diabetic patients must remit a 20% copayment for insulin
7 pump devices and related supplies on an ongoing basis, after meeting their yearly Part B
8 deductible;³ and

9
10 Whereas, T1DM patients using insulin pumps experience significant reductions in HbA1c, lower
11 rates of retinopathy and peripheral nerve abnormality, fewer hospitalizations, and superior
12 quality of life as compared to patients who use multiple daily injections (MDI);^{4,5,6} and

13
14 Whereas, Accumulating evidence has demonstrated the safety and efficacy of insulin pump
15 therapy in T2DM patients, particularly among those with poor glycemic control on MDI, and has
16 shown that pump therapy produces sustained and durable reductions in HbA1c, without
17 increasing the risk of hypoglycemia;^{7,8,9,10,11} and

18
19 Whereas, On September 1st, 2015, the Centers for Medicare & Medicaid Services announced a
20 forthcoming initiative to test a “Medicare Advantage Value-Based Insurance Design Model” for
21 chronic conditions, including diabetes, in which participating plans “choose to reduce or
22 eliminate cost sharing for items or services, including covered Part D drugs, that they have
23 identified as high-value for a given target population”, with broad flexibility with respect to items
24 and services eligible for reduced cost sharing;¹² and

¹ Boyd LC, Boyd ST. Insulin pump therapy training and management: an opportunity for community pharmacists. *J Manag Care Pharm.* 2008;14(8):790-4.

² FamilyHealthOnline. (2015) “Insulin Pumps”. Available at: http://www.familyhealthonline.ca/fho/diabetes/DI_insulinPumps_MDb08.asp. Accessed April 17th, 2016.

³ Centers for Medicare and Medicaid Services. “Medicare’s Coverage of Diabetes Supplies and Services.” Available at: <https://www.medicare.gov/Pubs/pdf/11022.pdf>. Accessed March 30, 2016.

⁴ Pérez-garcía L, Goñi-iriarte MJ, García-mouriz M. Comparison of treatment with continuous subcutaneous insulin infusion versus multiple daily insulin injections with bolus calculator in patients with type 1 diabetes. *Endocrinol Nutr.* 2015;62(7):331-7.

⁵ Zabeen B, Craig ME, Virk SA, et al. Insulin Pump Therapy Is Associated with Lower Rates of Retinopathy and Peripheral Nerve Abnormality. *PLoS ONE*.

⁶ Pickup JC. Management of diabetes mellitus: is the pump mightier than the pen?. *Nat Rev Endocrinol.* 2012;8(7):425-33.

⁷ Leinung MC, Thompson S, Luo M, Leykina L, Nardacci E. Use of insulin pump therapy in patients with type 2 diabetes after failure of multiple daily injections. *Endocr Pract.* 2013;19(1):9-13.

⁸ Reznik Y, Cohen O, Aronson R, et al. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. *Lancet.* 2014;384(9950):1265-72

⁹ Didangelos T, Iliadis F. Insulin pump therapy in adults. *Diabetes Res Clin Pract.* 2011;93 Suppl 1:S109-13.

¹⁰ Aronson R, Reznik Y, Conget I, et al. Sustained efficacy of insulin pump therapy, compared with multiple daily injections, in type 2 diabetes: 12-month data from the OpT2mise randomized trial. *Diabetes Obes Metab.* 2016;

¹¹ Conget I, Castaneda J, Petrovski G, et al. The Impact of Insulin Pump Therapy on Glycemic Profiles in Patients with Type 2 Diabetes: Data from the OpT2mise Study. *Diabetes Technol Ther.* 2015;

¹² Centers for Medicare & Medicaid Services. (2015). “Medicare Advantage Value-Based Insurance Design Model.” Available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-09-01.html>. Accessed March 30, 2016.

1 Whereas, United Healthcare recently studied implementation of a Value-Based Insurance
2 Design in their Diabetes Health Plan, which concluded that offering diabetes supplies, office
3 visits, and related prescription drugs at low or no cost to patients increased plan adherence and
4 improved patient health;^{13,14} and
5
6 Whereas, Existing AMA policy supports Medicare coverage of continuous glucose monitoring
7 systems for insulin-dependent diabetics (Medicare Coverage of Continuous Glucose Monitoring
8 Devices for Patients with Insulin-Dependent Diabetes H-330.885), and existing AMA Ethical
9 Opinion assigns physicians individually and collectively the ethical responsibility to ensure that
10 all persons have access to needed care regardless of their economic means (11.1.4 Financial
11 Barriers to Health Care Access); and
12
13 Whereas, Pursuant to its strategic focus area of Improving Health Outcomes, our AMA is
14 committed to a national effort to prevent Type 2 diabetes; and
15
16 Whereas, The estimated direct medical costs and indirect costs (disability, work loss, and
17 premature death) from diabetes in the United States in 2012 was \$245 billion;¹⁵ therefore be it
18
19 RESOLVED, That our American Medical Association work with relevant stakeholders to
20 encourage the development of plans for inclusion in the Medicare Advantage Value Based
21 Insurance Design Model that reduce copayments/coinsurance for diabetes prevention,
22 medication, supplies, and equipment including pumps and continuous glucose monitors, while
23 adhering to the principles established in AMA Policy H-185.939, Value-Based Insurance Design.
24 (Directive to Take Action)

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

Received: 08/29/16

RELEVANT AMA POLICY

Diabetic Documentation Requirements D-185.983

1. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority of the Centers for Medicare & Medicaid Services (CMS) and other health care insurers placing onerous barriers on diabetic patients to procure medically necessary durable medical equipment and supplies.
2. Our AMA Board of Trustees will consider a legal challenge, if appropriate, to the authority and policy of CMS and other insurers to practice medicine through their diabetes guidelines, and place excessive time and financial burdens without reimbursement on a physician assisting patients seeking reimbursement for supplies needed to treat their diabetes.

Citation: (Res. 730, A-13)

CMS Required Diabetic Supply Forms H-330.908

Our AMA requests that CMS change its requirement so that physicians need only re-write prescriptions for glucose monitors every twelve months, instead of a six month requirement, for Medicare covered diabetic patients and make the appropriate diagnosis code sufficient for the determination of medical necessity.

Citation: (Sub. Res. 102, A-00; Reaffirmation and Amended: Res. 520, A-02; Modified: CMS Rep. 4, A-12)

¹³ Managed Care. "Value-Based Insurance Design Helps Cut Plan's Diabetes Costs." Available at: <http://www.managedcaremag.com/archives/2013/2/value-based-insurance-design-helps-cut-plan's-diabetes-costs>. Accessed March 30, 2016.

¹⁴ Healthcare Web Summit. "Value-Based Plan Design for Diabetes" Available at: <http://www.healthwebsummit.com/diabetes030713.htm>. Accessed March 30, 2016.

¹⁵ Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA; 2014. Accessed Aug. 23, 2015. Available at: <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>.

Value-Based Insurance Design H-185.939

Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:

- a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.
- b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.
- c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.
- d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.
- e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.
- f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.
- g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties.
- h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.
- i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972).

Citation: CMS Rep. 2, A-13; Reaffirmed in lieu of Res. 122, A-15; Reaffirmed in lieu of: Res. 121, A-16

Medicare Coverage of Continuous Glucose Monitoring Devices for Patients with Insulin-Dependent Diabetes H-330.885

Our AMA supports efforts to achieve Medicare coverage of continuous glucose monitoring systems for patients with insulin-dependent diabetes.

Res. 126, A-14

Drug Issues in Health System Reform H-100.964

The AMA: (1) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.

(2) supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.

(3) reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.

(4) reaffirms AMA Policies H-120.974 and H-125.992, opposing the substitution of FDA B-rated generic drug products.

(5) supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.

(6) supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.

(7a) encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.

(7b) encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not

a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.

(8) recognizes the role of the pharmacist in counseling patients about their medicines in order to reinforce the message of the prescribing physician and improve medication compliance.

(9) reaffirms AMA Policies H-115.995 and H-115.997, opposing FDA-mandated patient package inserts for all marketed prescription drugs.

(10) opposes payment of pharmacists by third party payers on a per prescription basis when the sole purpose is to convince the prescribing physician to switch to a less expensive "formulary" drug because economic incentives can interfere with pharmacist professional judgment.

(11) reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.

(12) supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public disclosure of patient and reporter identities.

(13) opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.

(14) reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.

(15) encourages the use of three compendia (AMA's DRUG EVALUATIONS; United States Pharmacopeial-Drug Information, Volume I; and American Hospital Formulary Service-Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses.

(16) reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs.

(17) reaffirms AMA Policy H-120.983, urging the pharmaceutical industry to provide the same economic opportunities to individual pharmacies as given to mail service pharmacies.

Citation: (BOT Rep. 53, A-94; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CSA Rep. 3, A-97;

Amended: CSA Rep. 2, I-98; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-10; Reaffirmed in lieu of Res. 201, I-11)

Expansion of National Diabetes Prevention Program H-440.844

Our AMA: (1) supports evidence-based, physician-prescribed diabetes prevention programs, (2) supports the expansion of the NDPP to more CDC-certified sites across the country; and (3) will support coverage of the NDPP by Medicare and all private insurers.

Citation: (Sub. Res. 911, I-12)

Strategies to Increase Diabetes Awareness D-440.935

Our AMA will organize a series of activities for the public in collaboration with health care workers and community organizations to bring awareness to the severity of diabetes and measures to decrease its incidence.

Citation: (Res. 412, A-13)

Dysmetabolic Syndrome and Type 2 Diabetes in Children D-440.949

Our AMA (1) supports efforts to develop national-level data that would provide for the monitoring of the prevalence of diabetes among youth by type; and (2) encourages greater awareness by physicians of type 2 diabetes and its complications in children and will promote the availability of resources and information about the prevention and treatment of this growing public health threat.

Citation: (Res. 418, A-07)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 802
(I-16)

Introduced by: Medical Student Section

Subject: Eliminating Fail First Policy in Addiction Treatment

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Health insurers utilize “fail first” policies (also referred to as Step Therapy), which
2 require that patients with addiction attempt and fail an outpatient program prior to receiving
3 coverage for inpatient treatment, even if a healthcare provider recommends an inpatient
4 treatment, as a cost-saving measure;^{1,2} and

5
6 Whereas, Step therapy and fail-first protocols were associated with 4.7 times greater odds of a
7 medication access or continuity problem;³ and

8
9 Whereas, As of 2014, the rate of drug overdose deaths has increased 137% since 2000,
10 including a 200% increase in the rate of overdose deaths involving opioids;⁴ and

11
12 Whereas, The Mental Health Parity and Addiction Equity Act (MHPAEA) prevents group health
13 plans and health insurance issuers that provide mental health or substance use disorder
14 benefits from subjecting mental health and substance use disorder coverage to more restrictive
15 limitations than those applied to general medical care;^{5,6} and

16
17 Whereas, “Fail first” policies are classified as non-quantifiable treatment limitations under
18 MHPAEA regulations and can represent a violation of the act if they are more restrictive than
19 limitations applied to medical and surgical benefits;^{7,8} and

20
21 Whereas, The AMA supports enforcement of the Mental Health Parity Act at the federal and
22 state level (H-345.975); and

23
24 Whereas, The AMA opposes laws, policies, and procedures that would limit a patient's access
25 to medically necessary pharmacological therapies for opioid use disorder (H-95.944) and
26 recognizes that patients in need of treatment for alcohol or other drug-related disorders should
27 be treated for these medical conditions by qualified professionals in a manner consonant with
28 accepted practice guidelines and patient placement (H-95.951); and

¹ Olivencia, J. Roundtable Puts the Broken “Fail First” Drug Treatment Policy Under a Microscope. CSG Justice Center. June 16, 2014. Last accessed: August 9, 2016.

² Step Therapy and Fail First Policies Backgrounder. Available at: <https://failfirsthurts.org/ffh/wp-content/uploads/2012/10/WWP-Purple-Paper-Step-Therapy-and-Fail-First-Policies.pdf>. Last accessed: August 9, 2016.

³ Alanis-Hirsch, K. et al. Extended-Release Naltrexone: A Qualitative Analysis of Barriers to Routine Use. Journal of Substance Abuse Treatment. 2016 Mar; 62: 68-73.

⁴ Rudd, R. et al. Increases in Drug and Opioid Overdose Deaths — United States, 2000–2014. Morbidity and Mortality Weekly Report. 2016;64(50):1378-382. CDC.

⁵ Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, Public Law 110-343.

⁶ Horgan, C.M. et al. Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services. Psychiatric Services. 2016;7(2): 162-68.

⁷ Goodell, S. et al. Health Policy Brief: Enforcing Mental Health Parity. Health Affairs. November 9, 2015.

⁸ United States Department of Labor. Frequently Asked Questions for Employees about the Mental Health Parity and Addiction Equity Act. <http://www.dol.gov/ebsa/faqs/faq-mhpaea2.html>. Accessed April 20, 2016.

1 Whereas, One of the five goals of the AMA Task Force to Reduce Prescription Opioid Abuse is
2 to enhance patients' access to treatment for opioid addiction; therefore be it
3
4 RESOLVED, That our American Medical Association advocate for the elimination of the "fail
5 first" policy implemented by insurance companies for addiction treatment. (New HOD Policy)

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

Received: 08/29/16

RELEVANT AMA POLICY

Maintaining Mental Health Services by States H-345.975

Our AMA:

1. supports maintaining essential mental health services at the state level, to include maintaining state inpatient and outpatient mental hospitals, community mental health centers, addiction treatment centers, and other state-supported psychiatric services;
2. supports state responsibility to develop programs that rapidly identify and refer individuals with significant mental illness for treatment, to avoid repeated psychiatric hospitalizations and repeated interactions with the law, primarily as a result of untreated mental conditions;
3. supports increased funding for state Mobile Crisis Teams to locate and treat homeless individuals with mental illness;
4. supports enforcement of the Mental Health Parity Act at the federal and state level; and
5. will take these resolves into consideration when developing policy on essential benefit services.

Citation: (Res. 116, A-12; Reaffirmation A-15)

Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.

Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16

Substance Use Disorders as a Public Health Hazard H-95.975

Our AMA: (1) recognizes that substance use disorders are a major public health problem in the United States today and that its solution requires a multifaceted approach;

(2) declares substance use disorders are a public health priority;

(3) supports taking a positive stance as the leader in matters concerning substance use disorders, including addiction;

(4) supports studying innovative approaches to the elimination of substance use disorders and their resultant street crime, including approaches which have been used in other nations; and

(5) opposes the manufacture, distribution, and sale of substances created by chemical alteration of illicit substances, herbal remedies, and over-the-counter drugs with the intent of circumventing laws prohibiting possession or use of such substances.

Citation: (Res. 7, I-89; Appended: Sub. Res. 401, Reaffirmed: Sunset Rep., I-99; Reaffirmed: CSAPH Rep. 1, A-09; Modified and Reaffirmed: CSAPH Rep. 1, A-09)

Harm Reduction Through Addiction Treatment H-95.956

The AMA endorses the concept of prompt access to treatment for chemically dependent patients, regardless of the type of addiction, and the AMA will work toward the implementation of such an approach nationwide. The AMA affirms that addiction treatment is a demonstrably viable and efficient method of reducing the harmful personal and social consequences of the inappropriate use of alcohol and other psychoactive drugs and urges the Administration and Congress to provide significantly increased funding for treatment of alcoholism and other drug dependencies and support of basic and clinical research so that the causes, mechanisms of action and development of addiction can continue to be elucidated to enhance treatment efficacy.

Citation: (Res. 411, A-95; Appended: Res. 405, I-97; Reaffirmation I-03; Reaffirmed: CSAPH Rep. 1, A-13)

Third-Party Payer Policies on Opioid Use Disorder Pharmacotherapy H-95.944

Our AMA opposes federal, state, third-party and other laws, policies, rules and procedures, including those imposed by Pharmacy Benefit Managers working for Medicaid, Medicare, TriCare, and commercial health plans, that would limit a patient's access to medically necessary pharmacological therapies for opioid use disorder, whether administered in an office-based opioid treatment setting or in a federal regulated Opioid Treatment Program, by imposing limitations on the duration of treatment, medication dosage or level of care.

Citation: (Res. 710, A-13)

Role of Self-Help in Addiction Treatment H-95.951

The AMA: (1) recognizes that (a) patients in need of treatment for alcohol or other drug-related disorders should be treated for these medical conditions by qualified professionals in a manner consonant with accepted practice guidelines and patient placement criteria; and (b) self-help groups are valuable resources for many patients and their families and should be utilized by physicians as adjuncts to a treatment plan; and (2) urges managed care organizations and insurers to consider self-help as a complement to, not a substitute for, treatment directed by professionals, and to refrain from using their patient's involvement in self-help activities as a basis for denying authorization for payment for professional treatment of patients and their families who need such care.

Citation: (Res. 713, A-98; Reaffirmed: CSAPH Rep. 2, A-08)

Opioid Treatment and Prescription Drug Monitoring Programs D-95.980

Our AMA will seek changes to allow states the flexibility to require opioid treatment programs to report to prescription monitoring programs.

Citation: (BOT Rep. 11, A-10)

The Reduction of Medical and Public Health Consequences of Drug Abuse H-95.954

Our AMA: (1) encourages national policy-makers to pursue an approach to the problem of drug abuse aimed at preventing the initiation of drug use, aiding those who wish to cease drug use, and diminishing the adverse consequences of drug use; (2) encourages policy-makers to recognize the importance of screening for alcohol and other drug use in a variety of settings, and to broaden their concept of addiction treatment to embrace a continuum of modalities and goals, including appropriate measures of harm reduction, which can be made available and accessible to enhance positive treatment outcomes for patients and society; (3) encourages the expansion of opioid maintenance programs so that opioid maintenance therapy can be available for any individual who applies and for whom the treatment is suitable. Training must be available so that an adequate number of physicians are prepared to provide treatment. Program regulations should be strengthened so that treatment is driven by patient needs, medical judgment, and drug rehabilitation concerns. Treatment goals should acknowledge the benefits of abstinence from drug use, or degrees of relative drug use reduction; (4) encourages the extensive application of needle and syringe exchange and distribution programs and the modification of restrictive laws and regulations concerning the sale and possession of needles and syringes to maximize the availability of sterile syringes and needles, while ensuring continued reimbursement for medically necessary needles and

syringes. The need for such programs and modification of laws and regulations is urgent, considering the contribution of injection drug use to the epidemic of HIV infection; (5) encourages a comprehensive review of the risks and benefits of U.S. state-based drug legalization initiatives, and that until the findings of such reviews can be adequately assessed, the AMA reaffirm its opposition to drug legalization; (6) strongly supports the ability of physicians to prescribe syringes and needles to patients with injection drug addiction in conjunction with addiction counseling in order to help prevent the transmission of contagious diseases; and (7) encourages state medical associations to work with state regulators to remove any remaining barriers to permit physicians to prescribe needles for patients.

Citation: (CSA Rep. 8, A-97; Reaffirmed: CSA Rep. 12, A-99; Appended: Res. 416, A-00; Reaffirmation I-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 2, I-13)

Reduction of Medical and Public Health Consequences of Drug Abuse: Update D-95.999

Our AMA encourages state medical societies to advocate for the expansion of and increased funding for needle and syringe-exchange programs and methadone maintenance and other opioid treatment services and programs in their states.

Citation: (CSA Rep. 12, A-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09)

Evaluating Health System Reform Proposals H-165.888

1. Our AMA will continue its efforts to ensure that health system reform proposals adhere to the following principles:

- A. Physicians maintain primary ethical responsibility to advocate for their patients' interests and needs.
- B. Unfair concentration of market power of payers is detrimental to patients and physicians, if patient freedom of choice or physician ability to select mode of practice is limited or denied. Single-payer systems clearly fall within such a definition and, consequently, should continue to be opposed by the AMA. Reform proposals should balance fairly the market power between payers and physicians or be opposed.
- C. All health system reform proposals should include a valid estimate of implementation cost, based on all health care expenditures to be included in the reform; and supports the concept that all health system reform proposals should identify specifically what means of funding (including employer-mandated funding, general taxation, payroll or value-added taxation) will be used to pay for the reform proposal and what the impact will be.
- D. All physicians participating in managed care plans and medical delivery systems must be able without threat of punitive action to comment on and present their positions on the plan's policies and procedures for medical review, quality assurance, grievance procedures, credentialing criteria, and other financial and administrative matters, including physician representation on the governing board and key committees of the plan.
- E. Any national legislation for health system reform should include sufficient and continuing financial support for inner-city and rural hospitals, community health centers, clinics, special programs for special populations and other essential public health facilities that serve underserved populations that otherwise lack the financial means to pay for their health care.
- F. Health system reform proposals and ultimate legislation should result in adequate resources to enable medical schools and residency programs to produce an adequate supply and appropriate generalist/specialist mix of physicians to deliver patient care in a reformed health care system.
- G. All civilian federal government employees, including Congress and the Administration, should be covered by any health care delivery system passed by Congress and signed by the President.
- H. True health reform is impossible without true tort reform.

2. Our AMA supports health care reform that meets the needs of all Americans including people with injuries, congenital or acquired disabilities, and chronic conditions, and as such values function and its improvement as key outcomes to be specifically included in national health care reform legislation.

3. Our AMA supports health care reform that meets the needs of all Americans including people with mental illness and substance use / addiction disorders and will advocate for the inclusion of full parity for the treatment of mental illness and substance use / addiction disorders in all national health

care reform legislation.

4. Our AMA supports health system reform alternatives that are consistent with AMA principles of pluralism, freedom of choice, freedom of practice, and universal access for patients.

Citation: (Res. 118, I-91; Res. 102, I-92; BOT Rep. NN, I-92; BOT Rep. S, A-93; Reaffirmed: Res. 135, A-93; Reaffirmed: BOT Reps. 25 and 40, I-93; Reaffirmed in lieu of Res. 714, I-93; Res. 130, I-93; Res. 316, I-93; Sub. Res. 718, I-93; Reaffirmed: CMS Rep. 5, I-93; Res. 124, A-94; Reaffirmed by BOT Rep. 1- I-94; CEJA Rep. 3, A-95; Reaffirmed: BOT Rep. 34, I-95; Reaffirmation A-00; Reaffirmation A-01; Reaffirmed: CMS Rep. 10, A-03; Reaffirmed: CME Rep. 2, A-03; Reaffirmed and Modified: CMS Rep. 5, A-04; Reaffirmed with change in title: CEJA Rep. 2, A-05; Consolidated: CMS Rep. 7, I-05; Reaffirmation I-07; Reaffirmed in lieu of Res. 113, A-08; Reaffirmation A-09; Res. 101, A-09; Sub. Res. 110, A-09; Res. 123, A-09; Reaffirmed in lieu of Res. 120, A-12)

Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction D-95.981

1. Our AMA:

- a. will collaborate with relevant medical specialty societies to develop continuing medical education curricula aimed at reducing the epidemic of misuse of and addiction to prescription controlled substances, especially by youth;
- b. encourages medical specialty societies to develop practice guidelines and performance measures that would increase the likelihood of safe and effective clinical use of prescription controlled substances, especially psychostimulants, benzodiazepines and benzodiazepines receptor agonists, and opioid analgesics;
- c. encourages physicians to become aware of resources on the nonmedical use of prescription controlled substances that can assist in actively engaging patients, and especially parents, on the benefits and risks of such treatment, and the need to safeguard and monitor prescriptions for controlled substances, with the intent of reducing access and diversion by family members and friends;
- d. will consult with relevant agencies on potential strategies to actively involve physicians in being ?a part of the solution? to the epidemic of unauthorized/nonmedical use of prescription controlled substances; and
- e. supports research on: (i) firmly identifying sources of diverted prescription controlled substances so that solutions can be advanced; and (ii) issues relevant to the long-term use of prescription controlled substances.

2. Our AMA, in conjunction with other Federation members, key public and private stakeholders, and pharmaceutical manufacturers, will pursue and intensify collaborative efforts involving a public health approach in order to:

- a. reduce harm from the inappropriate use, misuse and diversion of controlled substances, including opioid analgesics and other potentially addictive medications;
- b. increase awareness that substance use disorders are chronic diseases and must be treated accordingly; and
- c. reduce the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction.

Citation: (CSAPH Rep. 2, I-08; Appended: Res. 517, A-15; Reaffirmed: BOT Rep. 5, I-15)

Federal Drug Policy in the United States H-95.981

The AMA, in an effort to reduce personal and public health risks of drug abuse, urges the formulation of a comprehensive national policy on drug abuse, specifically advising that the federal government and the nation should: (1) acknowledge that federal efforts to address illicit drug use via supply reduction and enforcement have been ineffective (2) expand the availability and reduce the cost of treatment programs for substance use disorders, including addiction; (3) lead a coordinated approach to adolescent drug education; (4) develop community-based prevention programs for youth at risk; (5) continue to fund the Office of National Drug Control Policy to coordinate federal drug policy; (6) extend greater protection against discrimination in the employment and provision of services to drug abusers; (7) make a long-term commitment to expanded research and data collection; (8) broaden the focus of national and local policy from drug abuse to substance abuse;

and (9) recognize the complexity of the problem of substance abuse and oppose drug legalization.
Citation: (BOT Rep. NNN, A-88; Reaffirmed: CLRPD 1, I-98; Reaffirmed: CSAPH Rep. 2, A-08;
Modified: CSAPH Rep. 2, I-13)

Background on the Organization "Physicians and Lawyers for National Drug Policy" (PLNDP)

D-95.986

Our AMA will: (1) express support to Physicians and Lawyers for National Drug Policy (PLNDP) for including in its statement of policy priorities the need for parity in insurance payments for addiction treatment; (2) encourage physicians to partner with lawyers and judges in their communities to become Lawyer and Physician Associates of PLNDP at no cost, and to work collaboratively in their communities to promote a more rational, public-health-focused approach to substance use and addiction; and (3) encourage individual members to join or collaborate with PLNDP efforts when they are consistent with and supportive of AMA policy goals.

Citation: (BOT Rep. 8, A-07)

Drug Abuse in the United States - the Next Generation H-95.976

Our AMA is committed to efforts that can help prevent this national problem from becoming a chronic burden. The AMA pledges its continuing involvement in programs to alert physicians and the public to the dimensions of the problem and the most promising solutions. The AMA, therefore:

- (1) supports cooperation in activities of organizations such as the National Association for Perinatal Addiction Research and Education (NAPARE) in fostering education, research, prevention, and treatment of substance abuse;
- (2) encourages the development of model substance abuse treatment programs, complete with an evaluation component that is designed to meet the special needs of pregnant women and women with infant children through a comprehensive array of essential services;
- (3) urges physicians to routinely provide, at a minimum, a historical screen for all pregnant women, and those of childbearing age for substance abuse and to follow up positive screens with appropriate counseling, interventions and referrals;
- (4) supports pursuing the development of educational materials for physicians, physicians in training, other health care providers, and the public on prevention, diagnosis, and treatment of perinatal addiction. In this regard, the AMA encourages further collaboration with the Partnership for a Drug-Free America in delivering appropriate messages to health professionals and the public on the risks and ramifications of perinatal drug and alcohol use;
- (5) urges the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the Federal Office for Substance Abuse Prevention to continue to support research and demonstration projects around effective prevention and intervention strategies;
- (6) urges that public policy be predicated on the understanding that alcoholism and drug dependence, including tobacco dependence as indicated by the Surgeon General's report, are diseases characterized by compulsive use in the face of adverse consequences;
- (7) affirms the concept that substance abuse is a disease and supports developing model legislation to appropriately address perinatal addiction as a disease, bearing in mind physicians' concern for the health of the mother, the fetus and resultant offspring; and
- (8) calls for better coordination of research, prevention, and intervention services for women and infants at risk for both HIV infection and perinatal addiction.

Citation: (BOT Rep. Y, I-89; Reaffirmed: Sunset Report, A-00; Reaffirmation A-09)

Treatment of Opioid Dependence D-120.953

Our AMA will work to end the limitation of 100 patients per certified physician treating opioid dependence after the second year of treatment as currently mandated by the Drug Addiction Treatment Act.

Citation: (Res. 524, A-1; Reaffirmation A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 803
(I-16)

Introduced by: Resident and Fellow Section

Subject: Reducing Perioperative Opioid Consumption

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Regional anesthesia and acute pain medicine is a burgeoning field that specializes in
2 the use of multimodal analgesia strategies to manage perioperative pain; and

4 Whereas, Management and treatment of acute pain is distinctly different from the management
5 and treatment of pre-existing chronic pain; and

7 Whereas, There is an increased demand for physicians trained to manage acute pain medicine
8 teams with the goal of providing individualized, comprehensive, and timely pain management for
9 both medical and surgical patients in the hospital; and

11 Whereas, These acute pain management teams can expeditiously manage requests for
12 assistance when pain intensity levels exceed those set forth in quality standards, or to prevent
13 pain intensity from reaching such level; and

15 Whereas, Acute pain management teams can improve the quality of pain control, reduce the
16 time to discharge and reduce the morbidity and mortality of patients; and

18 Whereas, Pain control is an important hospital quality metric used to determine ultimate
19 reimbursements to hospitals; and

21 Whereas, Narcotics are often the sole analgesic employed or aggressively used to manage
22 perioperative pain; and

24 Whereas, Narcotic misuse and addiction has been related to their excess consumption in the
25 perioperative period; and

27 Whereas, Narcotic addiction has been recognized as one of the United States' worst health
28 problems; and

30 Whereas, The employment of regional anesthetics and multimodal analgesia strategies can
31 significantly reduce the consumption of narcotics both acutely and chronically; therefore be it

33 RESOLVED, That our American Medical Association encourage hospitals to adopt practices for
34 the management of perioperative pain that include services dedicated to acute pain
35 management and the use of multimodal analgesia strategies aimed at minimizing opioid
36 administration without compromising adequate pain control during the perioperative period.
37 (New HOD Policy)

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

Received: 09/12/16

References:

<http://www.edmariano.com/archives/592>

RELEVANT AMA POLICY

Protection for Physicians Who Prescribe Pain Medication H-120.960

Our AMA supports the following:

(1) the position that physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines protecting physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection; (2) education of medical students and physicians to recognize addictive disorders in patients, minimize diversion of opioid preparations, and appropriately treat or refer patients with such disorders; and (3) the prevention and treatment of pain disorders through aggressive and appropriate means, including the continued education of doctors in the use of opioid preparations.

Our AMA opposes harassment of physicians by agents of the Drug Enforcement Administration in response to the appropriate prescribing of controlled substances for pain management. (BOT Rep. 1, I-97; Reaffirm: Res. 237, A-99; Appended: Res. 506, A-01; Appended: Sub. Res. 213, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Reaffirmed: BOT Rep. 3, I-13; Reaffirmation A-15)

Opioid Treatment and Prescription Drug Monitoring Programs D-95.980

Our AMA will seek changes to allow states the flexibility to require opioid treatment programs to report to prescription monitoring programs. (BOT Rep. 11, A-10)

Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone D-120.985

1. Our AMA will incorporate into its web site a directory consolidating available information on the safe and effective use of opioid analgesics in clinical practice.
2. Our AMA, in collaboration with Federation partners, will collate and disseminate available educational and training resources on the use of methadone for pain management. (Sub. Res. 508, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Appended: Res. 515, A-14; Reaffirmed: BOT Rep. 14, A-15)

Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose. (Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16)

Drug Abuse Related to Prescribing Practices H-95.990

1. Our AMA recommends the following series of actions for implementation by state medical societies concerning drug abuse related to prescribing practices:

A. Institution of comprehensive statewide programs to curtail prescription drug abuse and to promote appropriate prescribing practices, a program that reflects drug abuse problems currently within the state, and takes into account the fact that practices, laws and regulations differ from state to state. The program should incorporate these elements: (1) Determination of the nature and extent of the prescription drug abuse problem; (2) Cooperative relationships with law enforcement, regulatory agencies, pharmacists and other professional groups to identify "script doctors" and bring them to justice, and to prevent forgeries, thefts and other unlawful activities related to prescription drugs; (3) Cooperative relationships with such bodies to provide education to "duped doctors" and "dated doctors" so their prescribing practices can be improved in the future; (4) Educational materials on appropriate prescribing of controlled substances for all physicians and for medical students.

B. Placement of the prescription drug abuse programs within the context of other drug abuse control efforts by law enforcement, regulating agencies and the health professions, in recognition of the fact that even optimal prescribing practices will not eliminate the availability of drugs for abuse purposes, nor appreciably affect the root causes of drug abuse. State medical societies should, in this regard, emphasize in particular: (1) Education of patients and the public on the appropriate medical uses of controlled drugs, and the deleterious effects of the abuse of these substances; (2) Instruction and consultation to practicing physicians on the treatment of drug abuse and drug dependence in its various forms.

2. Our AMA:

A. promotes physician training and competence on the proper use of controlled substances;
B. encourages physicians to use screening tools (such as NIDAMED) for drug use in their patients;
C. will provide references and resources for physicians so they identify and promote treatment for unhealthy behaviors before they become life-threatening; and
D. encourages physicians to query a state's controlled substances databases for information on their patients on controlled substances.

3. The Council on Science and Public Health will report at the 2012 Annual Meeting on the effectiveness of current drug policies, ways to prevent fraudulent prescriptions, and additional reporting requirements for state-based prescription drug monitoring programs for veterinarians, hospitals, opioid treatment programs, and Department of Veterans Affairs facilities.

4. Our AMA opposes any federal legislation that would require physicians to check a prescription drug monitoring program (PDMP) prior to prescribing controlled substances. (CSA Rep. C, A-81; Reaffirmed: CLRPD Rep. F, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Appended: Res. 907, I-11; Appended: Res. 219, A-12; Reaffirmation A-15; Reaffirmation: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15)

Reduction of Medical and Public Health Consequences of Drug Abuse: Update D-95.999

Our AMA encourages state medical societies to advocate for the expansion of and increased funding for needle and syringe-exchange programs and methadone maintenance and other opioid treatment services and programs in their states. (CSA Rep. 12, A-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 804
(I-16)

Introduced by: Young Physicians Section

Subject: Parity in Reproductive Health Insurance Coverage for Same-Sex Couples

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, The World Health Organization (WHO) has classified infertility as a global public
2 health issue, and has "calculated that over 10% of women are inflicted (sic) – women who have
3 tried unsuccessfully, and have remained in a stable relationship for five years or more.
4 Estimates in women using a two year time frame, result in prevalence values 2.5 times larger;"¹
5 and

6
7 Whereas, In an Ethics Committee Opinion, the American Society for Reproductive Medicine
8 (ASRM) states that "ethical arguments supporting denial of access to fertility services on the
9 basis of marital status or sexual orientation cannot be justified;"² and

10
11 Whereas, This ASRM Ethics Committee Opinion also indicates that:
12 - Single individuals, unmarried heterosexual couples, and gay and lesbian couples have
13 interests in having and rearing children;
14 - Overall results of research suggest that the development, adjustment, and well-being of
15 children with lesbian and gay parents do not differ markedly from that of children with
16 heterosexual parents;
17 - Data do not support restricting access to assisted reproductive technologies on the basis of
18 a prospective parent's marital/partner status or sexual orientation; and
19 - Programs should treat all requests for assisted reproduction equally without regard to
20 marital/partner status or sexual orientation;² and

21
22 Whereas, The American College of Obstetricians and Gynecologists (ACOG) said of physicians
23 who refuse to provide infertility services to same-sex couples: "Allowing physicians to
24 discriminate on the basis of sexual orientation would constitute a deeper insult, namely
25 reinforcing the scientifically unfounded idea that fitness to parent is based on sexual orientation,
26 and, thus, reinforcing the oppressed status of same-sex couples;"³ and

27
28 Whereas, According to AMA Policy H-65.973, our AMA will "support measures providing same-
29 sex households with the same rights and privileges to health care, health insurance, and
30 survivor benefits, as afforded opposite-sex households;" and

31
32 Whereas, On 26 June 2015, the Supreme Court ruled that states cannot ban same-sex
33 marriage; and

1 Whereas, According to ASRM, "Six states (Connecticut, Illinois, Maryland, Massachusetts, New
2 Jersey, and Rhode Island) provide comprehensive or near-comprehensive coverage for
3 infertility treatment to at least some residents through state law mandates. These mandates
4 require that private insurers cover diagnosis and treatment of infertility, including IVF. Although
5 mandated coverage can result in better overall access, several state mandates carry significant
6 restrictions (e.g., Maryland imposes a two-year waiting period, exempts religious employers,
7 covers only married couples, and requires that the husband's sperm be used);"⁴ and
8

9 Whereas, Several insurance companies have been found to cover infertility treatments for
10 heterosexual couples but decline those treatments for same-sex couples; and
11

12 Whereas, Some of these insurance companies will cover donor sperm insemination for
13 heterosexual couples, but not for same-sex couples or single women; and
14

15 Whereas, The reasons for insurance companies to deny fertility coverage to same-sex couples
16 are varied, but are ultimately discriminatory, as they would often cover fertility treatments for a
17 heterosexual couple with azoospermia (lack of sperm), but not for a same-sex couple with a
18 similar lack of available sperm; and
19

20 Whereas, For married same-sex couples, the Maryland legislature in 2015 eliminated
21 restrictions that had (1) previously excluded lesbians from in vitro fertilization coverage
22 (because the previous law called for the use of the husband's sperm, in order for the couple to
23 receive coverage), and (2) previously required couples to demonstrate a history of infertility of at
24 least two years' duration before being eligible for fertility treatments (but now allows lesbians to
25 substitute six artificial insemination attempts instead);^{5,6} therefore be it
26

27 RESOLVED, That our American Medical Association support parity in insurance coverage for
28 fertility treatments for same-sex couples, when insurance provides coverage for fertility
29 treatments (New HOD Policy); and be it further
30

31 RESOLVED, That our AMA support local and state efforts to promote parity in reproductive
32 health insurance coverage for same-sex couples when insurance provides coverage for fertility
33 treatments. (New HOD Policy)

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

Received: 09/26/16

References:

1. "Infertility is a global public health issue" on the website of the World Health Organization, at <http://www.who.int/reproductivehealth/topics/infertility/perspective/en/>. Accessed 9/18/15.
2. "Access to fertility treatment by gays, lesbians, and unmarried persons: a committee opinion. Ethics Committee of the American Society for Reproductive Medicine. *Fertil Steril* 2013; 100: 1524-7.
3. ACOG Committee Opinion No 385. The limits of conscientious refusal in reproductive medicine. *Obstet Gynecol* 2007; 110:1203-8.
4. "Disparities in access to effective treatment for infertility in the United States: an Ethics Committee opinion. *Fertil Steril* 2015; *in press*.
5. "Maryland clears restrictions to in vitro fertilization coverage for same-sex couples." in Med City News, 7/10/15. Accessed at: <http://medcitynews.com/2015/07/in-vitro-fertilization-coverage-same-sex-couples/>.
6. "In vitro mandate bill for same-sex couples passes both chambers." In The Baltimore Sun, 3/24/15. Accessed at: <http://www.baltimoresun.com/news/maryland/politics/blog/bal-in-vitro-mandate-bill-for-samesex-couples-passes-both-chambers-20150324-story.html>.

RELEVANT AMA POLICY

H-65.973 Health Care Disparities in Same-Sex Partner Households

Our American Medical Association: (1) recognizes that denying civil marriage based on sexual orientation is discriminatory and imposes harmful stigma on gay and lesbian individuals and couples and their families; (2) recognizes that exclusion from civil marriage contributes to health care disparities affecting same-sex households; (3) will work to reduce health care disparities among members of same-sex households including minor children; and (4) will support measures providing same-sex households with the same rights and privileges to health care, health insurance, and survivor benefits, as afforded opposite-sex households.

(CSAPH Rep. 1, I-09; BOT Action in response to referred for decision Res. 918, I-09: Reaffirmed in lieu of Res. 918, I-09; BOT Rep. 15, A-11; Reaffirmed in lieu of Res. 209, A-12)

D-65.995 Health Disparities Among Gay, Lesbian, Bisexual and Transgender Families

Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and same sex parents in same sex households by supporting equality in laws affecting health care of members in same sex partner households and their dependent children.

(Res. 445, A-05; Modified: CSAPH Rep. 1, A-15)

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991

1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian gay bisexual and transgender (LGBT) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBT; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBT Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBT patients; (iii) encouraging the development of educational programs in LGBT Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBT people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBT communities to offer physicians the opportunity to better understand the medical needs of LGBT patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for women who have sex with women to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases.
3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBT health issues.
4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBT people.

CSA Rep. C, I-81 Reaffirmed: CLRPD Rep. F, I-91 CSA Rep. 8 - I-94 Appended: Res. 506, A-00 Modified and Reaffirmed: Res. 501, A-07 Modified: CSAPH Rep. 9, A-08 Reaffirmation A-12 Modified: Res. 08, A-16

Eliminating Health Disparities - Promoting Awareness and Education of Lesbian, Gay, Bisexual, and Transgender (LGBT) Health Issues in Medical Education H-295.878

Our AMA: (1) supports the right of medical students and residents to form groups and meet on-site to further their medical education or enhance patient care without regard to their gender, gender identity, sexual orientation, race, religion, disability, ethnic origin, national origin or age; (2) supports students and residents who wish to conduct on-site educational seminars and workshops on health issues in Lesbian, Gay, Bisexual, and Transgender communities; and (3) encourages the Liaison Committee on Medical Education (LCME), the American Osteopathic Association (AOA), and the Accreditation Council for Graduate Medical Education (ACGME) to include LGBT health issues in the cultural competency curriculum for both undergraduate and graduate medical education; and (4) encourages the LCME, AOA, and ACGME to assess the current status of curricula for medical student and residency education addressing the needs of pediatric and adolescent LGBT patients.

Res. 323, A-05 Modified in lieu of Res. 906, I-10 Reaffirmation A-11 Reaffirmation A-12 Reaffirmation A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 805
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Subject: Health Insurance Companies Should Collect Deductible From Patients After Full Payments To Physicians

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, One of the principles of the AMA is practice sustainability; and
2
3 Whereas, Health insurance companies and other payors serve as an intermediary between
4 physicians and patients; and
5
6 Whereas, This often disrupts the relationship and interferes with physicians and the
7 accompanying medical charges; and
8
9 Whereas, Health insurance companies created deductibles, co-insurance and even co-
10 payments to lower premium costs and transfer health care risk and cost to patients and
11 physicians; and
12
13 Whereas, High deductible health care plans have increased dramatically since the passage of
14 the Affordable Care Act (ACA) in quality and in the amount of the patient overall financial
15 responsibility; and
16
17 Whereas, Physicians are collecting less revenue from charges allocated towards deductibles as
18 compared to plans without deductibles since the ACA was implemented with the health
19 insurance exchange high deductible plans; therefore be it
20
21 RESOLVED, That our American Medical Association seek federal and state legislation that
22 requires health insurers to reimburse physicians the full negotiated payment rate for services to
23 enrollees in high deductible plans and that the health insurers collect any patient financial
24 responsibility, including deductibles and co-insurance, directly from the patient. (Directive to
25 Take Action)

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

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 806
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire,
Rhode Island, Vermont

Subject: Pharmaceutical Industry Drug Pricing is a Public Health Emergency

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, The pharmaceutical industry has repeatedly raised prices for the past 10 years
2 without regard to patient or societal affordability;¹ and
3
4 Whereas, These price increases have for the most part been unrelated to research or rate of
5 return on investment; and
6
7 Whereas, The pharmaceutical industry has as a whole ignored any reasonable calls for restraint
8 in price increases, putting a huge strain on the entire health care system;³ and
9
10 Whereas, These many price increases, some on a regular basis every few months, are
11 unrelated to any R&D demands;⁴ and
12
13 Whereas, These price increases are no longer able to be absorbed by the insurance industry
14 which will lead to marked rises in insurance premiums, causing large out of pocket expenses for
15 essential medications; and
16
17 Whereas, These price increases are straining state and federal budgets, and will require either
18 major tax increases or limits on medical care to many citizens;² and
19
20 Whereas, It is already AMA policy to request congress to repeal the Medicare prohibition on
21 drug price negotiation;⁵ and
22
23 Whereas, It is already AMA policy to request FDA encourage increased competition in the
24 generic drug market; and
25
26 Whereas, The high price of medication has led to adverse patient care with patients skipping or
27 missing medications due to exorbitant pricing;² and
28
29 Whereas, Our patients need Congress to convene urgent hearings and demand action from the
30 pharmaceutical industry regarding excessive price increases; therefore be it
31
32 RESOLVED, That our American Medical Association request that the Secretary of Health and
33 Human Services declare pharmaceutical drug pricing a public health emergency under section
34 319 of the Public Health Service Act and that the Secretary take appropriate actions in response
35 to the emergency, including investigations into the cause, treatment, or prevention of egregious
36 pharmaceutical drug pricing. (Directive to Take Action)

References:

¹The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform
Aaron S. Kesselheim, MD, JD, MPH¹; Jerry Avorn, MD¹; Ameet Sarpatwari, JD, PhD¹
JAMA. 2016;316(8):858-871. doi:10.1001/jama.2016.11237.

² "High Cost Generic Drugs" NEJM 2014;371;1859-1862

³"Surprise: generic drugs spike" Bloomberg News Dec 12, 2013

⁴ "Rapid price increases for generic drugs", NYT, July 8, 2014

⁵"Lawmakers look for ways to provide relief for rising cost of generic drugs", NYT, Nov 24,2014

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

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 807
(I-16)

Introduced by: Kentucky

Subject: Pharmacy Use of Medication Discontinuation Messaging Function

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Electronic prescribing of medications has been required as a component of
2 meaningful use; and
3
4 Whereas, Electronic prescribing software has the ability to support transmittal of medication
5 discontinuation messages; and
6
7 Whereas, Many pharmacies have elected to not activate this functionality; and
8
9 Whereas, Not using this functionality to its full extent can result in medications being
10 inappropriately continued and dispensed after a prescribing physician or other duly licensed
11 care provider has determined that it should be discontinued; and
12
13 Whereas, Continuation of medications after a physician or other duly licensed care provider has
14 discontinued them can result in patient harm; therefore be it
15
16 RESOLVED, That our American Medical Association strongly encourage all software providers
17 and those pharmaceutical dispensing organizations that create their own software to include the
18 functionality to accept discontinuation message transmittals in their electronic prescribing
19 software products (New HOD Policy); and be it further
20
21 RESOLVED, That our AMA strongly encourage all dispensing pharmacies accepting medication
22 prescriptions electronically to activate the discontinuation message transmittal functionality in
23 their electronic prescribing support software. (New HOD Policy)

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

Received: 09/27/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 808
(I-16)

Introduced by: Medical Student Section

Subject: A Study on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey and Healthcare Disparities

Referred to: Reference Committee J
(Candace E. Keller, Chair)

1 Whereas, The Centers for Medicare & Medicaid (CMS) is committed to using measures of
2 hospital quality that directly reflect the patient perspective to improve the overall quality of
3 hospital care;¹ and

4
5 Whereas, In accordance with the Affordable Care Act, CMS initiated the Hospital Value-Based
6 Purchasing (VBP) Program, which rewards acute-care hospitals with incentive payments for the
7 quality of care they provide Medicare beneficiaries;²

8
9 Whereas, The Hospital Consumer Assessment of Healthcare Providers and Systems
10 (HCAHPS) survey is a data collection methodology for measuring patients' perceptions of their
11 hospital experience;³ and

12
13 Whereas, The HCAHPS survey creates standardized, publicly-reported metrics that allow for
14 fair comparisons of patient experience in hospitals across the nation;⁴ and

15
16 Whereas, The HCAHPS survey is the most studied system for measuring patients' experience
17 of their care on an individual and hospital level and it is one measure within the HVBP program;⁴
18 and

19
20 Whereas, To withhold payouts due to poor quality of care for Medicare beneficiaries fails to
21 account for situations in which high-value care is at odds with patient satisfaction and may
22 disincentivize physicians to care for patients who are perceived as difficult to please, that is,
23 underserved minorities, those with lower socioeconomic status, and those with mental health
24 concerns;⁵ and

25
26 Whereas, Safety net hospitals⁶ typically do worse on patient experience metrics than their
27 counterparts that provide less care to underserved populations;⁶ and

¹ CMS Quality Strategy (2016). Available at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf>

² HCAHPS: Patients' Perspectives of Care Survey. Centers for Medicare & Medicaid Services. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-instruments/HospitalQualityInits/HospitalHCAHPS.html>

³ Tefera L, Lehrman W, Conway P. Measurement of the Patient Experience Clarifying Facts, Myths, and Approaches. JAMA Network 2016. Available at: <http://jama.jamanetwork.com/article.aspx?articleid=2503222>. Accessed March 27, 2016.

⁴ Jha AK, Orav EJ, Zheng J, Epstein AM. Patients' perception of hospital care in the United States. N Engl J Med. 2008;359(18):1921-1931.

⁵ Mehta SJ. Patient Satisfaction Reporting and Its Implications for Patient Care. The AMA Journal of Ethics 2015;17(7):616-621. doi:10.1001/journalofethics.2015.17.7.ecas3-1507

⁶ The Institute of Medicine defines safety net providers as "providers that organize and deliver a significant level of both health care and other health-related services to the uninsured, Medicaid, and other vulnerable populations," as well as providers "who by mandate or mission offer access to care regardless of a patient's ability to pay and whose patient population includes a substantial share of uninsured, Medicaid, and other vulnerable patients." <https://aspe.hhs.gov/report/environmental-scan-identify-major-research-questions-and-metrics-monitoring-effects-affordable-care-act-safety-net-hospitals/c-definition-safety-net-hospitals>.

1 Whereas, If institutions that have a greater safety net function have more challenging patient
2 populations and fewer resources to devote to improving low scores, financial incentives could
3 exacerbate existing inequities in care;⁶ and
4
5 Whereas, Existing AMA policy D-450.962 calls for the AMA to urge CMS to (a) evaluate the
6 relationship and apparent disparity between patient satisfaction, using the Hospital Consumer
7 Assessment of Health Providers and Systems (HCAHPS) and Emergency Department Patient
8 Experience of Care (ED-PEC) survey, and hospital performance on clinical process and
9 outcome measures used in the hospital value based purchasing program; therefore be it
10
11 RESOLVED, That our American Medical Association study the potential healthcare disparities
12 caused by Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) in
13 Medicare reimbursement. (Directive to Take Action)

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

Received: 09/29/16

RELEVANT AMA POLICY

Improve the HCAHPS Rating System D-450.960 - Our AMA will urge the Centers for Medicare & Medicaid Services to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) scoring system so that it assigns a unique value for each rating option available to patients.

Res. 806, I-13

Pain Management and the Hospital Value-Based Purchasing Program D-450.962 - 1. Our AMA urges the Centers for Medicare & Medicaid Services (CMS) to: (a) evaluate the relationship and apparent disparity between patient satisfaction, using the Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) and Emergency Department Patient Experience of Care (ED-PEC) survey, and hospital performance on clinical process and outcome measures used in the hospital value based purchasing program; and (b) reexamine the validity of questions used on the HCAHPS and ED-PEC surveys related to pain management as reliable and accurate measures of the quality of care in this domain.

2. Our AMA urges CMS to suspend the use of HCAHPS and ED-PEC measures addressing pain management until their validity as reliable and accurate measures of quality of care in this domain has been determined. BOT Rep. 9, A-13 Modified: BOT Rep. 5, I-15

Patient Satisfaction Surveys and Quality Parameters as Criteria for Physician Payment D-385.958 - Our AMA will work with the Centers for Medicare & Medicaid Services (CMS) and non-government payers to ensure that (1) subjective criteria, such as patient satisfaction surveys, be used only as an adjunctive and not a determinative measure of physician quality for the purpose of physician payment; and (2) physician payment determination, when incorporating quality parameters, only consider measures that are under the direct control of the physician.

Res. 102, A-13 Reaffirmed: Res. 806, I-13 Reaffirmed in lieu of Res. 814, I-14

Establishing Capitation Rates H-400.955 - 1. Our AMA believes Geographic variations in capitation rates from public programs (e.g., Medicare or Medicaid) should reflect only demonstrable variations in practice costs and correctly validated variations in utilization that reflect legitimate and demonstrable differences in health care need. In particular, areas that have relatively low utilization rates due to cost containment efforts should not be penalized with unrealistically low reimbursement rates. In addition, these payments should be adjusted at the

individual level with improved risk adjustors that include demographic factors, health status, and other useful and cost-effective predictors of health care use. 2. Our AMA will work to assure that any current or proposed Medicare or Medicaid (including waivers) capitated payments should be set at levels that would establish and maintain access to quality care. 3. Our AMA seeks modifications as appropriate to the regulations and/or statues affecting Medicare HMOs and other Medicare managed care arrangements to incorporate the revised Patient Protection Act and to ensure equal access to Medicare managed care contracts for physician-sponsored managed care organizations. 4. Our AMA supports development of a Medicare risk payment methodology that would set payment levels that are fair and equitable across geographic regions; in particular, such methodology should allow for equitable payment rates in those localities with relatively low utilization rates due to cost containment efforts.

CMS Rep. 3, A-95 CMS Rep. 7, I-95 Modified and Reaffirmed: Sub. Res. 120, A-97
Reaffirmation A-99 Reaffirmed: CMS Rep. 4, I-99 Reaffirmation A-00 Reaffirmation A-05
Reaffirmed: CMS Rep. 1, A-15

American Health Care Access, Innovation, Satisfaction and Quality D-450.966 - Our AMA will begin an international comparative study on health care quality that is a comprehensive and balanced study including comparisons of patient satisfaction, cancer outcomes, outcomes among more severe illnesses and injuries, rapidity of access and patient satisfaction as end points, and present their findings to the AMA House of Delegates at the 2012 Annual Meeting. Res. 104, A-11

Patient Satisfaction and Quality of Care H-450.982 - Our AMA believes that: (1) much may be gained by encouraging physicians to be sensitive to the goals and values of patients; and (2) efforts should be continued to improve the measurement of patient satisfaction and to document its relationship, if any, to favorable outcomes and other accepted criteria of high quality. CMS Rep. E, A-89 Reaffirmed: Sunset Report, A-00 Reaffirmed: CMS Rep. 6, A-10
Reaffirmed BOT Rep. 9, A-13

Accountable Care Organization Principles H-160.915 - Our AMA adopts the following Accountable Care Organization (ACO) principles: 1. Guiding Principle - The goal of an ACO is to increase access to care, improve the quality of care and ensure the efficient delivery of care. Within an ACO, a physician's primary ethical and professional obligation is the well-being and safety of the patient. 2. ACO Governance - ACOs must be physician-led and encourage an environment of collaboration among physicians. ACOs must be physician-led to ensure that a physician's medical decisions are not based on commercial interests but rather on professional medical judgment that puts patients' interests first. A. Medical decisions should be made by physicians. ACOs must be operationally structured and governed by an appropriate number of physicians to ensure that medical decisions are made by physicians (rather than lay entities) and place patients' interests first. Physicians are the medical professionals best qualified by training, education, and experience to provide diagnosis and treatment of patients. Clinical decisions must be made by the physician or physician-controlled entity. The AMA supports true collaborative efforts between physicians, hospitals and other qualified providers to form ACOs as long as the governance of those arrangements ensure that physicians control medical issues. B. The ACO should be governed by a board of directors that is elected by the ACO professionals. Any physician-entity [e.g., Independent Physician Association (IPA), Medical Group, etc.] that contracts with, or is otherwise part of, the ACO should be physician-controlled and governed by an elected board of directors. C. The ACO's physician leaders should be licensed in the state in which the ACO operates and in the active practice of medicine in the ACO's service area. D. Where a hospital is part of an ACO, the governing board of the ACO should be separate, and independent from the hospital governing board. 3. Physician and patient participation in an ACO should be voluntary. Patient participation in an ACO should be

voluntary rather than a mandatory assignment to an ACO by Medicare. Any physician organization (including an organization that bills on behalf of physicians under a single tax identification number) or any other entity that creates an ACO must obtain the written affirmative consent of each physician to participate in the ACO. Physicians should not be required to join an ACO as a condition of contracting with Medicare, Medicaid or a private payer or being admitted to a hospital medical staff. 4. The savings and revenues of an ACO should be retained for patient care services and distributed to the ACO participants. 5. Flexibility in patient referral and antitrust laws. The federal and state anti-kickback and self-referral laws and the federal Civil Monetary Penalties (CMP) statute (which prohibits payments by hospitals to physicians to reduce or limit care) should be sufficiently flexible to allow physicians to collaborate with hospitals in forming ACOs without being employed by the hospitals or ACOs. This is particularly important for physicians in small- and medium-sized practices who may want to remain independent but otherwise integrate and collaborate with other physicians (i.e., so-called virtual integration) for purposes of participating in the ACO. The ACA explicitly authorizes the Secretary to waive requirements under the Civil Monetary Penalties statute, the Anti-Kickback statute, and the Ethics in Patient Referrals (Stark) law. The Secretary should establish a full range of waivers and safe harbors that will enable independent physicians to use existing or new organizational structures to participate as ACOs. In addition, the Secretary should work with the Federal Trade Commission to provide explicit exceptions to the antitrust laws for ACO participants. Physicians cannot completely transform their practices only for their Medicare patients, and antitrust enforcement could prevent them from creating clinical integration structures involving their privately insured patients. These waivers and safe harbors should be allowed where appropriate to exist beyond the end of the initial agreement between the ACO and CMS so that any new organizational structures that are created to participate in the program do not suddenly become illegal simply because the shared savings program does not continue. 6. Additional resources should be provided up-front in order to encourage ACO development. CMS's Center for Medicare and Medicaid Innovation (CMI) should provide grants to physicians in order to finance up-front costs of creating an ACO. ACO incentives must be aligned with the physician or physician group's risks (e.g., start-up costs, systems investments, culture changes, and financial uncertainty). Developing this capacity for physicians practicing in rural communities and solo-small group practices requires time and resources and the outcome is unknown. Providing additional resources for the up-front costs will encourage the development of ACOs since the 'shared savings' model only provides for potential savings at the back-end, which may discourage the creation of ACOs (particularly among independent physicians and in rural communities). 7. The ACO spending benchmark should be adjusted for differences in geographic practice costs and risk adjusted for individual patient risk factors. A. The ACO spending benchmark, which will be based on historical spending patterns in the ACO's service area and negotiated between Medicare and the ACO, must be risk-adjusted in order to incentivize physicians with sicker patients to participate in ACOs and incentivize ACOs to accept and treat sicker patients, such as the chronically ill. B. The ACO benchmark should be risk-adjusted for the socioeconomic and health status of the patients that are assigned to each ACO, such as income/poverty level, insurance status prior to Medicare enrollment, race, and ethnicity and health status. Studies show that patients with these factors have experienced barriers to care and are more costly and difficult to treat once they reach Medicare eligibility. C. The ACO benchmark must be adjusted for differences in geographic practice costs, such as physician office expenses related to rent, wages paid to office staff and nurses, hospital operating cost factors (i.e., hospital wage index) and physician HIT costs. D. The ACO benchmark should include a reasonable spending growth rate based on the growth in physician and hospital practice expenses as well as the patient socioeconomic and health status factors. E. In addition to the shared savings earned by ACOs, ACOs that spend less than the national average per Medicare beneficiary should be provided an additional bonus payment. Many physicians and physician groups have worked hard over the years to establish systems and

practices to lower their costs below the national per Medicare beneficiary expenditures. Accordingly, these practices may not be able to achieve significant additional shared savings to incentivize them to create or join ACOs. A bonus payment for spending below the national average would encourage these practices to create ACOs and continue to use resources appropriately and efficiently. 8. The quality performance standards required to be established by the Secretary must be consistent with AMA policy regarding quality. The ACO quality reporting program must meet the AMA principles for quality reporting, including the use of nationally-accepted, physician specialty-validated clinical measures developed by the AMA-specialty society quality consortium; the inclusion of a sufficient number of patients to produce statistically valid quality information; appropriate attribution methodology; risk adjustment; and the right for physicians to appeal inaccurate quality reports and have them corrected. There must also be timely notification and feedback provided to physicians regarding the quality measures and results. 9. An ACO must be afforded procedural due process with respect to the Secretary's discretion to terminate an agreement with an ACO for failure to meet the quality performance standards. 10. ACOs should be allowed to use different payment models. While the ACO shared-savings program is limited to the traditional Medicare fee-for-service reimbursement methodology, the Secretary has discretion to establish ACO demonstration projects. ACOs must be given a variety of payment options and allowed to simultaneously employ different payment methods, including fee-for-service, capitation, partial capitation, medical homes, care management fees, and shared savings. Any capitation payments must be risk-adjusted. 11. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) Patient Satisfaction Survey should be used as a tool to determine patient satisfaction and whether an ACO meets the patient-centeredness criteria required by the ACO law. 12. Interoperable Health Information Technology and Electronic Health Record Systems are key to the success of ACOs. Medicare must ensure systems are interoperable to allow physicians and institutions to effectively communicate and coordinate care and report on quality. 13. If an ACO bears risk like a risk bearing organization, the ACO must abide by the financial solvency standards pertaining to risk-bearing organizations.

Res. 819, I-10 Reaffirmation A-11 Reaffirmed: Res. 215, A-11 Reaffirmation: I-12 Reaffirmed: CMS Rep. 6, I-13 Reaffirmed: Sub. Res. 711, A-15 Reaffirmation I-15 Reaffirmation: A-16

Monitoring Medicaid Managed Care H-290.985 - As managed care plans increasingly become the source of care for Medicaid beneficiaries, the AMA advocates the same policies for the conduct of Medicaid managed care that the AMA advocates for private sector managed care plans. In addition, the AMA advocates that the following criteria be used in federal and/or state oversight and evaluation of managed care plans serving Medicaid beneficiaries, and insists upon their use by the Federation in monitoring the implementation of managed care for Medicaid beneficiaries: (1) Adequate and timely public disclosure of pending implementation of managed care under a state program, so as to allow meaningful public comment. (2) Phased implementation to ensure availability of an adequate, sufficiently capitalized managed care infrastructure and an orderly transition for beneficiaries and providers. (3) Geographic dispersion and accessibility of participating physicians and other providers. (4) Education of beneficiaries regarding appropriate use of services, including the emergency department. (5) Availability of off-hours, walk-in primary care. (6) Coverage for clinically effective preventive services. (7) Responsiveness to cultural, language and transportation barriers to access. (8) In programs where more than one plan is available, beneficiary freedom to choose his/her plan, enforcement of standards for marketing/enrollment practices, and clear and comparable disclosure of plan benefits and limitations including financial incentives on providers. (9) Beneficiary freedom to choose and retain a given primary physician within the plan, and to request a change in physicians when dissatisfied. (10) Significant participating physician involvement and influence in plan medical policies, including development and conduct of quality assurance, credentialing and utilization review programs. (11) Ability of plan participating

physicians to determine how many beneficiaries and the type of medical problems they will care for under the program. (12) Adequate identification of plan beneficiaries and plan treatment restrictions to out-of-plan physicians and other providers. (13) Intensive case management for high utilizers and realistic financial disincentives for beneficiary misuse of services. (14) Treatment authorization requirements and referral protocols that promote continuity rather than fragment the process of care. (15) Preservation of private right of action for physicians and other providers and beneficiaries. (16) Ongoing evaluation and public reporting of patient outcomes, patient satisfaction and service utilization. (17) Full disclosure of plan physician and other provider selection criteria, and concerted efforts to qualify and enroll traditional community physicians and other existing providers in the plan. (18) Absence of gag rules. (19) Fairness in procedures for selection and deselection. (20) Realistic payment levels based on costs of care and predicted utilization levels. (21) Payment arrangements that do not expose practitioners to excessive financial risk for their own or referral services, and that tie any financial incentives to performance of the physician group over significant time periods rather than to individual treatment decisions. (22) Our AMA urges CMS to direct those state Medicaid agencies with Medicaid managed care programs to disseminate data and other relevant information to the state medical associations in their respective states on a timely and regular basis.

CMS Rep. 5 A-96 Reaffirmed and Appended: Sub. Res. 704, I-97 Reaffirmation A-00
Reaffirmation I-04 Reaffirmed: CMS Rep. 1, A-14

Work of the Task Force on the Release of Physician Data H-406.991 - Principles for the Public Release and Accurate Use of Physician Data: The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data when it is used in conjunction with program(s) designed to improve or maintain the quality of, and access to, medical care for all patients and is used to provide accurate physician performance assessments in concert with the following Principles: 1. Patient Privacy Safeguards - All entities involved in the collection, use and release of claims data comply with the HIPAA Privacy and Security Rules (H-315.972, H-315.973, H-315.983, H-315.984, H-315.989, H-450.947). - Disclosures made without patient authorization are generally limited to claims data, as that is generally the only information necessary to accomplish the intended purpose of the task (H-315.973, H-315.975, H-315.983). 2. Data Accuracy and Security Safeguards - Effective safeguards are established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data (H-406.996, H-450.947, H-450.961). - Reliable administrative, technical, and physical safeguards provide security to prevent the unauthorized use or disclosure of patient or physician-specific health care data and physician profiles (H-406.996, H-450.947, H-450.961). - Physician-specific medical practice data, and all analyses, proceedings, records and minutes from quality review activities are not subject to discovery or admittance into evidence in any judicial or administrative proceeding without the physician's consent (H-406.996, H-450.947, H-450.961). 3. Transparency Requirements - When data are collected and analyzed for the purpose of creating physician profiles, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure (H-315.973, H-406.993, H-406.994, H-406.998, H-450.947, H-450.961). - The limitations of the data sources used to create physician profiles are clearly identified and acknowledged in terms understandable to consumers (H-406.994, H-450.947). - The capabilities and limitations of the methodologies and reporting systems applied to the data to profile and rank physicians are publicly revealed in understandable terms to consumers (H-315.973, H-406.994, H-406.997, H-450.947, H-450.961). - Case-matched, risk-adjusted resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients (H-

285.931). 4. Review and Appeal Requirements - Physicians are provided with an adequate and timely opportunity to review, respond and appeal the results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release (H-315.973, H-406.996, H-406.998, H-450.941, H-450.947, H-450.961). - When the physician and the rater cannot reach agreement, physician comments are appended to the report at the physician's request (H-450.947). 5. Physician Profiling Requirements - The data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians (H-406.994, H-406.997, H-450.947, H-450.961). - Data reporting programs only use accurate and balanced data sources to create physician profiles and do not use these profiles to create tiered or narrow network programs that are used to steer patients towards certain physicians primarily on cost of care factors (450.951).

- When a single set of claims data includes a sample of patients that are skewed or not representative of the physicians' entire patient population, multiple sources of claims data are used (no current policy exists). - Physician efficiency of care ratings use physician data for services, procedures, tests and prescriptions that are based on physicians' patient utilization of resources so that the focus is on comparative physicians' patient utilization and not on the actual charges for services (no current policy exists). - Physician-profiling programs may rank individual physician members of a medical group but do not use those individual rankings for placement in a network or for reimbursement purposes (no current policy exists). 6. Quality Measurement Requirements - The data are used to profile physicians based on quality of care provided - never on utilization of resources alone -- and the degree to which profiling is based on utilization of resources is clearly identified (H-450.947). - Data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties, such as the Physician Consortium for Performance Improvement. (H-406.994, H-406.998, H-450.947, H-450.961). - These evidence-based measures are endorsed by the National Quality Forum (NQF) and/or the AQA and HQA, when available. When unavailable, scientifically valid measures developed in conjunction with appropriate medical specialty societies and practicing physicians are used to evaluate the data (no current policy exists). 7. Patient Satisfaction Measurement Requirements - Until the relationship between patient satisfaction and other outcomes is better understood, data collected on patient satisfaction is best used by physicians to better meet patient needs particularly as they relate to favorable patient outcomes and other criteria of high quality care (H-450.982). - Because of the difficulty in determining whether responses to patient satisfaction surveys are a result of the performance of a physician or physician office, or the result of the demands or restrictions of health insurers or other factors out of the control of the physician, the use of patient satisfaction data is not appropriate for incentive or tiering mechanisms (no current policy exists). - As in physician profiling programs, it is important that programs that publicly rate physicians on patient satisfaction notify physicians of their rating and provide a chance for the physician to appeal that rating prior to its publication (no current policy exists).

BOT Rep. 18, A-09 Reaffirmation A-10 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10 Reaffirmation I-10 Reaffirmed in lieu of Res. 808, I-10 Reaffirmed in lieu of Res. 824, I-10 Reaffirmation A-11 Reaffirmed: BOT Rep. 17, A-13 Reaffirmed: Res. 806, I-13

Pain Medicine D-450.958 - Our AMA: (1) continues to advocate that the Centers for Medicare & Medicaid Services (CMS) remove the pain survey questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); (2) continues to advocate that CMS not incorporate items linked to pain scores as part of the CAHPS Clinician and Group Surveys (CG-CAHPS) scores in future surveys; and (3) encourages hospitals, clinics, health plans, health systems, and academic medical centers not to link physician compensation,

employment retention or promotion, faculty retention or promotion, and provider network participation to patient satisfaction scores relating to the evaluation and management of pain. BOT Rep. 5, I-15

AMA Principles on Maintenance of Certification (MOC) H-275.924 - 1. Changes in specialty-board certification requirements for MOC programs should be longitudinally stable in structure, although flexible in content. 2. Implementation of changes in MOC must be reasonable and take into consideration the time needed to develop the proper MOC structures as well as to educate physician diplomats about the requirements for participation. 3. Any changes to the MOC process for a given medical specialty board should occur no more frequently than the intervals used by that specialty board for MOC. 4. Any changes in the MOC process should not result in significantly increased cost or burden to physician participants (such as systems that mandate continuous documentation or require annual milestones). 5. MOC requirements should not reduce the capacity of the overall physician workforce. It is important to retain a structure of MOC programs that permits physicians to complete modules with temporal flexibility, compatible with their practice responsibilities. 6. Patient satisfaction programs such as The Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient survey are neither appropriate nor effective survey tools to assess physician competence in many specialties. 7. Careful consideration should be given to the importance of retaining flexibility in pathways for MOC for physicians with careers that combine clinical patient care with significant leadership, administrative, research and teaching responsibilities. 8. Legal ramifications must be examined, and conflicts resolved, prior to data collection and/or displaying any information collected in the process of MOC. Specifically, careful consideration must be given to the types and format of physician-specific data to be publicly released in conjunction with MOC participation. 9. Our AMA affirms the current language regarding continuing medical education (CME): "Each Member Board will document that diplomats are meeting the CME and Self-Assessment requirements for MOC Part II. The content of CME and self-assessment programs receiving credit for MOC will be relevant to advances within the diplomat's scope of practice, and free of commercial bias and direct support from pharmaceutical and device industries. Each diplomat will be required to complete CME credits (AMA PRA Category 1 Credit?, American Academy of Family Physicians Prescribed, American College of Obstetricians and Gynecologists, and/or American Osteopathic Association Category 1A)." 10. In relation to MOC Part II, our AMA continues to support and promote the AMA Physician's Recognition Award (PRA) Credit system as one of the three major credit systems that comprise the foundation for continuing medical education in the U.S., including the Performance Improvement CME (PICME) format; and continues to develop relationships and agreements that may lead to standards accepted by all U.S. licensing boards, specialty boards, hospital credentialing bodies and other entities requiring evidence of physician CME. 11. MOC is but one component to promote patient safety and quality. Health care is a team effort, and changes to MOC should not create an unrealistic expectation that lapses in patient safety are primarily failures of individual physicians. 12. MOC should be based on evidence and designed to identify performance gaps and unmet needs, providing direction and guidance for improvement in physician performance and delivery of care. 13. The MOC process should be evaluated periodically to measure physician satisfaction, knowledge uptake and intent to maintain or change practice. 14. MOC should be used as a tool for continuous improvement. 15. The MOC program should not be a mandated requirement for licensure, credentialing, reimbursement, network participation or employment. 16. Actively practicing physicians should be well-represented on specialty boards developing MOC. 17. Our AMA will include early career physicians when nominating individuals to the Boards of Directors for ABMS member boards. 18. MOC activities and measurement should be relevant to clinical practice. 19. The MOC process should not be cost prohibitive or present barriers to patient care. 20. Any assessment should be used to guide physicians' self-directed study. 21. Specific content-based feedback after any assessment tests should be provided to physicians in a timely

manner. 22. There should be multiple options for how an assessment could be structured to accommodate different learning styles. 23. Physicians with lifetime board certification should not be required to seek recertification. 24. No qualifiers or restrictions should be placed on diplomats with lifetime board certification recognized by the ABMS related to their participation in MOC. 25. Members of our House of Delegates are encouraged to increase their awareness of and participation in the proposed changes to physician self-regulation through their specialty organizations and other professional membership groups.

CME Rep. 16, A-09 Reaffirmed: CME Rep. 11, A-12 Reaffirmed: CME Rep. 10, A-12 Reaffirmed in lieu of Res. 313, A-12 Reaffirmed: CME Rep. 4, A-13 Reaffirmed in lieu of Res. 919, I-13 Appended: Sub. Res. 920, I-14 Reaffirmed: CME Rep. 2, A-15 Appended: Res. 314, A-15 Modified: CME Rep. 2, I-15 Reaffirmation A-16 Reaffirmed: Res. 309, A-16

Appropriate Payment Level Differences by Place and Type of Service H-330.925 - Our AMA (1) encourages CMS to adopt policy and establish mechanisms to fairly reimburse physicians for office-based procedures; (2) encourages CMS to adopt a site neutral payment policy for hospital outpatient departments and ambulatory surgical centers; (3) advocates for the use of valid and reliable data in the development of any payment methodology for the provision of ambulatory services; (4) advocates that in place of the Consumer Price Index for all Urban Consumers (CPI-U), CMS use the hospital market basket index to annually update ambulatory surgical center payment rates; (5) encourages the use of CPT codes across all sites-of-service as the only acceptable approach to payment methodology; and (6) will join other interested organizations and lobby for any needed changes in existing and proposed regulations affecting payment for ambulatory surgical centers to assure a fair rate of reimbursement for ambulatory surgery.

Sub. Res. 104, A-98 Reaffirmation I-98 Appended: CMS Rep. 7, A-99 Reaffirmation A-00 Reaffirmation I-03 Reaffirmation A-11 Reaffirmed: CMS Rep. 3, A-13 Reaffirmed: Sub. Res. 104, A-14 Reaffirmed: Res. 116, A-14 Modified: CMS Rep. 3, A-14 Reaffirmation A-14 Reaffirmation A-15

Remove Pain Scores from Quality Metrics D-450.955 - Our AMA will work with the Centers for Medicare and Medicaid Services to remove uncontrolled pain scores from quality metrics that impact reimbursement for services rendered in the nursing facilities and from the five star rating system for nursing facilities.

Res. 236, A-16

CMS - Standards of Care, Hospital Admissions H-335.994 - The AMA supports federal government funding for an independent study to examine and assess the present impact on the quality of medical care from mandated utilization review, medical necessity standards, methods of reimbursement, denial of hospital admissions for illness, and surgical or invasive procedures. Sub. Res. 25, A-88 Reaffirmed: Sunset Report, I-98 Reaffirmed: CMS Rep. 4, A-08

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 809
(I-16)

Introduced by: Medical Student Section

Subject: Addressing the Exploitation of Restricted Distribution Systems by Pharmaceutical Manufacturers

Referred to: Reference Committee J
(Candace E. Keller, Chair)

1 Whereas, A litany of prescription drugs have recently experienced significant price increases
2 shortly after changes of ownership, such as colchicine, Thiola, Daraprim, and Makena, which in
3 the past five years have seen price increases of 2000%, 2000%, 5000%, and 15,000%,
4 respectively;^{1,2,3,4,5,6} and

5
6 Whereas, The mechanism by which companies are able to implement such price hikes involves,
7 in part, the transition from a traditional wholesaler-based supply chain model to a “restricted”,
8 “controlled”, or “closed” distribution system at the discretion of the manufacturer;^{7,8} and

9
10 Whereas, A restricted distribution system is a tightly-controlled supply chain model in which a
11 drug is only available to patients via specific specialty pharmacies, enabling drug manufacturers
12 to stringently control the distribution of their products; and

13
14 Whereas, Per the 1984 Hatch-Waxman Act and current FDA guidelines, in order for a generic
15 manufacturer to receive FDA approval to sell a generic variant of a brand-name drug, it must
16 demonstrate bioequivalence, necessitating the purchase of non-trivial quantities of the brand-
17 name drug, a process that is greatly complicated by restricted distribution;^{9,10} and

¹ Langreth, R. and Koons, C. (2015) 2,000% Drug Price Surge Is a Side Effect of FDA Safety Program. Bloomberg Business, Available at: <http://www.bloomberg.com/news/articles/2015-10-06/2-000-drug-price-surge-is-a-side-effect-of-fda-safety-program>

² Marketed Unapproved Drugs Compliance Policy Guide § 440.100 Marketed New Drugs Without Approved NDAs or ANDAs. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf>

³ Brozak, S. (2014) Retrophin, Gilead, And Our Healthcare Values. Forbes, Available at: <http://www.forbes.com/sites/stephenbrozak/2014/09/12/retrophin-gilead-and-our-healthcare-values/#2299c6f9fca4>

⁴ Patel Y, Rumore MM. Hydroxyprogesterone caproate injection (makena) one year later: to compound or not to compound that is the question. P T. 2012;37(7):405-11.

⁵ Stobbe, M. (2011) Premature Labor Drug Spikes from \$10 to \$1,500. NBC News, Available at: <http://www.nbcnews.com/id/41994697/ns/health-pregnancy/t/premature-labor-drug-spikes/>

⁶ Lorenzetti, L. (2015) This 62-Year-Old Drug Just Got 5000% More Expensive. Fortune, Available at: <http://fortune.com/2015/09/21/turing-pharmaceuticals-drug-prices-daraprim/>

⁷ Carrier, M and Kesselheim A. (2015) The Daraprim Price Hike and a Role for Antitrust. Health Affairs Blog, Available at: <http://healthaffairs.org/blog/2015/10/21/the-daraprim-price-hike-and-a-role-for-antitrust/>

⁸ Mahoney, M. (2015) New Pyrimethamine Dispensing Program: What Pharmacists Should Know. Pharmacy Times, Available at: <http://www.pharmacytimes.com/contributor/monica-v-golik-mahoney-pharmd-bcps-aq-id/2015/07/new-pyrimethamine-dispensing-program-what-pharmacists-should-know/#sthash.lruZY1k5.dpuf>

⁹ Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA. (2013). United States Food and Drug Administration. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377465.pdf>

¹⁰ Tucker D., Wells G., and Sheer, M. (2014) REMS: The Next Pharmaceutical Enforcement Priority? Antitrust. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2410950

1 Whereas, Often, though not always, a restricted distribution system implemented by FDA
2 mandate as part of a Risk Evaluation & Mitigation Strategy (REMS) when the drug in question is
3 associated with considerable health risks or other regulatory or clinical concerns such as
4 counterfeiting and abuse;^{7,8,11,12,13,14} and
5
6 Whereas, Restricted distribution systems, even when implemented by FDA mandate per a
7 REMS, are being exploited to block generic entry into the market by making it virtually
8 impossible for generic manufacturers to obtain the necessary materials to perform
9 bioequivalence testing, and the potential for exploitation is even greater when restricted
10 distribution is implemented unilaterally at the manufacturer's discretion;^{10,15,16,17} and
11
12 Whereas, Provisions of the Food and Drug Administration Amendments Act of 2007 sought to
13 address circumstances in which REMS can pose barriers to generic entry, but "it remains
14 unclear whether the FDA even has any authority to enforce the prohibition against companies
15 using a REMS to block generic entry" and the FDA has stated that it lacks an enforcement
16 mechanism;^{10,12,14,15,16} and
17
18 Whereas, The FDA has a backlog of some 4,300 generic drug applications pending approval as
19 of December 2015 and the median approval time rose from 27 months in 2010 to 36 months in
20 2013, despite the infusion of \$300 million from generic manufacturers in 2012 per the Generic
21 Drug User Fee Amendments, which was intended to facilitate faster approval;^{18,19,20} and
22
23 Whereas, On March 1, 2016, Senator Susan Collins introduced S. 2615 "Increasing Competition
24 in Pharmaceuticals Act", which directs the FDA to act within 150 days on generic drug
25 applications when there is only one competing product available, and creates a "generic priority
26 review voucher" program to speed approval of other generics;^{21,22} and
27
28 Whereas, Existing AMA policy seeks to address "the already high and escalating costs of
29 generic prescription drugs" (H-110.988) while recognizing their cost-saving potential (H-
30 125.984); therefore be it
31
32 RESOLVED, That our American Medical Association advocate with interested parties for
33 legislative or regulatory measures that require prescription drug manufacturers to seek Federal
34 Drug Administration and Federal Trade Commission approval before establishing a restricted
35 distribution system (New HOD Policy); and be it further

¹¹ Kirschenbaum BE. Specialty pharmacies and other restricted drug distribution systems: financial and safety considerations for patients and health-system pharmacists. *Am J Health Syst Pharm.* 2009;66(24 Suppl 7):S13-20.

¹² Battaglia, L. (2013) Risky Conduct with Risk Mitigation Strategies? The Potential Antitrust Issues Associated with REMS. *Antitrust Healthcare Chronicle*, Available at: <http://www.hlregulation.com/files/2013/10/Lauren-Battaglia-article1.pdf>

¹³ Oral Cancer Agents Are Changing The Distribution Channel. (2006) *Oncology Business Review*, Available at: <https://obroncology.com/journal-current-dtl.php?recordID=8>

¹⁴ Risk evaluation and mitigation strategies, 21 U.S.C. § 355–1 (2010).

¹⁵ Tucker D., Wells G., and Sheer, M. (2014) REMS: The Next Pharmaceutical Enforcement Priority? *Antitrust*. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2410950

¹⁶ Fabish, A. (2015). REMS Abuse And Antitrust Injury: Round Peg, Square Hole. *Law360*. Available at: <http://www.law360.com/articles/723053/rems-abuse-and-antitrust-injury-round-peg-square-hole>

¹⁷ Fabish, A. (2015). Why REMS Abuse Doesn't Belong In Antitrust Litigation. *Law360*. Available at: <http://www.law360.com/articles/645875/why-rems-abuse-doesn-t-belong-in-antitrust-litigation>

¹⁸ Herrick, D. (2015) What Is Increasing the Cost of Generic Drugs? Part I: The Supply Chain. *National Center for Policy Analysis*, Available at: <http://www.ncpa.org/pdfs/st371.pdf>

¹⁹ Kaplan, S. (2015) One Reason for High Drug Prices: a Huge Backlog of Unapproved Generic Drugs. *STAT*, Available at: <http://www.statnews.com/2015/12/29/generic-drugs-backlog/>

²⁰ Barlas S. Generic prices take flight: the FDA is struggling to ground them. *P T.* 2014;39(12):833-45.

²¹ To Increase Competition in the Pharmaceutical Industry, S. S. 2615, 114th Cong. (2016). Print. Available at: <https://www.congress.gov/bill/114th-congress/senate-bill/2615/text>

²² Brennan, Zachary. (2016) More Competition: Senator Proposes Priority Reviews for Some Generics, New Voucher Program. *Regulatory Affairs Professional Society*. Available at: <http://www.raps.org/Regulatory-Focus/News/2016/03/03/24466/More-Competition-Senator-Proposes-New-Priority-Reviews-for-Some-Generics-New-Voucher-Program/>

1 RESOLVED, That our AMA support the mandatory provision of samples of approved out-of-
2 patent drugs upon request to generic manufacturers seeking to perform bioequivalence assays
3 (New HOD Policy); and be it further

4
5 RESOLVED, That our AMA advocate with interested parties for legislative or regulatory
6 measures that expedite the FDA approval process for generic drugs, including but not limited to
7 application review deadlines and generic priority review voucher programs. (New HOD Policy)

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

Received: 09/29/16

RELEVANT AMA POLICY

Cost of New Prescription Drugs H-110.998 - Our AMA urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs.

Res. 112, I-89 Reaffirmed: Res. 520, A-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of Res. 229, I-14

Reducing Prescription Drug Prices D-110.993 - Our AMA will (1) continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs; and (2) encourage state medical associations and others that are interested in pharmaceutical bulk purchasing alliances, pharmaceutical assistance and drug discount programs, and other related pharmaceutical pricing legislation, to contact the National Conference of State Legislatures, which maintains a comprehensive database on all such programs and legislation.

CMS Rep. 3, I-04 Modified: CMS Rep. 1, A-14 Reaffirmation A-14 Reaffirmed in lieu of Res. 229, I-14

Inappropriate Extension of Patent Life of Pharmaceuticals D-110.994 - Our AMA will continue to monitor the implementation of the newly-enacted reforms to the Hatch-Waxman law to see if further refinements are needed that would prevent inappropriate extension of patent life of pharmaceuticals, and work accordingly with Congress and the Administration to ensure that AMA policy concerns are addressed.

BOT Rep. 21, A-04 Reaffirmed: BOT Rep. 19, A-14

The Evolving Culture of Drug Safety in the United States: Risk Evaluation and Mitigation Strategies (REMS) H-100.961 - Our AMA urges that: (1) The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) require sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; (c) clearly specify that sponsors must assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available; and (d) conduct a long-term assessment of the prescribing patterns of drugs with REMS requirements. (2) The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information. (3) To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common

definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed. (4) REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner. (5) The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) urge sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; and (c) recommend that sponsors assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available. (6) The FDA, in concert with the pharmaceutical industry, evaluate the evidence for the overall effectiveness of REMS with ETASU in promoting the safe use of medications and appropriate prescribing behavior. (7) The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information. (8) To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed. (9) REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner. (10) The FDA solicit input from the physician community before establishing any REMS programs that require prescriber training in order to ensure that such training is necessary and meaningful, requirements are streamlined and administrative burdens are reduced.

CSAPH Rep. 8, A-10 Reaffirmed: Res. 917, I-10 Appended: CSAPH Rep. 3, I-12

Pharmaceutical Cost H-110.987 - 1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives. 2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition. 3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry. 4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system. 5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies. 6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation. 7. Our AMA supports legislation to shorten the exclusivity period for biologics. 8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens. 9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and will report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.

CMS Rep. 2, I-15

Controlling the Skyrocketing Costs of Generic Prescription Drugs H-110.988 - 1. Our American Medical Association will work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the U.S. Food and Drug Administration, the U.S. Federal Trade Commission, and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs. 2. Our AMA will advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients. 3. Our AMA encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs. 4. Our AMA supports measures that increase price transparency for generic prescription drugs.

Sub. Res. 106, A-15 Reaffirmed: CMS 2, I-15

Study of Actions to Control Pharmaceutical Costs H-110.992 - Our AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs.

Sub. Res. 114, A-01 Reaffirmed: Res. 533, A-03 Reaffirmed: CMS Rep. 4, A-13 Reaffirmed in lieu of Res. 229, I-14 Reaffirmed: CMS 2, I-15

Cost of Prescription Drugs H-110.997 - Our AMA: (1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;(2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;(3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;(4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;(5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;(6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and(7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.

BOT Rep. O, A-90 Sub. Res. 126 and Sub. Res. 503, A-95 Reaffirmed: Res. 502, A-98 Reaffirmed: Res. 520, A-99 Reaffirmed: CMS Rep. 9, I-99 Reaffirmed: CMS Rep. 3, I-00 Reaffirmed: Res. 707, I-02 Reaffirmation A-04 Reaffirmed: CMS Rep. 3, I-04 Reaffirmation A-06 Reaffirmed in lieu of Res. 814, I-09 Reaffirmed in lieu of Res. 201, I-11

Generic Drugs H-125.984 - Our AMA believes that: (1) Physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice. (2) It should be recognized that generic drugs frequently can be less costly alternatives to brand-name

products. (3) Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products (i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician. (4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA's MedWatch program. (5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products. (6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength). (7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process.

CSA Rep. 6, A-02 Reaffirmed: CSAPH Rep. 2, A-07 Reaffirmation A-08 Reaffirmation A-09 Reaffirmed in lieu of Res. 525, A-10 Reaffirmed in lieu of Res. 224, I-14

Cost Sharing Arrangements for Prescription Drugs H-110.990 - Our AMA: 1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients; 2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and 3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition.

CMS Rep. 1, I-07 Reaffirmation A-08 Reaffirmed: CMS Rep. 1, I-12 Reaffirmed in lieu of Res. 105, A-13

Generic Changes in Medicare (Part D) Plans D-330.911 - 1. Our AMA will investigate the incidence and reasoning behind the conversion of one generic drug to another generic drug of the same class in Medicare Advantage drug plans. 2. Our AMA will request the Centers for Medicare & Medicaid Services to ensure that pharmaceutical vendors, when they do ask for generic transitions of drugs, list the drugs they believe are more cost effective along with their tier price and alternative drug names.

Res. 124, A-14

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 810
(I-16)

Introduced by: Women Physicians Section

Subject: Medical Necessity of Breast Reconstruction and Reduction Surgeries

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Macromastia is a common medical condition in the United States that results in
2 symptoms including skin excoriation, restriction of physical activities, nerve compression,
3 postural and skeletal changes, breast/back/neck/shoulder pain, headache, and bra strap
4 grooving resulting in permanent skin changes; and

5
6 Whereas, Symptoms associated with macromastia can significantly impact quality of life,
7 activity, and health; and

8
9 Whereas, Macromastia is a recognized condition that meets medical necessity criteria for
10 insurance coverage under certain conditions; and

11
12 Whereas, Many insurance policies base approval for coverage on required removal of certain
13 weights of tissue intraoperatively during reduction mammoplasty and these requirements are
14 often based on height/weight/ body mass index (BMI) or body surface area (BSA) criteria; and

15
16 Whereas, A wide variety of breast sizes, densities, and/or weights may exist for any specific
17 body height or weight and therefore BMI/BSA may not be the best predictors of medical
18 necessity in all cases; and

19
20 Whereas, Health outcomes have not been shown to specifically correlate with baseline,
21 preoperative breast size or specific weight of tissue resected intraoperatively; and

22
23 Whereas, Patient satisfaction and symptom improvement are significantly positive after surgical
24 reduction mammoplasty; therefore be it

25
26 RESOLVED, That our American Medical Association support efforts to adapt medical necessity
27 and insurance coverage decisions for assessment of preoperative symptomatology for
28 macromastia without requirements for weight of volume resected during breast reduction
29 surgery. (New HOD Policy)

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

Received: 09/30/16

References:

State Laws on Breast Reconstruction. Available at
<https://www.plasticsurgery.org/reconstructive-procedures/breast-reconstruction/breast-reconstruction-resources/state-laws-on-breast-reconstruction.html>.

RELEVANT AMA POLICY

Breast Reconstruction H-55.973

Our AMA: (1) believes that reconstruction of the breast for rehabilitation of the postmastectomy cancer patient should be considered reconstructive surgery rather than aesthetic surgery; (2) supports education for physicians and breast cancer patients on breast reconstruction and its availability; (3) recommends that third party payers provide coverage and reimbursement for medically necessary breast cancer treatments including but not limited to prophylactic contralateral mastectomy and/or oophorectomy; and (4) recognizes the validity of contralateral breast procedures needed for the achievement of symmetry in size and shape, and urges recognition of these ancillary procedures by Medicare and all other third parties for reimbursement when documentation of medical necessity is provided.

CCB/CLRPD Rep. 3, A-14

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 811
(I-16)

Introduced by: Texas

Subject: Opposition to CMS Mandating Treatment Expectations and Practicing Medicine

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, It is the goal of physicians to provide quality evidenced-based care to individual
2 patients based upon their varied acute medical conditions and underlying co-morbidities; and
3

4 Whereas, It is the appropriate responsibility of the federal Center for Medicare & Medicaid
5 Services (CMS) to oversee the quality and effectiveness of care paid for by the federal
6 government; and
7

8 Whereas, It is NOT appropriate for CMS to mandate clinical treatment for all patients, in all
9 circumstances regardless of the patient's condition or comorbidities, such as mandating
10 reporting of administration of 30cc/kg of crystalloid fluid for all patients with potential serious
11 infections, regardless of circumstance or comorbidities; and
12

13 Whereas, Administration of 30cc/kg of crystalloid fluid for all patients with potential serious
14 infections, regardless of circumstance, acuities and comorbidities can lead to intentional harm of
15 patients including loss of airway, generate complications such as pulmonary edema which may
16 require intubation, and death; and
17

18 Whereas, Physician treatment that causes harm to a patient is a violation of the Hippocratic
19 Oath, the Code of Medical Ethics, the Medical Practice Act, and may be found to constitute
20 'willful and wanton' negligence; and
21

22 Whereas, A current CMS-mandated reporting quality core measures requires "Resuscitation
23 with 30 ml/kg crystalloid fluid" for patients with potential serious infections, regardless of their
24 clinical circumstance and the interpretation of these Core Measures Sets (Go to
25 www.qualitynet.org/hospitals-inpatient/specifications/manual) by Quality Net
26 (www.Qualitynet.org¹) do not recognize any exception for congestive heart failure, renal failure,
27 or liver failure or recognize any alternatives such as pressors or intravascular expansions such
28 as use of albumin in cirrhotic live patients; and

¹ Please see the response from Quality Net (www.Qualitynet.org). This is the CMS support site, which is as follows: There are no exclusions to the 30 ml/kg amount based on comorbidities such as heart failure (HF), end stage renal disease (ESRD) or the patient's weight. The question has been presented to the measure stewards who have indicated the rationale is based on the sepsis literature. The literature supports addressing the most urgent life threatening condition first which is severe sepsis with hypotension or lactate ≥ 4 . After this has been stabilized changes in fluid management to address HF, ESRD or other conditions can be put into place to prevent potential or developing adverse effects of the fluid volume.

1 Whereas, Individual hospitals can lack the appropriate interpretation of CMS core measure²,
2 resulting in inappropriate sanctions of physicians for appropriate medical care; therefore be it
3
4 RESOLVED, That our American Medical Association oppose CMS creating mandatory
5 standards of care that may potentially harm patients, disrupt the patient-physician relationship,
6 and fail to recognize the importance of appropriate physician assessment, evidence-based
7 medicine and goal-directed care of individual patients (New HOD Policy); and be it further
8
9 RESOLVED, That our AMA communicate to hospitals that some CMS mandatory standards of
10 care do not recognize appropriate physician treatment and may cause unnecessary harm to
11 patients (Directive to Take Action); and be it further
12
13 RESOLVED, That our AMA communicate to members, state and specialty societies, and the
14 public the dangers of CMS' quality indicators potentially harming the patient-physician
15 relationship. (Directive to Take Action)

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

Received: 09/30/16

² Investigation results: "it is clear that patient [name] had Cirrhosis and severe anasarca and so can lead to fluid overload by administering CMS recommended 30ml/kg crystalloid fluids" with a response of "There are no exclusions to the 30 ml/kg amount based on comorbidities such as heart failure (HF), end stage renal disease (ESRD) or the patient's weight" and "Effective 07/01/2016: The ONLY acceptable fluids are crystalloid or balanced crystalloid solutions" and "Decision is upheld, variance remains".

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 812
(I-16)

Introduced by: Michigan

Subject: Enact Rules and Payment Mechanisms to Encourage Appropriate Hospice and Palliative Care Usage

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Hospice and palliative care are being underutilized, resulting in unnecessary and
2 expensive care during the last six months of life for many patients with complicated medical
3 issues; and

4 Whereas, Hospice has been impacted by an administrative cut in addition to a series of cuts
5 applied to most Medicare providers as part of health care reform and budget reduction efforts¹;
6 and

7 Whereas, Beginning in October 2009, the Centers for Medicare and Medicaid Services began a
8 seven-year phase out of the Budget Neutrality Adjustment Factor (BNAF), a key element in the
9 Medicare hospice wage index that will ultimately result in a permanent reduction in hospice
10 reimbursement rates of 4.2 percent²; and

11 Whereas, The 2009 Affordable Care Act imposed an additional change to the Medicare hospice
12 formula that will further cut hospice payments by approximately 11.8 percent over the next 10
13 years through the introduction of a “productivity adjustment” on the calculation of annual
14 payment updates for hospice; therefore be it

15 RESOLVED, That our American Medical Association (AMA) amend existing AMA Policy
16 H-85.955, Hospice Care, by addition to read as follows:

17 Our AMA: (1) approves of the physician-directed hospice concept to enable the
18 terminally ill to die in a more homelike environment than the usual hospital; and urges
19 that this position be widely publicized in order to encourage extension and third party
20 coverage of this provision for terminal care; (2) encourages physicians to be
21 knowledgeable of patient eligibility criteria for hospice benefits and, realizing that
22 prognostication is inexact, to make referrals based on their best clinical judgment; (3)
23 supports modification of hospice regulations so that it will be reasonable for
24 organizations to qualify as hospice programs under Medicare; (4) believes that each
25 patient admitted to a hospice program should have his or her designated attending
26 physician who, in order to provide continuity and quality patient care, is allowed and
27 encouraged to continue to guide the care of the patient in the hospice program; (5)
28 supports changes in Medicaid regulation and reimbursement of palliative care and
29 hospice services to broaden eligibility criteria concerning the length of expected survival
30 for pediatric patients and others, to allow provision of concurrent life-prolonging and

¹ Hospice action network. Reimbursement. Accessed at <http://hospiceactionnetwork.org/get-informed/issues/reimbursement/> on March 29, 2016.

² Ibid

1 palliative care, and to provide respite care for family care givers; and (6) advocates that
2 the Centers for Medicare and Medicaid Services enact rules and payment mechanisms
3 to encourage appropriate hospice and palliative care utilization for eligible patients; and
4 (7) seeks amendment of the Medicare law to eliminate the six-month prognosis under
5 the Medicare Hospice benefit and support identification of alternative criteria,
6 meanwhile supporting extension of the prognosis requirement from 6 to 12 months as
7 an interim measure. (Modify Current HOD Policy)

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

Received: 09/30/16

RELEVANT AMA POLICY

Hospice Care H-85.955

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

CCB/CLRPD Rep. 3, A-14

Hospice Services Under Medicare D-140.962

1. Our AMA recognizes the benefits to patients and their families that hospice represents in end-of-life care, and reaffirms that physicians (a) have a responsibility to see that hospice services are authorized in appropriate circumstances and settings, and (b) should be allowed and encouraged to remain actively involved in managing their patients? hospice care, in collaboration with hospice staff.
2. Our AMA will collaborate with interested organizations, including hospice organizations, and other medical societies, to develop educational materials and programs for physicians to ensure that hospice services are provided in the most cost-effective, appropriate settings.
3. Our AMA will call on the Centers for Medicare & Medicaid Services, in conjunction with stakeholder groups, to thoroughly study the Medicare hospice benefit, including its structure, payment methodology, quality assurance and regulatory scheme.

Citation: (Res. 4, A-10)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813
(I-16)

Introduced by: American Academy of Pediatrics

Subject: Physician Payment for Information Technology Costs

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, In 2009, the federal government developed and funded an incentive program to
2 encourage physicians to adopt electronic health records (American Recovery and Reinvestment
3 Act (ARRA), HiTech Act, Meaningful Use Program); and
4
5 Whereas, Most physicians have adopted electronic health records, at significant costs to their
6 practices; and
7
8 Whereas, Physicians are having significant difficulty qualifying for maximum Meaningful Use
9 payments; and
10
11 Whereas, Physicians are incurring significant ongoing information technology costs that are not
12 covered by ongoing Meaningful Use payment options; and
13
14 Whereas, Meaningful Use payments will be phased out in the near future (2021); and
15
16 Whereas, There is recent evidence that physicians spend two hours with the electronic health
17 record for every one hour of patient care; and
18
19 Whereas, Physician payment has not increased to help physicians pay for their ongoing costs
20 for adopting and implementing electronic health records; therefore be it
21
22 RESOLVED, That our American Medical Association assist in gathering and providing data that
23 physicians can use to convince public and private payers that payment must cover the
24 increasing information technology costs of physicians. (Directive to Take Action)

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

Received: 09/30/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 814
(I-16)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Subject: Addressing Discriminatory Health Plan Exclusions or Problematic Benefit Substitutions for Essential Health Benefits Under the Affordable Care Act

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Improving patient outcomes is an American Medical Association goal; and

2
3 Whereas, The Affordable Care Act requires that benefits are provided without discrimination
4 based on health condition, race, color, national origin, age, disability, sex, sexual orientation or
5 gender identity; and

6
7 Whereas, Covered benefits in states still vary widely, including gaps in coverage, arbitrary limits,
8 discriminatory benefit designs and/or cost-sharing on the basis of age, sex, gender, degree of
9 medical dependency, gender identity, disability, and quality of life; and

10
11 Whereas, Gaps in women's health coverage persist because insurers often exclude health
12 services women are likely to need, leaving women vulnerable to higher costs and denied claims
13 that threaten economic security and physical health; and

14
15 Whereas, Six categories of services are frequently excluded from insurance coverage that
16 disproportionately affect women such as treatment of conditions resulting from non-covered
17 services, (e.g. (e.g. Treatment of an infection after a non-covered prophylactic mastectomy)
18 maternity care, gender transition, maintenance therapy, genetic testing, self-inflicted conditions,
19 fetal surgeries, and preventive services; and

20
21 Whereas, Parity violations persist for a number of critical services, including, but not limited to
22 mental health and substance abuse disorders, and gaps persist in coverage for pediatric
23 services, including dental and vision services, habilitative services and prescription drugs; and

24
25 Whereas, Service exclusions and benefit substitutions are often described in health plan
26 materials in language that is difficult to fully comprehend; therefore be it

1 RESOLVED, That our American Medical Association work with state medical societies and their
2 state regulators to facilitate the following:

3 1. Prohibit health plans from imposing arbitrary limits that are unreasonable or potentially
4 discriminatory for coverage of the Essential Health Benefits.

5 2. Require any insurer, whose plans contain exclusions that are not in the state Essential
6 Health Benefits benchmark plan, demonstrate that its benefits are substantially similar and
7 actuarially equivalent to the benchmark, in compliance with federal regulations.

8 3. Define the state habilitative Essential Health Benefits definition that goes beyond the federal
9 minimum definition.³

10 4. Review current plans for discriminatory exclusions and require insurers to revise these plans
11 if discriminatory exclusions present;

12 5. Review consumer complaints for incidents of discriminatory benefit and formulary design,
13 cost-sharing, problematic Essential Health Benefits substitutions or exclusions.

14 6. Prohibit insurer benefit substitutions in the Essential Health Benefits (Directive to Take
15 Action); and be it further

16

17 RESOLVED, That our AMA work with federal regulators to:

18 1. Improve the Essential Health Benefits benchmark plan selection process to ensure arbitrary
19 limits and exclusions do not impede access to healthcare and coverage.

20 2. Develop policy to prohibit Essential Health Benefits substitutions that do not exist in a state's
21 benchmark plan or selective use of exclusions or arbitrary limits to prevent high-cost claims
22 or that encourage high-cost enrollees to drop coverage.

23 3. Review current plans for discriminatory exclusions and submit any specific incidents of
24 discrimination through an administrative complaint to Office for Civil Rights. (Directive to
25 Take Action)

References

¹ The Commonwealth Fund, August 2016, <http://www.commonwealthfund.org/>

² The National Women's Law Center, State of Women's Coverage: Health Plan Violations of the Affordable Care Act (NWLC 2015), National Women's Law Center, <http://nwlc.org/wpcontent/uploads/2015/04/stateofwomenscoverage2015final.pdf>

³ The federal definition of habilitative services is health care services that help a person keep, learn or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings. Found in the CMS glossary of medical terms and finalized in 2016.

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

Received: 10/11/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 815
(I-16)

Introduced by: Washington

Subject: Preservation of Physician-Patient Relationships and
Promotion of Continuity of Patient Care

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, Medicare (CMS) is rapidly moving towards bundled payment models (e.g. the
2 Comprehensive Care Joint Replacement Model and the Cardiac Bundled Payment Model); and
3
4 Whereas, Bundled payments involve setting one price per patient per episode of care; and
5
6 Whereas, There is interest in bundles encompassing chronic conditions and long-term diseases
7 including diabetes, obesity and cancer; and
8
9 Whereas, This promotes coordinated care but also requires data collection, reviewing care
10 processes and cost accounting; and
11
12 Whereas, CMS has both voluntary Bundled Payment for Care Improvement Initiatives as well as
13 mandatory bundled payments; and
14
15 Whereas, Bundled payment models can encourage in-hospital referrals, in turn interfering with
16 established relationships between patients and their preferred physicians; therefore be it
17
18 RESOLVED, That our American Medical Association support policies that encourage the
19 freedom of patients to choose the health care delivery system that best suits their needs and
20 provides them with a choice of physicians (New HOD Policy); and be it further
21
22 RESOLVED, That our AMA support the freedom of choice of physicians to refer their patients to
23 the physician practice or hospital that they think is most able to provide the best medical care
24 (New HOD Policy); and be it further
25
26 RESOLVED, That our AMA support policies that encourage patients to return to their
27 established primary care provider after emergency department visits, hospitalization or specialty
28 consultation. (New HOD Policy)

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

Received: 10/13/16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 816
(I-16)

Introduced by: Senior Physicians Section

Subject: Support for Seamless Physician Continuity of Patient Care

Referred to: Reference Committee J
(Candace E. Keller, MD, Chair)

1 Whereas, With an aging population and shortage of physicians facing America, the AMA Senior
2 Physicians Section (AMA-SPS) will work to engage senior physicians (age 65 and older), both
3 active and retired, to ensure high-quality care and safety for patients by collaboration with other
4 stakeholders in the changing health care system; and
5
6 Whereas, Senior physicians (and others) come out of training programs where continuity was
7 considered one of the critical foundations of a quality medical practice; and
8
9 Whereas, There has been extreme growth of the present day practice of separating inpatient
10 care from office care as far as the role of the physician is concerned; and
11
12 Whereas, Systems are not yet commonplace that assure seamless care between the inpatient
13 and office care settings; and
14
15 Whereas, Those physicians and others who choose to provide care in both the inpatient and
16 office settings are being precluded by health insurance system policies; therefore be it
17
18 RESOLVED, That our American Medical Association clearly support the concept of seamless
19 continuity of care between hospital inpatient and outpatient care (New HOD Policy); and be it
20 further
21
22 RESOLVED, That our AMA study whether there are instances of health insurers or HMO's
23 precluding physicians via contracts from providing care to their patients in the in-patient setting
24 for which the physician has clinical privileges. (Directive to Take Action)

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

Received: 10/13/16

RELEVANT AMA POLICY

Admitting Officer and Hospitalist Programs H-285.964

AMA policy states that: (1) managed care plan enrollees and prospective enrollees should receive prior notification regarding the implementation and use of "admitting officer" or "hospitalist" programs; (2) participation in "admitting officer" or "hospitalist programs" developed and implemented by managed care or other health care organizations should be at the voluntary discretion of the patient and the patient's physician; (3) hospitalist programs when initiated by a hospital or managed care organization should be developed consistent with AMA policy on medical staff bylaws and implemented with the formal approval of the organized medical staff by at least the same notification and voting threshold required to approve a bylaws change to assure that the principles and structure of the autonomous and self-governing medical staff are retained; (4) Hospitals and other health care organizations should not compel physicians by contractual obligation to assign their patients to "Hospitalists" and that no punitive measure should be imposed on physicians or patients who decline participation in "hospitalists programs"; and (5) AMA opposes any hospitalist model that disrupts the patient/physician relationship or the continuity of patient care and jeopardizes the integrity of inpatient privileges of attending physicians and physician consultants.

Sub. Res. 714, I-95 Amended by CMS Rep. 4, A-98 Reaffirmed: Res. 819, A-99 Reaffirmation I-99 Reaffirmed: Res. 812, A-02 Reaffirmed: BOT Rep. 15, A-05 Reaffirmed in lieu of Res. 734, A-05 Modified: Res. 731, A-07

Preserving Physician/Patient Relationships During Hospitalizations H-225.946

1. Our AMA advocates that hospital admission processes should include: a determination of whether the patient has an existing relationship with an actively treating primary care or specialty physician; where the patient does not object, prompt notification of such actively treating physician(s) of the patient's hospitalization and the reason for inpatient admission or observation status; to the extent possible, timely communication of the patient's medical history and relevant clinical information by the patient's primary care or specialty physician(s) to the hospital-based physician; notice to the patient that he/she may request admission and treatment by such actively treating physician(s) if the physician has the relevant clinical privileges at the hospital; honoring requests by patients to be treated by their physician(s) of choice; and allowing actively treating physicians to treat to the full extent of their hospital privileges.

2. Our AMA advocates that a medical staff incorporate the above principles into medical staff bylaws, rules and regulations.

Res. 812, I-15 Modified: CMS Rep. 06, A-16

The Emerging Use of Hospitalists: Implications for Medical Education D-225.999

(1) Our AMA, through its Council on Medical Education and Council on Medical Service, will collect data on the following areas: (a) the emergence of educational opportunities for hospitalist physicians at the residency level, including the curriculum of hospitalist tracks within residency training programs; (b) the availability and content of continuing medical education opportunities for hospitalist physicians; (c) the policies of hospitals and managed care organizations related to the maintenance of hospital privileges for generalist physicians who do not typically care for inpatients; and (d) the quality and costs of care associated with hospitalist practice.

(2) Our Council on Medical Education and Council on Medical Service will monitor the evolution of hospitalist programs, with the goal of identifying successful models.

(3) Our AMA will encourage dissemination of information about the education implications of the emergence of hospitalism to medical students, resident physicians, and practicing physicians.

CME Rep. 2, A-99 Reaffirmed: CME Rep. 2, A-09

Voluntary Use of Hospitalists and Required Consent H-225.960

It is the policy of our AMA that the use of a hospitalist physician as the physician of record during a hospitalization must be voluntary and the assignment of responsibility to the hospitalist physician must be based on the consent of the patient's personal physician and the patient.

CME Rep. 2, A-99 Reaffirmation I-99 Reaffirmed: Res. 812, A-02 Reaffirmed with change in title: BOT Rep. 15, A-05 Reaffirmed in lieu of Res. 734, A-05 Reaffirmed: CME Rep. 1, A-15