REPORTS OF THE COUNCIL ON MEDICAL SERVICE

The following reports, 1–7, were presented by Peter S. Lund, MD, Chair:

1. INFERTILITY BENEFITS FOR VETERANS
(RESOLUTION 223-I-15)

Reference committee hearing: see report of [Reference Committee J](#).

HOUSE ACTION: **RECOMMENDATIONS ADOPTED**
IN LIEU OF RESOLUTION 223-I-15
REMAINDER OF REPORT FILED
See Policy H-510.984

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

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

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

BACKGROUND

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

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

COMBAT-RELATED INFERTILITY

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

Gunshot wounds and exposure to hazardous materials are also common causes of infertility. Approximately 1,400 service members returned from Iraq and Afghanistan with severe injuries to their reproductive organs. It is estimated that thousands more sustained paralysis, brain injuries or other conditions that make IVF their best option to

conceive a child. Results from the National Health Study for a New Generation of US Veterans indicated that about 16 percent of female veterans and 14 percent of male veterans reported experiencing infertility.[1] According to the most recent Centers for Disease Control and Prevention surveys, approximately 11 percent of female and male civilians aged 15-44 experience infertility.[2,3]

ACCESS TO IN VITRO FERTILIZATION

TRICARE

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

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

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

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

Veterans Affairs

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

Service members who complete a length of service in any branch of the armed forces are classified as veterans as long as they were not dishonorably discharged. Retired veterans are service members who remain on active duty or have served in the Army National Guard, Army Reserve, Navy Reserve, Marine Corps Reserve, Air National Guard, Air Force Reserve or the Coast Guard Reserve for a sufficient period of time, which is usually a minimum of 20 years. Veterans who are not retired do not qualify for the TRICARE program, whereas retired veterans do qualify with the stipulation that they are no longer eligible for the IVF benefit. Service members who become disabled while on duty may be medically retired and receive a disability retirement before serving 20 years in the military. Most of

the seriously or severely ill or injured service members are medically retired before serving 20 years, receive the same benefits as other retirees, are eligible to enroll in TRICARE and may qualify for IVF.

Private Insurance

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

MEDICAL ASSISTANCE FOR IN VITRO FERTILIZATION

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

RELEVANT AMA POLICY

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

DISCUSSION

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

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

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

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

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

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) support lifting the congressional ban on the Department of Veterans Affairs (VA) from covering in vitro fertilization (IVF) costs for veterans who have become infertile due to service-related injuries.

2. That our AMA encourage interested stakeholders to collaborate in lifting the congressional ban on the VA from covering IVF costs for veterans who have become infertile due to service-related injuries.

3. That our AMA encourage the Department of Defense (DOD) to offer service members fertility counseling and information on relevant health care benefits provided through TRICARE and the VA at pre-deployment and during the medical discharge process.

4. That our AMA support efforts by the DOD and VA to offer service members comprehensive health care services to preserve their ability to conceive a child and provide treatment within the standard of care to address infertility due to service-related injuries.

REFERENCES

1. US Department of Veterans Affairs. Health Study for a New Generation of US Veterans. Military Medicine. 2016. Available at: http://www.publichealth.va.gov/epidemiology/studies/new-generation/Index.asp
2. Centers for Disease Control and Prevention. National Center for Health Statistics. National Survey of Family Growth. (2010-2013). Available at: http://www.cdc.gov/nchs/nsfg/
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.
5. US Department of Defense. Department of Defense Press Briefing by Secretary Carter on Force of the Future Reforms in the Pentagon Press Briefing Room. Secretary of Defense Ash Carter. 2016. Available at: http://cc.bingj.com/cache.aspx?q=Department+of+Defense+2016+Press+Briefing+by+Secretary+Carter+on+Force+of+the+Future+Reforms+in+the+Pentagon+Press+Briefing+Room&d=5007576942773710&mkt=en-US&setlang=en-US&w=ludcUoi4DlzlLvyKwa1p6wPPuvW0kyOa
6. US Department of Health and Human Services. Health Resources and Services Administration. Veterans Health Care Act of 1992, Public Law 102-585. 1992. Available at: http://www.hrsa.gov/opa/programrequirements/publiclaw102585.html
7. Fast Facts about Infertility. Resolve: The National Infertility Association. 2015. Available at: http://www.resolve.org/about/fast-facts-about-fertility.html?referrer=https://www.google.com/
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/

2. HEALTH CARE WHILE INCARCERATED
(RESOLUTION 118-A-16)

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 118-A-16
REMAINDER OF REPORT FILED
See Policies H-430.986 and D-430.997

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

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

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

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

BACKGROUND

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

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

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

AFFORDABLE CARE ACT MEDICAID EXPANSION

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

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

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

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

In April 2016, CMS issued a letter to state health officials providing guidance on facilitating successful re-entry for individuals transitioning from incarceration into their communities.[14] The guidance specified that individuals on probation, parole or community release pending trial are eligible for Medicaid as are individuals residing in corrections-related, supervised community residential facilities.

HEALTH CARE MODELS

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

Local: Maricopa County Jail System, Phoenix, AZ

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

Federal: Federal Bureau of Prisons

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

BEHAVIORAL HEALTH CARE

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

Cook County Jail, Chicago, IL

Chicago's Cook County Jail is often referred to as the nation's largest mental health facility with approximately 30 percent of the 9,000 daily detainees having a serious mental health diagnosis. The executive director of the jail is a clinical psychologist. The correctional facility includes a mental health transition center that provides mental health care, psychoeducation, peer support and re-entry services. Ongoing treatment at the center is available once an inmate is released.[23] The Cook County Circuit Court has a countywide network of specialty courts that includes mental health and drug treatment courts to assist individuals who have committed non-violent, nonsexual felonies, and are more in need of health care treatment than incarceration. A team of professionals coordinate efforts between members of the court system and outside organizations to guarantee that participants receive intensive treatment, interventions and supervision. The program has succeeded in significantly reducing its participants' recidivism rates.

RELEVANT AMA POLICY

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

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

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

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

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

AMA ACTIVITY

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

DISCUSSION

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

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

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

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

Resolution 118-A-16 requested that our AMA advocate for the reversal of the "Medicaid Inmate Payment Exclusion" so that detainees can retain their Medicaid eligibility throughout the incarceration process. The Council cautions that advocating for the elimination of the exclusion necessitates the redistribution of Medicaid funding and could have unintended consequences regarding the provision of care and payment to physicians. AMA Policy H-60.919[7] addresses continuity of Medicaid eligibility by encouraging states to suspend rather than terminate

Medicaid coverage for juveniles following arrest and detention. Consistent with Policy H-60.919[7], which was adopted at the 2016 Annual Meeting, the Council believes that Medicaid eligibility for both juveniles and adults should be suspended rather than terminated during the entire incarceration process and that coverage should be reinstated when the individual transitions back into the community.

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

RECOMMENDATIONS

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

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

2. That our AMA advocate for adequate payment to health care providers, including primary care and mental health and addiction treatment professionals, to encourage improved access to comprehensive physical and behavioral health care services to juveniles and adults throughout the incarceration process from intake to re-entry into the community.

3. That our AMA support partnerships and information sharing between correctional systems, community health systems and state insurance programs to provide access to a continuum of health care services for juveniles and adults in the correctional system.

4. That our AMA advocate for necessary programs and staff training to address the distinctive health care needs of incarcerated women and adolescent females, including gynecological care and obstetrics care for pregnant and postpartum women.

5. That our AMA encourage state Medicaid agencies to accept and process Medicaid applications from juveniles and adults who are incarcerated.

6. That our AMA encourage state Medicaid agencies to work with their local departments of corrections, prisons, and jails to assist incarcerated juveniles and adults who may not have been enrolled in Medicaid at the time of their incarceration to apply and receive an eligibility determination for Medicaid.

7. That our AMA encourage state Medicaid agencies to suspend rather than terminate Medicaid eligibility of juveniles and adults upon intake into the criminal justice system and throughout the incarceration process, and to reinstate coverage when the individual transitions back into the community.

8. That our AMA urge the Centers for Medicare & Medicaid Services (CMS) and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release from correctional facilities in order to help establish coverage effective upon release, assist with transition to care in the community and help reduce recidivism.

9. That our AMA rescind Policy D-430.994, which requested the study accomplished by this report.

REFERENCES

1. Peter Wagner and Bernadette Rabuy. Mass Incarceration: The Whole Pie 2016. Prison Policy Initiative. Available at: http://www.prisonpolicy.org/reports/pie2016.html
2. Lauren Glaze, Danielle Kaeble, Todd Minton and Anastasios Tsoutis. Correctional Populations in the United State, 2014. Bureau of Justice Statistics Special Report. US Department of Justice. 2015. Available at: http://www.bjs.gov/index.cfm?ty=pbdetail&iid=5519
3. *Ibid.*

4.   Kamala Mallik-Kane. Returning Home Illinois Policy Brief Health and Prisoner Reentry. Urban Institute. 2005. Available at: http://www.urban.org/research/publication/returning-home-illinois-policy-brief-health-and-prisoner-reentry

5.   Alexandra Gates, Samantha Artiga and Robin Rudowitz. Health Coverage and Care for the Adult Criminal Justice-Involved Population. The Kaiser Commission on Medicaid and the Uninsured. 2014. Available at: https://kaiserfamilyfoundation.files.wordpress.com/2014/09/8622-health-coverage-and-care-for-the-adult-criminal-justice-involved-population1.pdf

6.   Bureau of Justice Statistics. Annual Survey of Jails, Annual Survey of Parole, Annual Survey of Probation, Census of Jail Inmates & National Prisoner Statistics, 1980-2014. Available at: http://www.bjs.gov/index.cfm?ty=kfdetail&iid=487

7.   Alexandra Gates, Samantha Artiga and Robin Rudowitz. Health Coverage and Care for the Adult Criminal Justice Involved Population. The Kaiser Commission on Medicaid and the Uninsured. 2014. Available at:

8.   Carly B. Dierkhising et al. Trauma Histories Among Justice-Involved Youth: Findings from the National Child Traumatic Stress Network. European Journal of Psychotraumatol. 2013. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3714673/

9.   Estelle v. Gamble, 429 U.S. 97, 97 S. Ct. 285 (1976).

10.   Alexandra Gates, Samantha Artiga and Robin Rudowitz. Health Coverage and Care for the Adult Criminal Justice-Involved Population. The Kaiser Commission on Medicaid and the Uninsured. 2014. Available at: https://kaiserfamilyfoundation.files.wordpress.com/2014/09/8622-health-coverage-and-care-for-the-adult-criminal-justice-involved-population1.pdf

11.   1905(a)(29) of the Social Security Act

12.   Department of Health and Human Services. Centers for Medicare and Medicaid Services. Letter issued to State Medicaid Directors: Ending Chronic Homelessness. 2004. Available at: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Long-Term-Services-and-Supports/Community-Living/Downloads/Ending-Chronic-Homelessness-SMD-Letter.pdf

13.   Catherine McKee, Sarah Somers, Samantha Artiga and Alexandra Gates. State Medicaid Eligibility Policies for Individuals Moving Into and Out of Incarceration. The Kaiser Commission on Medicaid and the Uninsured. 2015. Available at: http://files.kff.org/attachment/issue-brief-state-medicaid-eligibility-policies-for-individuals-moving-into-and-out-of-incarceration

14.   Department of Health and Human Services. Centers for Medicare and Medicaid Services. Letter issued to state health officials providing guidance on how to facilitate successful re-entry for individuals transitioning from incarceration to their communities. 2016. Available at: https://www.medicaid.gov/federal-policy-guidance/downloads/sho16007.pdf

15.   Maricopa County Sheriff's Office. Adult Programs. Available at: https://www.maricopa.gov/pdweb/docs/Adult_Programs_offered_for_PD_Oct_2014.pdf_v0_0_1.pdf

16.   Maricopa County Correctional Health: "Best in the Nation." 2015. Available at: http://www.maricopa.gov/pr_detail.aspx?releaseID=3037

17.   National Commission on Correctional Health Care. Looking Back – Moving Forward. 2015. Annual Report. Available at: http://www.ncchc.org/filebin/Publications/2015_NCCHC_Annual_Report.pdf

18.   State Reform. Opportunities for Enrolling Justice-Involved Individuals in Medicaid. 2015. Available at: https://www.statereform.org/weekly-insight/enrolling-justice-involved-individuals-in-medicaid

19.   Federal Bureau of Prisons. Clinical Practice Guidelines. Available at: https://www.bop.gov/resources/health_care_mngmt.jsp

20.   National Commission on Correctional Health Care. Looking Back, Moving Forward. 2015 Annual Report. Available at: http://www.ncchc.org/filebin/Publications/2015_NCCHC_Annual_Report.pdf

21.   Fuller Torrey, Aaron Kennard, Don Eslinger, Richard Lamb and James Pavle. More Mentally Ill Persons Are in Jails and Prisons Than Hospitals: A Survey of the States. Treatment Advocacy Center and the National Sheriffs' Association. 2010. Available at: http://www.treatmentadvocacycenter.org/storage/documents/final_jails_v_hospitals_study.pdf

22.   Fuller Torrey, Mary Zdanowicz, Aaron Kennard, Richard Lamb, Donald Eslinger, Micheal Biasotti and Doris Fuller. The Treatment of Persons with Mental Illness in Prisons and Jails: A State Survey. Treatment Advocacy Center. 2014. Available at: http://s3.documentcloud.org/documents/1095566/persons-with-mental-illness-in-jails-and-prisons-2.pdf

23.   American's Largest Mental Hospital Is a Jail. The Atlantic. 2015. Available at: http://www.theatlantic.com/politics/archive/2015/06/americas-largest-mental-hospital-is-a-jail/395012/

24.   Bureau of Justice Statistics, US Department of Justice. Drug Use and Dependence, State and Federal Prisoners, 2004. 2006. Available at: http://www.bjs.gov/content/pub/pdf/dudsfp04.pdf

25.   James, D. and Glaze, L. Mental Health Problems of Prison and Jail Inmates. Bureau of Justice Statistics Special Report. US Department of Justice. 2006. Available at: http://www.bjs.gov/content/pub/pdf/mhppji.pdf

3. PROVIDERS AND THE ANNUAL WELLNESS VISIT
(RESOLUTION 824-I-15)

Reference committee hearing: see report of [Reference Committee J](#).

HOUSE ACTION: **RECOMMENDATIONS ADOPTED**
                      IN LIEU OF RESOLUTION 824-I-15
                      REMAINDER OF REPORT FILED
                      See Policies H-160.921, H-330.879 and H-425.997

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

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

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

BACKGROUND

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

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

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

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

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

CONTINUITY OF CARE

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

NON-PHYSICIAN COMMERCIAL ENTITIES PROVIDING THE ANNUAL WELLNESS VISIT

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

RELEVANT AMA POLICY

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

Policy H-425.997 addresses preventive services and encourages the development of policies and mechanisms to assure the continuity, coordination, and continuous availability of patient care, including preventive care and early-detection screening services. Policy H-425.997 states further that preventive care should ideally be coordinated by a patient's physician. To promote continuity of care, Policy H-160.921 states that store-based health clinics must establish protocols for ensuring continuity of care with practicing physicians within the local community and should be encouraged to use electronic health records as a means of communicating patient information and facilitating continuity of care. Further, Policy H-160.921 states that store-based health clinics should encourage patients to establish care with a primary care physician to ensure continuity of care.

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

AMA ACTIVITY

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

DISCUSSION

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

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

Retail clinics and other non-physician facilities may provide a limited scope of services to patients that may seem to be timely and convenient. However, these clinics can ultimately lead to fragmentation if not properly coordinated with the patient's primary physician's office or usual source of care. This fragmentation compromises patient care and health care quality and cost. Using a retail health clinic for the AWV may result in a missed opportunity to address more complex patient needs. Care delivered in retail clinics and other non-physician facilities must work in coordination with the patient's current and regular sources of care to mitigate the effects of fragmentation. Fragmentation and unaccountable silos of care are in direct opposition to achieving continuous whole-person care with improved health outcomes.[15] Accordingly, while there is no statutory authority to require that one must be physician or member of a physician-led health care team to provide the AWV, it is crucial to note that the AWV is most appropriately provided by a physician or member of a physician-led health care team to promote efficient, quality care that either establishes or continues to provide ongoing continuity of care. Further, the Council recommends reaffirming Policy H-160.921 on protocols for store-based health clinics to ensure and promote continuity of care. Notably, the Council will be preparing an updated report on retail health clinics for the 2017 Annual meeting. Additionally, the Council recommends that any clinic performing the AWV enumerate all relevant findings and make provisions for all appropriate follow-up care. The Council believes this recommendation will more explicitly hold other clinicians to a reasonable reporting and follow-up standard.

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

RECOMMENDATIONS

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

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

2. That our AMA reaffirm Policy H-160.921 on protocols for store-based health clinics to ensure continuity of care.

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

4. That our AMA support that, at a minimum, any clinician performing the AWV must enumerate all relevant findings from the visit and make provisions for all appropriate follow-up care.

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

6. That our AMA encourage CMS to educate Medicare enrollees, that, in choosing their primary care physician, they are encouraged to make their AWVs with their primary care physician in order to facilitate continuity and coordination of their care.

REFERENCES

1. Arnold E. Cuenca, Making Medicare Wellness Visits Work in Practice. American Academy of Family Physicians. Available at http://www.aafp.org/fpm/2012/0900/p11.pdf.
2. Available at http://prevent.org/data/files/news/hraawvguidancereportfinal.pdf.
3. *Supra* note 1.
4. Medicare Preventive Services National Provider Call: The Initial Preventive Physical Exam and the Annual Wellness Visit. Centers for Medicare & Medicaid Services. Available at https://www.cms.gov/outreach-and-education/outreach/npc/downloads/ippe-awv-faqs.pdf.
5. 42 CFR 410.15. Available at https://www.law.cornell.edu/cfr/text/42/410.15
6. *Id.*
7. *Supra* note 5.
8. 42 U.S.C. § 1861. Available at https://www.ssa.gov/OP_Home/ssact/title18/1861.htm.
9. *Supra* note 4.
10. Joseph Ladapo and Dave Chokshi. Continuity of Care for Chronic Conditions: Threats, Opportunities, and Policy. Health Affairs. Available at http://healthaffairs.org/blog/2014/11/18/continuity-of-care-for-chronic-conditions-threats-opportunities-and-policy-3/.
11. Doctors Worried about Non-physician Entities Providing Medicare Wellness Visits. Texas Medical Association. Available at https://www.texmed.org/Template.aspx?id=32247.
12. *Supra* note 9.
13. Definition of Continuity of Care. American Academy of Family Physicians. Available at http://www.aafp.org/about/policies/all/definition-care.html.
14. Artemis March. Perspective: Consistency, Continuity, and Coordination-The 3Cs of Seamless Patient Care. Commonwealth Fund. Available at http://www.commonwealthfund.org/publications/newsletters/quality-matters/2006/june/perspective-consistency-continuity-and-coordination-the-3cs-of-seamless-patient-care.
15. *Id.*

4. CONCURRENT HOSPICE AND CURATIVE CARE
(RESOLUTION 804-I-15)

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 804-I-15 AND RESOLUTION 812
REMAINDER OF REPORT FILED
See Policies H-85.951 and H-85.966

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

H-85.955, "Hospice Care"
Our AMA: (1) approves of the physician-directed hospice concept to enable the terminally ill to die in a more homelike environment than the usual hospital; and urges that this position be widely publicized in order to encourage extension and third party coverage of this provision for terminal care; (2) encourages physicians to be knowledgeable of patient eligibility criteria for hospice benefits and, realizing that prognostication is inexact, to make referrals based on their best clinical judgment; (3) supports modification of hospice regulations so that it will be reasonable for organizations to qualify as hospice programs under Medicare; (4) believes that each

patient admitted to a hospice program should have his or her designated attending physician who, in order to provide continuity and quality patient care, is allowed and encouraged to continue to guide the care of the patient in the hospice program; (5) supports changes in Medicaid regulation and reimbursement of palliative care and hospice services to broaden eligibility criteria concerning the length of expected survival for pediatric patients and others, to allow provision of concurrent life-prolonging and palliative care, and to provide respite care for family care givers; and (6) seeks amendment of the Medicare law to eliminate the six-month prognosis under the Medicare Hospice benefit and support identification of alternative criteria, meanwhile supporting extension of the prognosis requirement from 6 to 12 months as an interim measure.; and (7) supports changes in Medicare regulation to allow provision of concurrent curative and hospice care.

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

BACKGROUND

The American Academy of Hospice and Palliative Medicine (AAHPM) defines palliative care as that which relieves suffering and improves quality of life for people with serious illnesses, no matter whether they can be cured. Hospice is a specific type of palliative care for people who likely have six or fewer months to live. Not all palliative care is hospice, although hospice care is always palliative. Hospice is a distinct delivery system for which eligibility is usually defined by public and private insurers offering the benefit. Curative care under the Medicare program refers to health care practices that treat patients with the intent of curing them or modifying their underlying disease as opposed to managing symptoms such as pain or stress.

Medicare's Hospice Benefit

Medicare is the largest insurer of end-of-life medical care, with spending on patients during their last year of life making up 25 percent of total Medicare spending on patients 65 years of age and older.[1] Predictably, Medicare is also the largest payer of hospice care, most frequently in patients' homes but also at Medicare-certified hospices, hospitals and skilled nursing facilities. In 2014, more than 1.3 million people received Medicare hospice services from 4,100 certified for-profit and non-profit providers at a cost of $15.1 billion. Average length of stay was about 88 days; however, median length of stay was only 17 days. Spending on Medicare's hospice benefit has doubled since 2000 but held steady between 2012 and 2014.[2]

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

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

Medicare pays for hospice care using per diem payment categories encompassing four levels of care: (1) routine home care, for which Medicare pays $187 per day for the first 60 days and $147 per day thereafter; (2) general inpatient care, paid $720 per day; (3) continuous home care, paid at a rate of $39 per hour; and (4) inpatient respite care, for which Medicare pays $167 per day (payment rates are for fiscal year 2016).[6] Service intensity add-on

payments are also made when hospice provides direct patient care by a registered nurse or social worker during patients' last seven days of life. In keeping with the hospice philosophy, routine home care accounts for the large majority of hospice payments.

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

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

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

Palliative Care

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

Concurrent Curative Care

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

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

Medicare Care Choices Model

In January 2016, the Center for Medicare and Medicaid Innovation (CMMI) launched a concurrent care demonstration project called the Medicare Care Choices Model (MCCM). According to the CMMI, this pilot will

test the impact of patient access to concurrent hospice and curative care on quality of care and patient and family satisfaction.[13]

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

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

AMA POLICY

The AMA has longstanding policy on hospice and palliative care. Policy H-85.966 maintains that the use of hospice care should provide the patient and family with appropriate support, but not preclude or prevent the use of appropriate palliative therapies to continue to treat the underlying disease. Under Policy D-140.962, the AMA recognizes the benefits of hospice, 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. Policy D-140.962 also asks the AMA to call on the Centers for Medicare & Medicaid Services (CMS) to thoroughly study Medicare's hospice benefit.

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

DISCUSSION

A 2014 report from the Institute of Medicine (IOM), *Dying in America*, found that "improving the quality and availability of medical and social services for patients and their families could not only enhance quality of life through the end of life, but may also contribute to a more sustainable care system." The IOM panel further recommended "a major reorientation of payment systems to incentivize the integration of medical and social services, the coordination of care across multiple care settings, and the use of advance care planning and shared decision making to better align the services patients receive with their care goals and preferences."[16] The Council found these recommendations sensible and worthy of consideration during its discussions. The Council reviewed the literature on hospice and palliative care and will monitor evaluations of the MCCM as they become available, revisiting hospice payment and coverage issues as needed. Valuable feedback was also solicited and received from the AAHPM.

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

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

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

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

Numerous studies have shown that palliative care improves pain and symptom control, increases satisfaction with care among seriously ill patients and reduces costs. The Council underscores the AMA's support for palliative care services, and recommends that the AMA encourage CMS to identify ways to optimize patient access to palliative care, which relieves suffering and improves quality of life for people with serious illnesses regardless of whether they can be cured, and to provide appropriate coverage and payment for these services.

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

RECOMMENDATIONS

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

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

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

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

4. That our AMA encourage physicians to be familiar with local hospice and palliative care resources and their benefit structures, as well as clinical practice guidelines developed by national medical specialty societies, and to refer seriously ill patients accordingly.

REFERENCES

1. Kaiser Family Foundation. Medicare Spending at the End of Life: A Snapshot of Beneficiaries Who Died in 2014 and the Cost of Their Care. July 14, 2016. Available online at http://kff.org/medicare/issue-brief/medicare-spending-at-the-end-of-life/?utm_campaign.
2. Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. March 2016.
3. Hogan, C. Spending in the Last Year of Life and the Impact of Hospice on Medicare Outlays. 2015. Available online at: http://medpac.gov/documents/contractor-reports/spending-in-the-last-year-of-life-and-the-impact-of-hospice-on-medicare-outlays-(updated-august-2015).pdf?sfvrsn=0.
4. Code of Federal Regulations. The Social Security Act: Title 42, Chapter IV, Subpart B, Part 418 (USC §418.24 Election of Hospice Care)
5. Code of Federal Regulations. The Social Security Act: Title 42, Chapter IV, Subpart B, Part 418 (USC §418.24 Election of Hospice Care)
6. Centers for Medicare & Medicaid Services. Medicare Learning Network (MLN): Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and Hospice Prices for Fiscal Year (FY) 2016.
7. Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. March 2016.
8. Aldridge, M et al. Has Hospice Utilization Changed? 2000-2010 Utilization Patterns. Med Care. 53(1):95-101. January 2015.
9. Kaiser Family Foundation. 10 FAQs: Medicare's Role in End-of-Life Care. November 5, 2015. Available online at: http://kff.org/medicare/fact-sheet/10-faqs-medicares-role-in-end-of-life-care/.
10. Aldridge, M et al. Has Hospice Utilization Changed? 2000-2010 Utilization Patterns. Med Care. 53(1):95-101. January 2015.
11. Carlson, MDA, Barry, CL et al. Hospices' Enrollment Policies May Contribute to Underuse of Hospice Care in the United States. *Health Affairs*: Vol. 31, No. 12 (2013), 2690-2696.
12. Kelly, AS and Morrison, RS. Palliative Care for the Seriously Ill. *New England Journal of Medicine* 373;8. August 20, 2015. Available online at: http://content.healthaffairs.org/content/28/5/1357.full.pdf+html.
13. Centers for Medicare & Medicaid Services. Fact Sheet: Medicare Care Choices Model Awards. July 20, 2015.
14. Centers for Medicare & Medicaid Services. Fact Sheet: Medicare Care Choices Model Awards. July 20, 2015.
15. Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. March 2016.
16. Institute of Medicine. Dying in America: Improving quality and honoring individual preferences near the end of life. The National Academies Press: September 2014.

5. INCORPORATING VALUE INTO PHARMACEUTICAL PRICING
(RESOLUTION 712-A-16)

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
**   IN LIEU OF RESOLUTION 712-A-16**
**   REMAINDER OF REPORT FILED**
                   See Policies H-110.986, H-155.960, H-185.939, H-450.933, H-460.909 and D-390.961

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

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

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

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

BACKGROUND

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

Prescription drug spending increased by 12.6 percent in 2014, with a higher rate of spending growth also estimated for 2015. From 2013 to 2018, prescription drug spending is projected to increase by an average of 7.3 percent per year.[1] Leading contributors to the growth in prescription drug spending in the US include the prices and uptake of brand-name drugs and biologics new to the market, the prices of protected brands, the lessening impact of major patent expirations, invoice price increases of brand-name drugs, biologics and generic drugs, and increases in the number of prescriptions per person.[1,2] The prices of new treatments for multiple sclerosis, HIV, hepatitis C, oncology and autoimmune conditions have contributed to new brand spending growth, as well as specialty drugs making up 36 percent of drug spending in 2015. At the same time, the uptake levels of specialty drugs have contributed to the growth rate in pharmaceutical spending. For example, approximately 250,000 new patients received treatment for hepatitis C in 2015, with over 400,000 patients having been treated with at least one of the six drugs brought to the market in the past two years. In addition, there has been a rapid uptake in the use of PD-1 inhibitors, new immuno-oncology drugs.[2]

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

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

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

AMA POLICY ADDRESSING PHARMACEUTICAL PRICING AND VALUE

Council on Medical Service Report 2-I-15, which established Policy H-110.987, stipulates that our AMA:

- 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 Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs;
- Advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients;
- Encourage the development of methods that increase choice and competition in the development and pricing of generic prescription drugs; and
- Support measures that increase price transparency for generic prescription drugs.

Addressing the integration of value in the health care system, Policy H-460.909 outlines principles for creating a centralized comparative effectiveness research entity, including a principle that states that the comparative

effectiveness research entity must not have a role in making or recommending coverage or payment decisions for payers. Of note, the Patient-Centered Outcomes Research Institute (PCORI), which sunsets in 2019, does not fund studies conducting formal cost-effectiveness analyses or directly comparing the costs of care between two or more alternative approaches to providing care due to restrictions outlined in the Affordable Care Act.

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

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

POTENTIAL MECHANISMS TO DETERMINE THE VALUE OF PHARMACEUTICALS

During its review of AMA policy addressing pharmaceutical pricing, as well as responses to address the high costs of pharmaceuticals, the Council determined that policy had a noteworthy gap with respect to value-based pricing–an approach that has the potential to impact the prices of drugs across the health care system. Policy H-460.909 defines value as "the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information." However, the pricing of prescription drugs, which is market-based in nature, is often not clearly commensurate with the drug's clinical outcomes, and reductions in morbidity and mortality.

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

Outcomes-Based Pricing Initiatives

Public and private payers have moved forward with initiatives that would tie how much they pay for drugs to patient health outcomes. Cigna entered into value-based contracts with both Amgen and Sanofi/Regeneron for their PCSK9 inhibitors, Repatha and Praluent, which reduce the amount of harmful LDL cholesterol circulating in the bloodstream. Under the agreement, if Cigna enrollees who take the drugs do not achieve reductions in their LDL-C levels as was experienced in clinical trials, the two pharmaceutical companies would give Cigna discounts on the original negotiated price. If the drugs meet or exceed the expected LDL-C reduction target, the original negotiated price remains in place.[6] Express Scripts has launched its Oncology Care Value Program, which is aiming to align the cost of cancer treatment with its outcomes. This year, the program is focusing on prostate cancer, lung cancer, and renal cell carcinoma.[4] In addition, the Centers for Medicare & Medicaid Services (CMS) released a proposed

rule that put forward a two-phase drug payment model under Medicare Part B, the second phase of which includes a proposal to allow CMS to enter into voluntary agreements with manufacturers to link health care outcomes to payment. As outlined in the proposed rule, these outcomes-based risk-sharing agreements "tie the final price of a drug to results achieved by specific patients rather than using a predetermined price based on historical population data. Manufacturers agree to provide rebates, refunds, or price adjustments if the product does not meet targeted outcomes." CMS proposed that value would be measured "through data collection likely, though not necessarily, provided by the prescriber," intended to address factors such as long-term safety and outcomes, effects on individual patients, patient adherence, or impact on utilization and costs.[7]

Institute for Clinical and Economic Review (ICER)

The Value Assessment Framework developed by ICER includes two components: a drug's long-term care value and the potential short-term budget impact following a drug's introduction to the marketplace. ICER determines care value by evaluating a drug's comparative clinical effectiveness, incremental costs per outcomes achieved, other benefits or disadvantages (e.g., methods of administration, public health benefit) and contextual considerations (e.g., future competition in the marketplace). In measuring incremental costs per outcomes achieved, ICER uses quality-adjusted life years (QALYs) and sets thresholds of reasonable ratios of cost-effectiveness at $100,000 (high care value) to $150,000 (intermediate care value) per QALY. ICER measures provisional health system value to assess the short-term budget impact of a drug in comparison with its long-term care value. To measure the short-term budget impact of a drug, ICER estimates the net change in total health care costs during the five years following the launch of a new drug into the marketplace. ICER developed an affordability threshold of a drug's short-term budgetary impact to serve as an "alarm bell" to indicate whether additional responses may be needed due to a drug's short-term budgetary impact. The short-term affordability threshold represents the contribution of a new drug to the growth in overall health care spending of no more than the anticipated growth in national gross domestic product plus one percent. Therefore, ICER calculates its value-based price benchmark using long-term cost-effectiveness as well as potential short-term budget impact, developing prices to achieve cost-effectiveness thresholds of $100,000 per QALY and $150,000 per QALY, as well as a maximum price using its affordability threshold. For example, in its review of PCSK9 drugs, which have a list price of $14,350, ICER concluded that the drugs would have to be priced at $5,404 to achieve a cost-effectiveness ratio of $100,000 per QALY; $7,735 to achieve a cost-effectiveness ratio of $150,000 per QALY; and $2,177 to meet its affordability threshold. In its review of Entresto, which has a list price of $4,560, ICER determined that the drug would have to be priced at $9,480 to achieve a cost-effectiveness ratio of $100,000 per QALY; $14,472 to achieve a cost-effectiveness ratio of $150,000 per QALY; and $4,168 to meet its affordability threshold.[8]

DrugAbacus, Memorial Sloan Kettering Cancer Center

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

National Comprehensive Cancer Network (NCCN) Evidence Blocks

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

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

The ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures provides a value framework for practice guideline and performance measurement development that establishes the benefit of diagnostic approaches and treatment compared with risk (COR), assesses the level/quality of evidence, and gives each approach/treatment a level of value. CORs can range from class I (highest) to III (lowest). The level/quality of evidence underlying a diagnostic approach and treatment would be given a value of A, B or C. In addition, the approach or treatment would be given a value level of high, intermediate, low or uncertain, or value not assessed, based on QALYs gained.[11]

American Society of Clinical Oncology (ASCO)

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

Public Health Approaches to Drug Pricing

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

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

ANALYZING THE IMPACT OF MEDICARE DRUG PRICE NEGOTIATION

In addition to reviewing and analyzing approaches to value-based pricing of prescription drugs, the Council, based on feedback received from the Task Force on Pharmaceutical Costs, reviewed policy addressing Medicare drug price negotiation, and analyzed whether additional changes should be made to increase the policy's ability to achieve cost savings and political feasibility. Policy D-330.954 states that our AMA will support federal legislation which gives the Secretary of HHS the authority to negotiate contracts with manufacturers of covered Part D drugs, and will work toward eliminating Medicare prohibition on drug price negotiation.

Policy D-330.954 responds to the "noninterference clause" in the Medicare Modernization Act of 2003 (MMA), which states that the Secretary of HHS "may not interfere with the negotiations between drug manufacturers and pharmacies and [prescription drug plan] PDP sponsors, and may not require a particular formulary or institute a

price structure for the reimbursement of covered part D drugs." Instead, participating Part D plans compete with each other based on plan premiums, cost-sharing and other features, which provides an incentive to contain prescription drug spending. To contain spending, Part D plans not only establish formularies, implement utilization management measures and encourage beneficiaries to use generic and less-expensive brand-name drugs, but are required under the MMA to provide plan enrollees access to negotiated drug prices. These prices are achieved through direct negotiation with pharmaceutical companies to obtain rebates and other discounts, and with pharmacies to establish pharmacy reimbursement amounts.

Lack of Bipartisan Support

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

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

Limited Ability to Achieve Savings Without Additional Negotiating Leverage

In addition, questions have been raised whether HHS could achieve much greater savings than what is currently achieved by health plans and pharmacy benefit managers in Part D. The Congressional Budget Office (CBO), as well as CMS actuaries, have estimated that providing the Secretary of HHS broad negotiating authority by itself would not have any effect on negotiations taking place between Part D plans and drug manufacturers or the prices that are ultimately paid by Part D.[18,19] Therefore, it is projected that legislation granting the Secretary of HHS broad authority to negotiate drug prices would likely have a negligible effect on federal spending.

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

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

Any Positive Impact Primarily Limited to Medicare Part D Beneficiaries

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

Unintended Consequences of Amending Policy

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

DISCUSSION

The integration of value into pharmaceutical pricing has the potential to build off of 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 believes that the establishment of principles are necessary to guide AMA advocacy. Initiatives to determine value-based pricing for pharmaceuticals should aim to ensure patient access to necessary prescription drugs and allow for patient variation and physician discretion. In addition, such initiatives should limit administrative burdens on physician practices and patients. The Council is concerned that some value-based pricing approaches, by being dependent on the tracking and reporting of outcomes, have the potential to impose administrative burdens on physicians and patients.

Processes that determine value-based prices of pharmaceuticals need to be evidence-based, transparent, and objective, and involve the input of practicing physicians and researchers. The Council notes that the strength and accuracy of any framework to support value-based pricing of pharmaceuticals depends on the validity, reliability and comprehensiveness of necessary inputs and data, which could come from clinical trials, clinical data registries and comparative effectiveness research, as well as an integrated information infrastructure. 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 in the pharmaceutical arena is imperative so patients, physicians and other stakeholders are aware of differences between the prescription drugs available within the same category or class. The Council believes that the AMA must continue to advocate for adequate investment in comparative effectiveness research, as called for in Policies H-460.909 and D-390.961. 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. In addition, your Council recognizes that clinical data registries, as addressed in Policy H-450.933, may be useful in measuring and tracking short- and long-term clinical outcomes of pharmaceuticals.

Value-based pharmaceutical pricing can also be incorporated into health insurance benefit design, to limit patient cost-sharing for pharmaceuticals that have a high clinical benefit. Policies H-155.960 and H-185.939, which are also

relevant to alternative payment models, support the use of value-based insurance design, determining patient cost-sharing requirements based on the clinical value of a health care service or treatment. Policy also states that consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance. Importantly, Policy H-185.939 states that value-based 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.

With respect to Resolution 712-A-16, 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, which will impact disease transmission rates as well as overall treatment costs. Existing models, including the VFC program and the AIDS Drug Assistance Program, show the potential for using the direct purchasing approach for other drugs. The Council notes that 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.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) reaffirm Policies H-155.960 and H-185.939, which support the use of value-based insurance design, determining patient cost-sharing requirements based on the clinical value of a treatment.

2. That our AMA reaffirm Policy H-450.933, which establishes guidelines to help maximize opportunities for clinical data registries to enhance the quality of care provided to patients.

3. That our AMA reaffirm Policies H-460.909 and D-390.961 in support of adequate investments in comparative effectiveness research.

4. That our AMA support value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles:

    a. Value-based prices of pharmaceuticals should be determined by objective, independent entities;
    b. Value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes;
    c. Processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role;
    d. Processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients;
    e. Processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and
    f. Value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.

5. That our AMA support the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.

6. That our AMA support direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size.

REFERENCES

1. Office of the Assistant Secretary for Planning and Evaluation, US Department of Health and Human Services. Observations on Trends in Prescription Drug Spending. March 8, 2016. Available at: https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf.

2. IMS Institute for Healthcare Informatics. Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020. April 2016.

3. Schondelmeyer, S and Purvis, L. Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 2013. AARP. February 2016. Available at: http://www.aarp.org/content/dam/aarp/ppi/2016-02/RX-Price-Watch-Trends-in-Retail-Prices-Prescription-Drugs-Widely-Used-by-Older-Americans.pdf.

4. Express Scripts. 2015 Drug Trend Report. March 2016. Available at: http://lab.express-scripts.com/lab/drug-trend-report.

5. Hoadley, J, Cubanski, J and Neuman, T. Medicare Part D at Ten Years: The 2015 Marketplace and Key Trends, 2006–2015. Kaiser Family Foundation. October 2015. Available at: http://files.kff.org/attachment/report-medicare-part-d-at-ten-years-the-2015-marketplace-and-key-trends-2006-2015.

6. Loftus, P, and Wilde Mathews, A. Health Insurers Push to Tie Drug Prices to Outcomes. The Wall Street Journal. May 11, 2016. Available at: http://www.wsj.com/articles/health-insurers-push-to-tie-drug-prices-to-outcomes-1462939262.

7. Centers for Medicare and Medicaid Services. Medicare Program; Part B Drug Payment Model; Proposed Rule. 42 CFR Part 511. March 11, 2016. Available at: https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf.

8. Institute for Clinical and Economic Review. ICER Value Assessment Framework: 1.0 to 2.0. 2016. Available at: http://icer-review.org/wp-content/uploads/2016/02/Value-Assessment-Framework-slides-for-July-29-webinar-FINAL-corrected-8-22.pdf.

9. Memorial Sloan Kettering Cancer Center, Evidence Driven Drug Pricing Project. Drug Abacus: Methods. Accessed August 29, 2016 at http://www.drugabacus.org/drug-abacus/methods/.

10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) with NCCN Evidence Blocks™. Accessed August 29, 2016 at https://www.nccn.org/evidenceblocks/.

11. Anderson, J et al. ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures: A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. J Am Coll Cardiol. 2014; 63(21): 2304-2322.

12. Schnipper, L, Davidson, N, Wollins, D et al. American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options. J Clin Oncol. 33: 2563-2577, 2015.

13. Schnipper, L, Davidson, N, Wollins, D et al. Updating the American Society of Clinical Oncology Value Framework: Revisions and Reflections in Response to Comments Received. J Clin Oncol. May 31, 2016. Available at: http://jco.ascopubs.org/content/early/2016/05/25/JCO.2016.68.2518.

14. Centers for Disease Control and Prevention. Hepatitis C FAQs for Health Professionals. July 21, 2016. Available at: http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm.

15. Centers for Disease Control and Prevention. The VFC Program: At a Glance. February 18, 2016. Available at: http://www.cdc.gov/vaccines/programs/vfc/about/.

16. National Alliance of State & Territorial AIDS Directors. AIDS Drug Assistance Programs: Getting the Best Price. April 2016. Available at: https://www.nastad.org/sites/default/files/Getting_the_Best_Price_Final_2016.pdf.

17. Kesselheim, A, Avorn, J and Sarpatwari, A. The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform. JAMA. 2016; 316(8): 858-871.

18. Congressional Budget Office. Letter to Senator Ron Wyden (D-OR) relating to options for allowing the Secretary of HHS to negotiate over the prices paid for drugs under that Medicare Part D. April 10, 2007. Available at: https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf.

19. Centers for Medicare & Medicaid Services. CMS Actuaries Conclude That H.R. 4 Would Have No Effect on Lowering Drug Prices. January 11, 2007. Available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2007-Press-releases-items/2007-01-11.html.

20. Office of Management and Budget. Budget of the United States Government, Fiscal Year 2017, Summary Tables. Available at: https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/tables.pdf.

21. Office of Management and Budget. Budget of the United States Government, Fiscal Year 2016, Summary Tables. Available at: https://www.gpo.gov/fdsys/pkg/BUDGET-2016-BUD/pdf/BUDGET-2016-BUD-6.pdf.

22. Congressional Budget Office. Proposals for Health Care Programs - CBO's Estimate of the President's Fiscal Year 2016 Budget. March 12, 2015. Available at: https://www.cbo.gov/publication/50013.

23. Congressional Budget Office. Proposals for Health Care Programs - CBO's Estimate of the President's Fiscal Year 2017 Budget. March 29, 2016. Available at: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/dataandtechnicalinformation/51431-HealthPolicy.pdf.

6. INTEGRATION OF MOBILE HEALTH APPLICATIONS AND DEVICES INTO PRACTICE

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
                              REMAINDER OF REPORT FILED
                              See Policies H-100.980, H-480.943, H-480.946 and D-480.967

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

BACKGROUND

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

- Mobile applications (mobile apps): A software application that can be run on a mobile product such as a mobile phone, smartphone, or tablet (with or without wireless connectivity) or a web-based software application run on a server, but meant to be used through a mobile product (such as a smartphone).

- Mobile health applications (also referred to as mobile health or mHealth apps): A mobile app that delivers health-related services using a mobile phone, smartphone or tablet. These apps cover a wide spectrum of functions to support health and fitness, as well as disease management.

- Mobile medical device applications: A mobile app that meets the definition of a device in the Federal Food, Drug, and Cosmetic Act is considered by the US Food and Drug Administration (FDA) to be a medical device, subject to risk-based oversight and regulation. A mobile medical device app could be considered a regulated subset of mHealth apps.

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

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

Mobile health apps vary greatly in their functionality, accuracy, safety and effectiveness. Most mHealth apps have limited functionality, with many solely providing information without additional capabilities. In fact, providing information is the most common capability of mHealth apps. On the other hand, most apps lack the ability to communicate or connect with the systems of physicians and other health care providers. While the percentage of

mHealth apps with the capacity to output user data increased between 2013 and 2015, the ability of mHealth apps to communicate externally, including with patients' treating physicians, remained the same. Approximately 10 percent of mHealth apps have the ability to connect to a device, which not only include fitness apps, but also disease management apps that monitor blood pressure and blood glucose levels.[2]

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

REGULATORY AND LEGISLATIVE ACTIVITY

The Council notes that most mHealth apps available to consumers have not received clearance or approval by the FDA. In 2015, the FDA released guidance on mobile medical applications for industry and FDA staff.[7] The guidance reiterated that the focus of FDA oversight of mobile health apps is on those meeting the statutory definition of a medical device; either are intended to be used as an accessory to a regulated medical device, or convert a mobile platform into a regulated medical device; and pose a risk to patient safety if they do not function as intended. Accordingly, the FDA regulates mobile health apps that use a mobile platform's built-in features (light, vibrations, camera, etc.) to perform medical device functions. In addition, the FDA regulates mobile health apps that control the operation or function of an implantable or body worn medical device. Finally, the FDA regulates mobile health apps that are used in active patient monitoring.[8]

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

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

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

In addition to supporting health information technology (health IT) policy, ONC is charged with establishing the certification and testing criteria for health IT products required by Centers for Medicare & Medicaid Services (CMS) reporting programs. These programs, including the electronic health records (EHR) incentive, or "Meaningful Use" program, require eligible physicians to adopt and use health IT specifically designed to

accommodate CMS objectives and measures. While some base-level EHR functionality requirements can benefit physicians and patients, CMS places additional requirements on the use of those functions – influencing the design of the software. With the release of ONC's 2015 Edition Health IT Certification requirements, by 2018 many physicians participating in CMS reporting programs must use EHRs that include application programing interfaces (API). These APIs will allow an app to access patient information stored in the EHR.

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

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

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

COVERAGE AND PAYMENT OF MOBILE HEALTH APPS AND MEDICAL DEVICES

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

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

There is a wide variation of how mobile apps are priced; pricing can include the initial purchase price, in-app purchases and annual subscription costs. In addition, the functionality of some mobile apps are dependent upon the purchase of an associated device, sensor or tracker. Increasingly, sensors and trackers are increasingly built into the mobile device itself. One-third of apps studied by IMS Institute for Healthcare Informatics in 2015 required a paid

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

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

RELEVANT AMA POLICY AND ACTIVITIES

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

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

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

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

The AMA also has hosted regular meetings with national medical specialty societies to encourage the development of objectives and initiatives to support digital medicine adoption, including the use of telemedicine and mobile medical apps. The AMA is a member of Health Level Seven International (HL7), a not-for-profit, standards developing organization accredited by the American National Standards Institute (ANSI), with its current Fast Healthcare Interoperability Resources (FHIR) standard being recognized as having the capacity to facilitate interoperability in the mHealth space. The AMA is working with others to develop an industry collaborative representing diverse stakeholder perspectives whose objective is to develop guidance for the mHealth community that focuses on issues of importance to physicians and their patients, to be used in the development and evaluation of

digital health tools. This activity and forthcoming guidance will fulfill the intent of Policy D-480.972, which calls for the AMA to develop and publically disseminate a list of best practices guiding the development and use of mobile medical applications.

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

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

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

The AMA conducted a survey of 1,300 physicians during the summer of 2016, which focused on physicians' understanding digital health and their attitudes regarding adoption. The survey covered a broad range of digital health tools, including telemedicine and telehealth, mobile health apps, wearables and remote patient monitoring technologies. The purpose of the survey was to obtain a summary view of physicians' thoughts regarding digital health, to understand what motivates them to want to use various emerging digital tools, and what their requirements are for successfully integrating them into patient care and their practices. The survey results and report were released at the end of September, and can be accessed at ama-assn.org/ama/pub/news/news/2016/2016- 09-26-digital-health-innovation.page. Survey results show that in order to spur physician adoption of digital health technologies, including mobile health apps, physicians require such tools to fit within their existing systems and practices, including being linked to and working within their EHRs. The survey found that physicians need experts to ensure the data privacy and security of such tools. Results also indicated that physicians need digital health tools to be covered by liability insurance and linked to appropriate physician payment. In addition, as part of its work to bridge and increase interactions between physicians and digital health stakeholders, the AMA has plans to pilot the AMA Physician Innovation Network, which will connect physicians and health technology entrepreneurs and industry for interaction and feedback. The AMA continues to monitor the evolution of the digital health sector.

DISCUSSION

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

While some mobile apps and devices are subject to FDA regulation, others are not, and do not undergo rigorous evaluation before deployment for general use, which raises quality and patient safety concerns. However, without ensuring that there is strong and sufficient evidence that provides clinical validation to mHealth apps and associated

devices, trackers and sensors, the Council recognizes that physicians will not fully integrate mHealth apps into their practices. In addition, health insurers will not be as likely to consider payment for interventions stemming from mHealth apps, and employers will not be as likely to incorporate mHealth apps in their wellness programs. As such, the Council believes more investment is needed in expanding the evidence base necessary to show the accuracy, effectiveness, safety and security of mHealth apps, and believes that research should also focus on showing the impact of mHealth apps on costs, practice efficiencies and improvement in outcomes to facilitate mHealth app uptake and integration in alternative payment models. Overall, coverage of and payment for mHealth apps and associated devices should be contingent upon a clinical evidence base to support their use in order to ensure app safety and effectiveness.

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

Other obstacles to the acceptance and widespread utilization of mHealth technologies include the current drivers of physician payment, as well as health insurance coverage and other mechanisms to limit patient cost exposure or provide financial incentives to patients. While the shift to alternative payment models is propelling the increased use of digital and mobile health tools, the lack of insurance payment for related services remains an obstacle. Health insurance payment for mobile apps and associated devices has the potential to serve as a pathway to assist patients and physicians in monitoring patient health indicators, as well as improve medication and treatment adherence. For any mHealth app or device that facilitates the delivery of any telemedicine service, the Council stresses that Policy H-480.946, which guides the appropriate coverage of and payment for telemedicine services, must be followed. In addition, the Council believes that additional principles are necessary to guide health plan coverage and payment decisions, employer wellness program inclusions and FSA 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.

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

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

Patient privacy and data security need to be a priority in the digital health space, as mobile apps and devices can be subject to privacy and data breaches. Accordingly, the Council recommends that mHealth apps and associated devices, trackers and sensors must abide by applicable laws addressing the privacy and security of patients' medical information. In addition, physicians should consider whether the mHealth apps they wish to use offer encryption, and whether the level of encryption satisfies HIPAA's standards. Mobile health app developers may not readily disclose whether their apps are encrypted, and the level of encryption may be unclear. If the physician is unsure of whether the mHealth app meets HIPAA's standards, he or she should consult with qualified legal counsel; the physician should also 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. The Council recognizes that questions remain regarding liability risks to physicians who use, recommend or prescribe mHealth apps. As such, 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.

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

RECOMMENDATIONS

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

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

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

3. That our AMA support the establishment of coverage, payment and financial incentive mechanisms to support the use of mobile health applications (mHealth apps) and associated devices, trackers and sensors by patients, physicians and other providers that:

    a. support the establishment or continuation of a valid patient-physician relationship;
    b. have a high-quality clinical evidence base to support their use in order to ensure mHealth app safety and effectiveness;
    c. follow evidence-based practice guidelines, especially those developed and produced by national medical specialty societies and based on systematic reviews, to ensure patient safety, quality of care and positive health outcomes;
    d. support care delivery that is patient-centered, promotes care coordination and facilitates team-based communication;
    e. support data portability and interoperability in order to promote care coordination through medical home and accountable care models;
    f. abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services facilitated by the app;
    g. require that physicians and other health practitioners delivering services through the app be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board; and
    h. ensure that the delivery of any services via the app be consistent with state scope of practice laws.

4. That our AMA support that mHealth apps and associated devices, trackers and sensors must abide by applicable laws addressing the privacy and security of patients' medical information.

5. That our AMA encourage the mobile app industry and other relevant stakeholders to conduct industry-wide outreach and provide necessary educational materials to patients to promote increased awareness of the varying levels of privacy and security of their information and data afforded by mHealth apps, and how their information and data can potentially be collected and used.

6. That our AMA encourage the mHealth app community to work with the AMA, national medical specialty societies, and other interested physician groups to develop app transparency principles, including the provision of a standard privacy notice to patients if apps collect, store and/or transmit protected health information.

7. That our AMA encourage physicians to consult with qualified legal counsel if unsure of whether an mHealth app meets Health Insurance Portability and Accountability Act standards and also inquire about any applicable state privacy and security laws.

8. That our AMA encourage physicians to 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.

9. That our AMA 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.

10. That our AMA assess the feasibility of state and federal legislation, as well as other innovative alternatives, in an effort to mitigate the physician's potential risk of liability from the use or recommendation of mHealth apps.

11. That our AMA support further development of research and evidence regarding the impact that mHealth apps have on quality, costs, patient safety and patient privacy.

12. That our AMA encourage national medical specialty societies to develop guidelines for the integration of mHealth apps and associated devices into care delivery.

REFERENCES

1. Pew Research Center. US Smartphone Use in 2015. April 2015. Available at: http://www.pewinternet.org/2015/04/01/us-smartphone-use-in-2015/.
2. IMS Institute for Healthcare Informatics. Patient Adoption of mHealth: Use, Evidence and Remaining Barriers to Mainstream Acceptance. September 2015. Available at: http://www.imshealth.com/en/thought-leadership/ims-institute/reports/patient-adoption-of-mhealth.
3. Singh, K et al. Developing a Framework for Evaluating the Patient Engagement, Quality and Safety of Mobile Health Applications. The Commonwealth Fund. February 2016. Available at: http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2016/feb/1863_singh_framework_evaluating_mobile_health_apps_ib_v2.pdf.
4. Huckvale, K, Adomaviciute, S, Prieto, J, Leow, M, Car, J. Smartphone apps for calculating insulin dose: a systematic assessment. BMC Med. 2015; 13: 106.
5. Ferrero, N, Morrell, D, Burkhart, C. Skin scan: A demonstration of the need for FDA regulation of medical apps on iPhone. J Am Acad Dermtol. 2013; 68(3): 515-516.
6. Cortez, N, Cohen, G, Kesselheim, A. FDA Regulation of Mobile Health Technologies. NEJM. 2014; 371(4): 372-379.
7. Food and Drug Administration. Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff. February 2015. Available at: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf.
8. Food and Drug Administration. Examples of MMAs the FDA Regulates. September 22, 2015. Available at: http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368743.htm.
9. Federal Trade Commission. Mobile Health Apps Interactive Tool. April 2016. Available at: https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool.
10. Federal Trade Commission. Mobile Health App Developers: FTC Best Practices. April 2016. Available at: https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices.

7. HOSPITAL DISCHARGE COMMUNICATIONS

Reference committee hearing: see report of Reference Committee J.

HOUSE ACTION:	**RECOMMENDATIONS ADOPTED AS FOLLOWS**
	IN LIEU OF RESOLUTION 818
	REMAINDER OF REPORT FILED
	See Policies H-160.902, H-160.942, D-160.924, D-160.945 and D-478.995

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

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

BACKGROUND

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

At the time of discharge, hospital-based physicians—generally hospitalists or proceduralists—hand over clinical responsibility for patients to primary care or other community physicians, or post-acute care facilities. The discharge summary is typically used during discharge transitions to document diagnostic findings and plans for post-discharge follow-up care. The Joint Commission stipulates that discharge summaries include the following elements: the reason for the hospitalization; significant findings; procedures and treatments provided; the patient's condition at discharge; instructions for patients and families, including necessary follow-up, medication changes and dietary needs; and the attending physician's signature. Notwithstanding these standards, hospital discharge summaries vary in terms of content, quality and relevancy. Discharge summaries may be incomplete or lack salient patient information such as pending diagnostic or laboratory tests. Transmittal of discharge summaries to outpatient physicians may be delayed or never reach the appropriate treating physicians. Patients and/or their families may not fully understand discharge instructions and the importance of follow-up appointments and treatment.

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

Quality improvement projects that have demonstrated reductions in hospital readmissions by improving hospital discharge processes are numerous and varied. Examples of effective, multifaceted interventions include the SafeMed care transitions model, Project BOOST (Better Outcomes for Older Adults through Safe Transitions), and Project RED (Re-Engineered Discharge). SafeMed uses intensive medication reconciliation, home visits and telephone

follow-up to manage high-risk/high needs patients as they transition from the hospital to outpatient setting. As part of its *STEPS Forward*[TM] initiative, the AMA developed a module for implementing the SafeMed model within primary care practices. Project BOOST is the Society of Hospital Medicine's signature mentoring program for improving the care of patients as they transition home from the hospital or to other care facilities. Project RED, developed by Boston University Medical Center, is a multilayered intervention that includes dedicated discharge advocates, improved medication reconciliation and enhanced discharge instructions.

Patient/Family Engagement

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

A proposed rule by the Centers for Medicare & Medicaid Services (CMS), in the fall of 2015 highlighted the importance of focusing on patients' goals and preferences during the hospital discharge process, and also better preparing patients and their families/caregivers to be active partners in post-discharge care. The proposed rule implements the requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. It proposed modifying hospital Conditions of Participation by requiring all hospital inpatients, as well as many outpatients–including those receiving observation care or undergoing same-day procedures that require sedation–to be evaluated for their discharge needs and have a written plan developed. Discharge plans would need to be developed within 24 hours of admission, completed before the patient is discharged, and sent to the physician responsible for follow-up care within 48 hours of discharge. The proposed rule would also require a medication reconciliation process and a post-discharge follow-up process. Hospitals would be required to provide detailed discharge instructions to patients going home and to continuing care facilities for patients being discharged to these settings. A post-discharge follow-up process to check on patients who return home would also be required.[10]

Physician Payment

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

AMA POLICY

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

AMA policy recognizes the importance of effective communication between hospital-based and primary care physicians. Policy D-160.945 directs the AMA to advocate for timely and consistent inpatient and outpatient communications among hospital-based physicians and the patient's primary care referring physician to decrease gaps that may occur in the coordination of care process. Policy D-160.945 directs the AMA to explore new

mechanisms to facilitate and incentivize this communication and the transmission of important data. Policy H-155.994 encourages the sharing of patients' diagnostic findings and urges hospitals to return information to attending physicians at patient discharge.

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

DISCUSSION

The Council recognizes that the health care landscape is evolving in terms of care delivery models and improvements in health IT, and that implementation of a single hospital discharge standard across diverse clinical practice settings is impractical at this time. Improved EHR capabilities, which will enable more widespread use of direct messaging (e.g., admit/discharge/transfer messaging) and standardized electronic forms (e.g., the Continuity of Care Document), have the potential to enhance communication and the timely exchange of patient information among providers across multiple care settings. The Council recognizes that the AMA continues to engage in extensive advocacy to improve EHRs and address technology barriers that impede the exchange of meaningful patient information during care transitions, and that numerous AMA policies guide this work. The Council recommends reaffirming Policy D-478.995, which directs the AMA to continue its advocacy to expedite interoperability of EHR systems, standardize key EHR elements, and engage the vendor community to promote improvements in EHR usability.

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

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

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

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

The Council discussed the importance of engaging patients and their families/caregivers in the discharge process to increase patient involvement in discharge planning and encourage self-management of care after hospitalizations.

Communication with patients, and those persons who will be caring for patients post-discharge, is critical to improving patient outcomes and preventing re-hospitalizations and emergency department visits. The Council believes it is good clinical practice to not only provide detailed discharge instructions and education, but also to confirm understanding of this information by patients and their families/caregivers. Accordingly, the Council recommends new AMA policy that encourages active engagement of patients and their families/caregivers in the discharge process, and offers guidelines to ensure that patient needs, including communication needs, are taken into account and that discharge instructions are fully understood.

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

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

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

RECOMMENDATIONS

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

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

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

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

4. That our AMA encourage the initiation of the discharge planning process, whenever possible, at the time patients are admitted for inpatient or observation services and, for surgical patients, prior to hospitalization.

5. That our AMA encourage the development of discharge summaries that are presented to physicians in a meaningful format that prominently highlight salient patient information, such as the discharging physician's narrative and recommendations for ongoing care.

6. That our AMA encourage hospital engagement of patients and their families/caregivers in the discharge process, using the following guidelines:

   a.   Information from patients and families/caregivers is solicited during discharge planning, so that discharge plans are tailored to each patient's needs, goals of care and treatment preferences.
   b.   Patient language proficiency, literacy levels, cognitive abilities and communication impairments (e.g., hearing loss) are assessed during discharge planning. Particular attention is paid to the abilities and limitations of patients and their families/caregivers.
   c.   Specific discharge instructions are provided to patients and families or others responsible for providing continuing care both verbally and in writing. Instructions are provided to patients in layman's terms, and whenever possible, using the patient's preferred language.
   d.   Key discharge instructions are highlighted for patients to maximize compliance with the most critical orders.
   e.   Understanding of discharge instructions and post-discharge care, including warning signs and symptoms to look for and when to seek follow-up care, is confirmed with patients and their families/caregiver(s) prior to discharge from the hospital.

7.   That our AMA support making hospital discharge instructions available to patients in both printed and electronic form, and specifically via online portals accessible to patients and their designated caregivers.

8.   That our AMA support implementation of medication reconciliation as part of the hospital discharge process. The following strategies are suggested to optimize medication reconciliation and help ensure that patients take medications correctly after they are discharged:

   a.   All discharge medications, including prescribed and over-the-counter medications, should be reconciled with medications taken pre-hospitalization.
   b.   An accurate list of medications, including those to be discontinued as well as medications to be taken after hospital discharge, and the dosage and duration of each drug, should be communicated to patients.
   c.   Medication instructions should be communicated to patients and their families/caregivers verbally and in writing.
   d.   For patients with complex medication schedules, the involvement of physician-led multidisciplinary teams in medication reconciliation including, where feasible, pharmacists should be encouraged.

9.   That our AMA encourage patient follow-up in the early time period after discharge as part of the hospital discharge process, particularly for medically complex patients who are at high-risk of re-hospitalization.

10. That our AMA encourage hospitals to review early readmissions and modify their discharge processes accordingly.

11. That our AMA develop model guidelines for physicians to improve communications to other physicians, hospital staff and patients, and promote these guidelines to payers, hospitals and patients.

REFERENCES

1.   Kripalani S, Jackson AT et al. Promoting Effective Transitions of Care at Hospital Discharge: a review of key issues for hospitalists. *Journal of Hospital Medicine*. 2007: Vol. 2, No. 5, Sept./Oct. 2007.
2.   Hansen LO, Young RS et al. Interventions to reduce 30-day rehospitalization: a systematic review. *Annals of Internal Medicine*. 2011;155:520-528.
3.   Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies. *Federal Register*: Nov. 3, 2015.
4.   Moore C, MdGinn T et al. Tying up loose ends: Discharging patients with unresolved medical issues. *Archives of Internal Medicine*. 2007: 167(12):1305.
5.   Kripalani S, LeFevre F et al. Deficits in Communication and Information Transfer Between Hospital-Based and Primary Care Physicians: Implications for Safety and Continuity of Care. *JAMA*. Vol. 297, No. 8. February 28, 2007.
6.   Kripalani S, Jackson AT et al. Promoting Effective Transitions of Care at Hospital Discharge: a review of key issues for hospitalists. *Journal of Hospital Medicine*. 2007: Vol. 2, No. 5, Sept./Oct. 2007.
7.   Verhaegh, KJ et al. Transitional Care Interventions Prevent Hospital Readmissions for Adults with Chronic Illness. *Health Affairs*. 2014: 33, no. 9.
8.   Kripalani S, Jackson AT et al. Promoting Effective Transitions of Care at Hospital Discharge: a review of key issues for hospitalists. *Journal of Hospital Medicine*. 2007: Vol. 2, No. 5, Sept./Oct. 2007.
9.   The Joint Commission. Transitions of care: Engaging patients and families. Quick Safety – Issue 18, November 2015.

10. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies. *Federal Register*: Nov. 3, 2015.

11. Centers for Medicare & Medicaid Services. Medicare Learning Network: Transitional Care Management Services. March 2016.

APPENDIX

H-160.942 Evidence-Based Principles of Discharge and Discharge Criteria
(1) The AMA defines discharge criteria as organized, evidence-based guidelines that protect patients' interests in the discharge process by following the principle that the needs of patients must be matched to settings with the ability to meet those needs. (2) The AMA calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients and that are flexible to meet advances in medical and surgical therapies and adapt to local and regional variations in health care settings and services. (3) The AMA encourages incorporation of discharge criteria into practice parameters, clinical guidelines, and critical pathways that involve hospitalization. (4) The AMA promotes the local development, adaption and implementation of discharge criteria. (5) The AMA promotes training in the use of discharge criteria to assist in planning for patient care at all levels of medical education. Use of discharge criteria will improve understanding of the pathophysiology of disease processes, the continuum of care and therapeutic interventions, the use of health care resources and alternative sites of care, the importance of patient education, safety, outcomes measurements, and collaboration with allied health professionals. (6) The AMA encourages research in the following areas: clinical outcomes after care in different health care settings; the utilization of resources in different care settings; the actual costs of care from onset of illness to recovery; and reliable and valid ways of assessing the discharge needs of patients. (7) The AMA endorses the following principles in the development of evidence-based discharge criteria and an organized discharge process: (a) As tools for planning patients' transition from one care setting to another and for determining whether patients are ready for the transition, discharge criteria are intended to match patients' care needs to the setting in which their needs can best be met. (b) Discharge criteria consist of, but are not limited to: (i) Objective and subjective assessments of physiologic and symptomatic stability that are matched to the ability of the discharge setting to monitor and provide care. (ii) The patient's care needs that are matched with the patient's, family's, or caregiving staff's independent understanding, willingness, and demonstrated performance prior to discharge of processes and procedures of self care, patient care, or care of dependents. (iii) The patient's functional status and impairments that are matched with the ability of the care givers and setting to adequately supplement the patients' function. (iv) The needs for medical follow-up that are matched with the likelihood that the patient will participate in the follow-up. Follow-up is time-, setting-, and service-dependent. Special considerations must be taken to ensure follow-up in vulnerable populations whose access to health care is limited. (c) The discharge process includes, but is not limited to: (i) Planning: Planning for transition/discharge must be based on a comprehensive assessment of the patient's physiological, psychological, social, and functional needs. The discharge planning process should begin early in the course of treatment for illness or injury (prehospitalization for elective cases) with involvement of patient, family and physician from the beginning. (ii) Teamwork: Discharge planning can best be done with a team consisting of the patient, the family, the physician with primary responsibility for continuing care of the patient, and other appropriate health care professionals as needed. (iii) Contingency Plans/Access to Medical Care: Contingency plans for unexpected adverse events must be in place before transition to settings with more limited resources. Patients and caregivers must be aware of signs and symptoms to report and have a clearly defined pathway to get information directly to the physician, and to receive instructions from the physician in a timely fashion. (iv) Responsibility/Accountability: Responsibility/accountability for an appropriate transition from one setting to another rests with the attending physician. If that physician will not be following the patient in the new setting, he or she is responsible for contacting the physician who will be accepting the care of the patient before transfer and ensuring that the new physician is fully informed about the patient's illness, course, prognosis, and needs for continuing care. If there is no physician able and willing to care for the patient in the new setting, the patient should not be discharged. Notwithstanding the attending physician's responsibility for continuity of patient care, the health care setting in which the patient is receiving care is also responsible for evaluating the patient's needs and assuring that those needs can be met in the setting to which the patient is to be transferred. (v) Communication: Transfer of all pertinent information about the patient (such as the history and physical, record of course of treatment in hospital, laboratory tests, medication lists, advanced directives, functional, psychological, social, and other assessments), and the discharge summary should be completed before or at the time of transfer of the patient to another setting. Patients should not be accepted by the new setting without a copy of this patient information and complete instructions for continued care. (8) The AMA supports the position that the care of the patient treated and discharged from a treating facility is done through mutual consent of the patient and the physician; and (9) Policy programs by Congress regarding patient discharge timing for specific types of treatment or procedures be discouraged. (CSA Rep. 4, A-96; Reaffirmation I-96; Modified by Res. 216, A-97; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed: BOT Rep. 1, A-08)

D-160.945 Communication Between Hospitals and Primary Care Referring Physicians
Our AMA: (1) advocates for continued Physician Consortium for Performance Improvement® (PCPI) participation in the American College of Physicians (ACP), the Society of General Internal Medicine (SGIM), and the Society of Hospital Medicine (SHM) work to develop principles and standards for care transitions that occur between the inpatient and outpatient settings; (2) advocates for timely and consistent inpatient and outpatient communications to occur among the hospital and hospital-based

providers and physicians and the patient's primary care referring physician; including the physician of record, admitting physician, and physician-to-physician, to decrease gaps that may occur in the coordination of care process and improve quality and patient safety; (3) will continue its participation with the Health Information Technology Standards Panel (HITSP) and provide input on the standards harmonization and development process; (4) continues its efforts with The Joint Commission, the Centers for Medicare & Medicaid Services, and state survey and accreditation agencies to develop accreditation standards that improve patient safety and quality; and (5) will explore new mechanisms to facilitate and incentivize communication and transmission of data for timely coordination of care (via telephone, fax, email, 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)