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REPORT OF THE BOARD OF TRUSTEES

B of T Report 9-I-18

Subject:	Hospital Closures and Physician Credentialing (Resolution 716-A-18)
Presented by:	Jack Resneck, Jr., MD, Chair
Referred to:	Reference Committee J (Steven Chen, MD, Chair)

At the 2018 Annual Meeting, the House of Delegates (HOD) referred Resolution 716-A-18, "Hospital Closures and Physician Credentialing." Resolution 716 was sponsored by the Organized Medical Staff Section and asked the AMA to:

> work with appropriate stakeholders–such as the AMA Organized Medical Staff Section and National Association Medical Staff Services (NAMSS)–to produce an AMA credentialing repository that would allow hospitals and other organizations that credential physicians to access verified credentialing information for physicians who were on staff at a hospital (or one of its departments) at the time of closure, and report back at the 2018 Interim Meeting.

Testimony largely supported the intent of Resolution 716. However, some members noted that not only would the cost of implementing Resolution 716 be significant, but there are also many unanswered questions about the demand for such a service and how it would work. Other members were concerned as to whether the AMA is the organization best positioned to take up this issue.

DISCUSSION

Resolution 716 suggests that a lack of institutional policies for preserving medical staff credentialing files when a hospital closes can lead to undue delays in future credentialing efforts due to inaccessibility of historical credentialing information. To minimize the potentially devastating impact this shortcoming may have on physicians and other displaced medical staff members, Resolution 716 asks that the AMA create a centralized repository to facilitate the verification of credentialing information as it relates to a physician's hospital affiliation history.

Existing AMA policy supports the appropriate disposition of physician credentialing records following the closure of hospitals, ambulatory surgery facilities, nursing homes and other health care facilities. Policy H-230.956, "Hospital, Ambulatory Surgery Facility, Nursing Home, or Other Health Care Facility Closure: Physician Credentialing Records" states that, where in accordance with state law and regulations, "...[t]he governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility shall be responsible for making arrangements for the disposition of physician credentialing records or CME information upon the closing of a facility..." and "...make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, CME information, and medical staff status." Policy H-230.956 also states that the closing facility "...shall attempt to make arrangements with a comparable facility for the transfer and receipt of the physician credentialing records or CME information."

Notwithstanding this comprehensive policy, a thorough review of existing law reveals few requirements for the retention of physician credentialing records when a hospital closes. While some states require hospitals to implement policies for the preservation of medical staff credentialing files (e.g., Illinois and New York), most states have no specific law or regulations providing for the timely transfer of medical staff credentialing files and proper notification to physicians of the location of those files. As a starting point, the AMA should encourage emulation of appropriate existing laws and regulations by developing model state legislation that supports timely physician access to credentialing files following the closure of a hospital.

Even if closing hospitals were required by law to preserve credentialing files, it remains to be seen where and how this information would be most appropriately stored. Resolution 716 suggests the development of a comprehensive and centralized repository of credentialing files from closed hospitals. States, payors, and other stakeholders are already in the process of developing credentialing repositories for verification of physicians' current and past hospital affiliations. For example, Oregon passed legislation to establish a centralized credentialing database from which medical staff professionals, hospitals, health plans, and other organizations can get up-to-date information on every licensed physician in the state. Additionally, the National Association Medical Staff Services (NAMSS) has launched an online repository to provide medical staff offices a place to quickly find and upload physician affiliation history. Either of these efforts could be expanded to address the problems raised by closed facilities. Recognizing the value that the AMA could provide alongside expert leaders in the credentialing industry, the AMA should continue to monitor these efforts and explore the feasibility of developing a universal clearinghouse that centralizes the verification of physician practice and affiliation history.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 716-A-18 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-230.956, which states that the governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility should be responsible for making arrangements for the disposition of physician credentialing records upon the closing of a facility and should make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, and medical staff status. (Reaffirm HOD Policy)

2. That our AMA develop model state legislation and regulations that would require hospitals to: (a) implement a procedure for preserving medical staff credentialing files in the event of the closure of the hospital; and (b) provide written notification to its state health agency and medical staff before permanently closing its facility indicating whether arrangements have been made for the timely transfer of credentialing files and the exact location of those files. (Directive to Take Action)

3. That our AMA: (a) continue to monitor the development and implementation of physician credentialing repository databases that track hospital affiliations; and (b) explore the feasibility of developing a universal clearinghouse that centralizes the verification of credentialing information as it relates to physician practice and affiliation history, and report back to the House of Delegates at the 2019 Interim Meeting. (Directive to Take Action)

Fiscal Note: Modest – Between $1,000 and $5,000

Relevant AMA Policy

H-230.956, "Hospital, Ambulatory Surgery Facility, Nursing Home, or Other Health Care Facility Closure: Physician Credentialing Records"

1. AMA policy regarding the appropriate disposition of physician credentialing records following the closure of hospitals, ambulatory surgery facilities, nursing homes and other health care facilities, where in accordance with state law and regulations is as follows:

    A. Governing Body to Make Arrangements: The governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility shall be responsible for making arrangements for the disposition of physician credentialing records or CME information upon the closing of a facility.

    B. Transfer to New or Succeeding Custodian: Such a facility shall attempt to make arrangements with a comparable facility for the transfer and receipt of the physician credentialing records or CME information. In the alternative, the facility shall seek to make arrangements with a reputable commercial storage firm. The new or succeeding custodian shall be obligated to treat these records as confidential.

    C. Documentation of Physician Credentials: The governing body shall make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, CME information, and medical staff status.

    D. Maintenance and Retention: Physician credentialing information and CME information transferred from a closed facility to another hospital, other entity, or commercial storage firm shall be maintained in a secure manner intended to protect the confidentiality of the records.

    E. Access and Fees: The new custodian of the records shall provide access at a reasonable cost and in a reasonable manner that maintains the confidential status of the records.

2. Our AMA advocates for the implementation of this policy with the American Hospital Association.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 1-I-18

Subject:	Prescription Drug Importation for Personal Use (Resolution 226-I-17)
Presented by:	James G. Hinsdale, MD, Chair
Referred to:	Reference Committee J (Steven Chen, MD, Chair)

At the 2017 Interim Meeting, the House of Delegates referred Resolution 226-I-17, "Prescription Drug Importation for Personal Use," which was sponsored by the Minnesota delegation. Resolution 226-I-17 asked that our American Medical Association (AMA) support legislation that would allow for the personal purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy, provided such drugs are for personal use and of a limited quantity. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2018 Interim Meeting.

This report addresses the in-person purchase and importation of prescription drugs obtained directly from a licensed, "brick-and-mortar" Canadian pharmacy, not the importation of drugs via online or mail-order pharmacies. The Council notes that Policy D-100.983 guides AMA advocacy on these aspects of the prescription drug importation issue, and states that our AMA will:

1) support the legalized importation of prescription drug products by wholesalers and pharmacies only if:
    a) all drug products are Food and Drug Administration (FDA)-approved and meet all other FDA regulatory requirements, pursuant to United States laws and regulations;
    b) the drug distribution chain is "closed," and all drug products are subject to reliable, "electronic" track and trace technology; and
    c) the Congress grants necessary additional authority and resources to the FDA to ensure the authenticity and integrity of prescription drugs that are imported;

2) oppose personal importation of prescription drugs via the Internet until patient safety can be assured;

3) review the recommendations of the forthcoming report of the Department of Health and Human Services (HHS) Task Force on Drug Importation and, as appropriate, revise its position on whether or how patient safety can be assured under legalized drug importation; and

4) educate its members regarding the risks and benefits associated with drug importation and reimportation efforts.

This report provides background on prescription drug pricing and spending in the United States and Canada; summarizes US federal law and regulatory authority addressing prescription drug

importation; highlights activities to ensure US pharmaceutical chain integrity; reviews how prescription drugs and pharmacies are regulated in Canada; outlines relevant legislative and administrative activity; and presents policy recommendations.

BACKGROUND

In 2016, the US had the highest pharmaceutical spending per capita in the world at $1,443, versus $613 in Canada. Retail spending on prescription drugs per capita was also highest in the US at $1,026, with Canada's retail per capita spending amounting to roughly half that of the US. Public spending on prescription drugs accounted for 36 percent of total pharmaceutical spending in Canada, and 34 percent in the US. Private insurance accounted for 36 percent of total pharmaceutical spending in the US and 30 percent in Canada, with private out-of-pocket spending accounting for 34 percent in Canada, and 30 percent in the US.[1]

Differential pricing for pharmaceuticals between the US and Canada reflects differences in how pharmaceutical prices are determined in each country. Contributing factors to pharmaceutical pricing include the level of government negotiation authority, price controls mandated by law, and market exclusivity and manipulations. In Canada, the Patented Medicine Prices Review Board, a federal, independent, quasi-judicial body, regulates the prices of patented medications to ensure that they are not excessive. Price increases of existing patented drugs cannot exceed the Consumer Price Index. Of note, the Board only regulates the price at which patented drugs are sold to wholesalers, hospitals, pharmacies and other entities by their respective patent holders, and does not have jurisdiction over wholesale or pharmacy prices. In addition, the Board only has the authority to regulate the prices of patented drugs, not generic drugs. Provinces have the authority over the pricing of generic drugs, as well as the pricing of prescription drugs under public drug plans.[2,3] In addition, the pan-Canadian Pharmaceutical Alliance, with the participation of provinces, territories and federal drug plans, conducts joint negotiations for the pricing of publicly covered drugs.[4]

When faced with high out-of-pocket costs for prescription drugs, some patients in the US pursue the importation of their medications from other countries, including Canada. In fact, eight percent of respondents in a recent Kaiser Health Tracking Poll indicated that they or someone in their household had imported prescription drugs from Canada or other countries outside of the US.[5]

FEDERAL LAW ADDRESSING PRESCRIPTION DRUG IMPORTATION

Under current US law, based on provisions of the Medicare Modernization Act of 2003 as well as the Medicine Equity and Drug Safety Act of 2000, HHS has the authority to permit importation of prescription drugs from Canada if the HHS Secretary certifies to Congress that they would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of the drugs to Americans. However, no HHS Secretary has been willing to provide the enabling certification for prescription drug importation, thus preventing its implementation.[6] Because prescription drugs from other countries often have not been approved by the FDA for use and sale in the US, it generally remains illegal for individuals to import prescription drugs into the US for personal use. Without FDA approval and enforcement authority, the safety and effectiveness of imported drugs cannot be assured.

Current law, however, also gives the FDA discretion in enforcement of the importation of prescription drugs by individuals, which allows the FDA's "personal-use" or "compassionate-use" policy. Under the policy, the FDA allows the personal importation of prescription drugs under very limited circumstances, described by the agency as:

- The drug is for use for a serious condition for which effective treatment is not available in the US;
- There is no commercialization or promotion of the drug to US residents;
- The drug does not represent an unreasonable risk;
- The individual importing the drug verifies in writing that it is for personal use, and provides contact information for the doctor providing treatment or shows the product is for the continuation of treatment begun in a foreign country; and
- Generally, not more than a 3-month supply of the drug is imported.[7]

The FDA also has utilized its enforcement discretion to allow importation in the case of a shortage of a prescription drug. In the case of such shortages, when manufacturers of an FDA-approved prescription drug cannot resolve a shortage immediately, the FDA sometimes has had to turn to foreign versions of the drug with the same active ingredient manufactured by firms the FDA deems as reputable and reliable. As a result, the limited importation of the foreign version of the drug has been allowed until the shortage is resolved.[8] Of note, such enforcement discretion has been used sparingly, including for propofol in 2010 and 2012, ethiodol in 2011 and 2015, methotrexate injection and liposomal doxorubicin in 2012 and tretinoin capsules in 2016.[9]

US PHARMACEUTICAL SUPPLY CHAIN INTEGRITY

In the US, the FDA has the authority to ensure the integrity of the US pharmaceutical supply chain, from raw materials to manufacturing facilities to use by patients. The FDA is undergoing several initiatives to protect the global prescription drug supply chain, responding to the fact that approximately 40 percent of finished prescription drugs are imported in the US, and 80 percent of active pharmaceutical ingredients come from overseas sources. Such initiatives are targeted at preventing substandard, adulterated and counterfeit drugs from entering the US, and appropriately communicating risks to patients and providers. The FDA completed 4,936 Good Manufacturing Practice inspections of registered drug and device establishments in 2017, and issues annual reports outlining such inspections as well as the percentage of the FDA budget used to fund such inspections. The FDA also has administrative detention authority to prevent the distribution or subsequent use of drugs suspected to be adulterated or misbranded at the time of inspection until the agency determines what action it should take concerning the drugs, including the initiation of legal action.[10,11] In addition, the FDA is working towards fully implementing the Drug Supply Chain Security Act by 2023. The Act, which was Title II of the Drug Quality and Security Act, was enacted into law in 2013 and outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the US.[12]

CANADIAN REGULATION OF PRESCRIPTION DRUGS AND PHARMACIES

Health Canada reviews prescription drugs to assess their safety, effectiveness and quality before they are authorized for sale in Canada, and performs continuous evaluations after such drugs are on the market, including monitoring adverse reactions. Once approved for sale, prescription drugs in Canada are issued an eight-digit Drug Identification number, which indicates that Health Canada considers the drug safe and effective, and provides a mechanism to track adverse reactions. Also, Health Canada licenses and conducts inspections of pharmaceutical manufacturers, importers and distributors. In order to prevent unauthorized drug products from entering Canada, including counterfeit and adulterated drugs, Health Canada works in cooperation and coordination with the Canada Border Services Agency.[13,14] The FDA has voiced its confidence in Health Canada in providing effective oversight of drugs approved for use by Canadian patients.[15]

There are 10,947 licensed pharmacies in Canada, including 10,463 community pharmacies.[16] Provincial and territorial pharmacy regulatory authorities regulate the practice of pharmacy and the operation of pharmacies in their respective jurisdictions in Canada. This includes the licensing of pharmacies in Canada, including traditional "brick-and-mortar" pharmacies and storefront pharmacies that conduct business online.[17]

RELEVANT ADMINISTRATIVE AND LEGISLATIVE ACTIVITY

In response to the request of HHS Secretary Alex Azar in July 2018, a work group will assess how to safely import prescription drugs from other countries under certain narrow circumstances not involving a shortage, namely in the event of a significant price increase for a prescription drug that is only produced by one manufacturer and not protected by patents or exclusivities. The FDA Commissioner has stressed that if drugs that fall under this categorization can be imported in a manner that ensures safety and effectiveness, such importation would be temporary until there is sufficient competition.[18,19]

In addition, legislation has been introduced to permit prescription drug importation. Legislative approaches to prescription drug importation vary in many respects. For example, while some bills focus on the importation of prescription drugs from Canada, therefore requiring the Secretary of HHS to promulgate the necessary regulations on this issue, other bills could potentially allow prescription drug importation from additional countries that meet standards for ensuring the safety and effectiveness of drugs that are at least as protective as such standards in the US. Bills also vary in defining the foreign pharmacies and entities from which individuals can import prescription drugs.

Senator John McCain (R-AZ) and Congresswoman Chellie Pingree (D-ME) have introduced S 64/HR 1480, the Safe and Affordable Drugs from Canada Act of 2017. S 64/HR 1480, if enacted into law, would compel the HHS Secretary to promulgate regulations within 180 days permitting individuals to import a prescription drug purchased from an approved Canadian pharmacy that: is dispensed by a pharmacist licensed in Canada; is purchased for personal use in quantities not greater than a 90-day supply; is filled using a valid prescription issued by a physician licensed to practice in the US; and has the same active ingredients, route of administration, dosage form, and strength as a prescription drug approved under the Federal Food, Drug, and Cosmetic Act. The legislation does not authorize importation of certain medications, including controlled substances and biological products. The bill establishes a certification process for approving Canadian pharmacies and HHS would have to publish a list of approved Canadian pharmacies.[20,21] Senator McCain also introduced S 92, legislation with the same title and most of the same text as S 64, but differing in that it would give HHS 185 days to promulgate regulations permitting individuals to import a prescription drug purchased from an approved Canadian pharmacy instead of 180 days.[22]

Congressman Keith Ellison (D-MN) has introduced HR 934, the Personal Drug Importation Fairness Act of 2017. If enacted into law, the legislation would allow a drug to be imported by a person other than the drug's manufacturer if the drug has the same active ingredients, route of administration, and strength as an approved drug. The bill also states that drugs could be imported or reimported from the following countries if the FDA determines that they have standards for ensuring drug safety and effectiveness that are at least as protective as US standards: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, a member-state of the European Union, or a country in the European Economic Area. Prescription drugs to be imported would be required to be dispensed by a licensed pharmacist; be shipped directly to, or imported by, the ultimate consumer; and shipped or imported in quantities that do not exceed a 90-day supply. The bill would prohibit the importation of controlled substances.[23]

Senator Bernie Sanders (I-VT) and Congressman Elijah Cummings (D-MD) have introduced S 469/HR 1245, the Affordable and Safe Prescription Drug Importation Act. If enacted into law, the legislation would require HHS to issue regulations within 180 days allowing wholesalers, licensed US pharmacies, and individuals to import qualifying prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers. After two years, the Secretary would have the authority to permit importation from countries in the Organisation for Economic Co-operation and Development that meet specified statutory or regulatory standards that are comparable to US standards. The bill would prohibit the importation of controlled substances, anesthetic drugs inhaled during surgery, and compounded drugs. The bill stipulates that an individual may import a qualifying prescription drug for personal use in quantities not greater than a 90-day supply from an online pharmacy or by a certified foreign seller that is a licensed foreign pharmacy. The bill also would require that individuals importing qualifying prescription drugs must provide to the licensed foreign pharmacy a valid prescription issued by a health care practitioner licensed to practice in the US.[24,25]

There also has been state activity in the arena of prescription drug importation. Nine states have introduced drug importation legislation this year, with Vermont enacting a law that would allow drug importation from Canada through authorized wholesalers.[26] The state is required to submit a drug importation proposal for federal approval.[27] Without federal approval, Vermont's law will face the same fate as Maine's, which was enacted in 2013 to allow its citizens to import prescription drugs from Canada, New Zealand, Australia, and the United Kingdom. However, in 2015, a federal district court ruled that Maine's law was unconstitutional, as federal law preempts state law on this issue.[28]

DISCUSSION

Supporting the ability of US patients to purchase and import prescription drugs in-person from a licensed Canadian pharmacy has the potential to improve patient cost-sharing levels if significant cost savings could be achieved, which would positively address one barrier to medication adherence. The Council notes that under such a policy, some patient medications, including controlled substances and biologicals, may not be allowed to be imported. Nevertheless, the Council believes that a risk to patients who pursue the importation of prescription drugs from Canada remains, especially those who import such drugs via the Internet which increases the risk of receiving substandard, adulterated and counterfeit drugs.

Policy D-100.983 provides a strong, balanced approach to guide the support of our AMA for the legalized importation of prescription drug products by wholesalers and pharmacies, as well as the personal importation of prescription drugs via the Internet. Critically, the policy predicates AMA support for prescription drug importation on ensuring that safety concerns with imported prescription drugs are addressed, to ensure that they are of the same quality and chemical makeup as those currently distributed in the US. While in-person importation from licensed pharmacies in Canada may face fewer safety concerns than importing prescription drugs via the Internet which would then be shipped to patients, ensuring the safety of such imported drugs must remain a priority. Therefore, the Council recommends that our AMA support the in-person purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity. The Council also believes that the FDA needs new and additional resources to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the safety of in-person importation can be assured.

Also addressing the critical issue of safety of imported prescription drugs, the Council recommends the reaffirmation of Policy D-100.985, which states that our AMA will continue to actively oppose illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting. In addition, the policy calls for our AMA to work with the Congress, the FDA, the Drug Enforcement Administration, and other federal agencies, the pharmaceutical industry, and other stakeholders to ensure that these illegal activities are minimized.

Allowing for the in-person importation of prescription drugs from licensed Canadian pharmacies is not a comprehensive, long-term solution to addressing the problem of unaffordability of prescription drugs in the US. The Council believes that sustainable solutions to addressing high and unaffordable prescription drug prices can be found by addressing the flaws and inefficiencies in the US pharmaceutical marketplace. However, patients that face high and unaffordable costs for their prescription drugs need relief in the meantime. Your Council believes that supporting the in-person purchase and importation of prescription drugs from Canada, if the safety of importation can be assured, represents a measured and conservative option to lower patient costs for prescription drugs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 226-I-17, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the in-person purchase and importation of prescription drugs obtained directly from a licensed Canadian pharmacy when product integrity can be assured, provided such drugs are for personal use and of a limited quantity. (New HOD Policy)

2. That our AMA advocate for an increase in funding for the US Food and Drug Administration to administer and enforce a program that allows the in-person purchase and importation of prescription drugs from Canada, if the integrity of prescription drug products imported for personal use can be assured. (New HOD Policy)

3. That our AMA reaffirm Policy D-100.983, which outlines criteria for supporting the legalized importation of prescription drug products by wholesalers and pharmacies, and opposes the personal importation of prescription drugs via the Internet until patient safety can be assured. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy D-100.985, which opposes the illegal importation of prescription drugs and drug counterfeiting, and supports working with Congress, federal agencies and other stakeholders to ensure that these illegal activities are minimized. (Reaffirm HOD Policy)

Fiscal Note: Less than $500

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REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2-I-18

Subject: Air Ambulance Regulations and Payments

Presented by: James G. Hinsdale, MD, Chair

Referred to: Reference Committee J
(Steven Chen, MD, Chair)

At the American Medical Association's (AMA) 2017 Interim Meeting, the House of Delegates adopted policy D-130.964, "Air Ambulance Regulations and Reimbursements," which directs the AMA and appropriate stakeholders to study the role, clinical efficacy, and cost-effectiveness of air ambulance services, including barriers to adequate competition, reimbursement, and quality improvement.

This report provides background on air ambulances including an outline of the various air ambulance business models in the market, discusses the costs and insurance coverage of air ambulance services, summarizes relevant AMA policy, provides an overview of legislative activity on air ambulances, and suggests policy recommendations.

BACKGROUND

Helicopters provide emergency scene responses and interfacility transfers while fixed-wing aircraft provide longer distance airport-to-airport transports. For the purposes of this report, the Council focuses on helicopter air ambulances, which account for about 74 percent of all air ambulances and most of the research on air ambulances.[1] Furthermore, Policy D-130.964 directs the report's scope to focus on the role, clinical efficacy, and cost for air ambulance services.

Air ambulances are used to expeditiously transport critically ill patients during life-threatening emergencies. Air ambulances are equipped with medical equipment and staffed by medical professionals similar to traditional ground ambulances. Air ambulances are widely considered to have a beneficial impact on improving the chances of survival and recovery for both trauma victims and other patients in critical condition. In some rural areas that lack advanced-care facilities like trauma centers, air ambulances fill a critical gap and provide patients timely access to the treatment they need.[2]

Air ambulances allow for optimization of patient care and outcomes. In emergency medicine, the "golden hour" refers to a time period lasting for about one hour following traumatic injury or medical emergency during which there is the highest probability that rapid medical treatment will prevent further deterioration or death. Air ambulances increase the likelihood of patients receiving needed care within the "golden hour" because of their ability to land at accident sites and quickly fly to nearby hospitals therefore reducing transport times. Unlike other aviation and medical services, air ambulance transfers take place in response to time-sensitive medical emergencies and generally are not scheduled ahead of time.[3] Patients often have little to no ability to make cost-saving decisions before the transport, such as ensuring that the air ambulance provider participates in the patient's insurance plan.

It is estimated that more than 550,000 patients in the US use air ambulance services every year. Further, air ambulance services have increased significantly in recent years. In 2002, there were about 400 air ambulances in use across the US, and that number more than doubled to over 800 air ambulances by 2008.[4] This increase in the number of air ambulances has sparked criticism from consumer groups of oversupply and contributing to the overuse of air ambulance services that may not be medically necessary. It is estimated that nearly a third of patients transported via air ambulance helicopter were minimally injured.[5] In addition to possible unnecessary use of air ambulances, other reasons for the growth in the industry include an aging population, a decrease in the number of emergency departments in hospitals, and changes in health care delivery in rural settings.

Air ambulances have emerged as one solution to the problem of rural health care facility closures. A quarter of Americans, or 85 million people, are estimated to be unable to access health care in less than an hour of travel time without an air ambulance, and such ambulances may be the only viable means of transporting patients to the care center they need.[6] However, over the past decade, many states have reported issues with air ambulance providers who are not affiliated with any hospital or insurance carrier.

AIR AMBULANCE BUSINESS MODEL

Air ambulance providers generally function in one of three business models based on the entity that owns the air ambulance and the individuals providing medical services aboard the aircraft. The first model is a hospital-based model wherein the hospital provides medical services and staff and typically contracts with third parties for the pilots, aircraft, and maintenance. The second model is the independent model wherein operations are not controlled by a specific medical facility. Independent models may consist of for-profit or non-profit providers who directly employ the medical and flight crews to provide services. The third model is the government model where a state, municipal government, or military unit owns and operates the air ambulances.[7]

Until 2002, air ambulances were primarily owned and operated by hospitals. However, in 2002, Medicare created a national fee schedule for air ambulances based on a thorough investigation into the “reasonable cost” for emergency medical services (EMS). The national fee schedule had the effect of increasing the Medicare reimbursement rate for helicopter air ambulance transport and in particular raising the rate of payment for rural air transports.[8]

Due in part to the establishment of the fee schedule, for-profit companies established and expanded their air ambulance businesses. Currently, it is estimated that more than half of the air ambulance industry is controlled by four for-profit air ambulance operators. The doubling of the number of air ambulances since 2002 potentially may be attributed to the closure of clinics and hospitals in rural areas.

COST AND COVERAGE OF SERVICES

Patients typically have little to no choice over the service or provider of an air ambulance due to the urgent nature of the transports. Furthermore, air ambulance providers generally do not turn away patients based on their ability to pay and garner payments from patients’ insurance companies. Air ambulance providers typically charge standard rates based on an established lift-off fee and per mile fee for all transports and receive payments from various sources at differing rates depending on a patient’s insurance coverage. Further, the amount paid by private health insurance hinges on whether the air ambulance provider participates in a contract with the private insurer.

Depending on insurance coverage, patients can be billed for air ambulance charges that have potentially significant financial consequences. Costs for the average air ambulance trip run in the tens of thousands of dollars. According to the Centers for Medicare & Medicaid Services (CMS) and private health insurance data, between 2010 and 2014, the median prices providers charged for air ambulance service doubled from about $15,000 to about $30,000 per transport.[9] According to numerous air ambulance providers, privately insured patients account for the largest percentage of their revenue. The median payment that three large national private insurers paid per air ambulance transport increased from about $15,600 to $26,600 from 2010 to 2014, an increase of 70 percent. With insurers under pressure to cut costs, they have been reducing payments for air ambulances.[10]

Although air ambulances account for less than one percent of total ambulance claims, they represent about eight percent of Medicare spending on ambulance services due to their significant cost. Air ambulance providers are not permitted to balance bill Medicare and Medicaid patients beyond deductibles and coinsurance requirements. Patients with private insurance may be balance billed only if the air ambulance provider is out-of-network. Patients without insurance may be billed for the total price of the air ambulance bill. Due to a lack of information, it is unclear to what extent air ambulance providers balance bill.

Numerous factors likely contribute to the high costs of air ambulance services, including the price and maintenance of the necessary equipment and employment of specialized medical personnel around-the-clock. In order to stay in operation, air ambulance providers must earn revenue sufficient to cover their costs. The median cost per base for independent air programs is almost $3 million, with 77 percent of the costs incurred being fixed costs associated with operating a base.[11] To increase revenue, air ambulance providers need to increase the number of transports or the cost charged per transport. According to eight air ambulance providers, the average cost they incurred per transport is between $6,000 to $13,000.[12]

A more thorough look into the factors affecting air ambulance pricing is not possible due to lack of data. For example, the cost incurred by air ambulance providers to provide service is not readily available, and there is no national database with this information. Moreover, there are no data available that address cost differences of air ambulance service capabilities and how cost is affected not only by transport but also service level. In addition, available data are insufficient to discern the prices charged by air ambulances, charges across various air ambulance business models, and charges to individuals with varying coverage statuses. The lack of systematic data collection makes it impossible to determine the market share of particular air ambulance providers and corresponding price information.

LEGISLATIVE ACTIVITY

Though some states have attempted to create consumer protections from costly air ambulance bills, federal preemption has largely prevented state regulation. The Airline Deregulation Act (ADA) of 1978 prohibits states from regulating the price, route, or service of an air carrier for the purposes of keeping national commercial air travel competitive.[13] The ADA applies to air carriers that provide air ambulance services and are, therefore, protected from state attempts to regulate their price, route, and service. Accordingly, air ambulance providers generally are not subject to the price competition that usually occurs in competitive markets wherein high prices will lead consumers to find lower-cost alternatives.

In contrast to air ambulances, ground ambulances are regulated under the Affordable Care Act (ACA) and applicable state laws.[14] However, for air ambulances, such protections are applied only with the model in which the ambulance service is affiliated with the hospital and, therefore, considered an extension of the emergency department service.

Numerous states have attempted to pass legislation to protect consumers from out-of-network air ambulance bills; however, these laws have been preempted by the ADA.[15] Federal legislation is necessary in order to give states the authority to address the issue. Generally, state insurance regulators support legislation allowing states the flexibility to protect consumers from excessive out-of-network charges. Regulators have shown a willingness to regulate how air ambulance carriers are paid, participate in networks, balance bill, and make information transparent to consumers.

RELEVANT AMA POLICY

Policy H-285.904 includes principles related to unanticipated out-of-network care and states that patients must not be financially penalized for receiving unanticipated care from an out-of-network provider, insurers must meet appropriate network adequacy standards, and patients seeking emergency care should be protected under the "prudent layperson" legal standard. Similarly, Policy D-130.975 advocates that insurers pay for EMTALA services regardless of in-network and out-of-network status.

Policy D-130.989 states that legislation and regulation should be used to require all health payers to cover emergency services. Policy H-130.970 promulgates principles on access to emergency services and states that all physician and health care facilities have an ethical and moral responsibility to provide needed emergency services to all patients, regardless of their ability to pay. Importantly, the policy notes that health plans should educate enrollees regarding the appropriate use of emergency facilities. Similarly, Policy H-130.954 supports the education of physicians and the public about the costs of inappropriate use of emergency patient transportation systems and encourages the development of non-emergency patient transportation systems that are affordable to the patient, thereby ensuring cost effective and accessible health care. Moreover, Policy H-130.970 states that all health plans should be required to cover emergency services provided by physicians and hospitals to plan enrollees without regard to prior authorization or the emergency care physician's contractual relationship with the payer. The policy also encourages states to enact legislation holding health plans and third-party payers liable for patient harm resulting from any restrictions on the provision of emergency services. Policy D-130.975 similarly states that all insurers should be required to assign payments directly to any health care provider who has provided EMTALA-mandated emergency care, regardless of network status.

Policy H-240.978 supports changes in Medicare regulations governing ambulance service coverage guidelines that would expand the term "appropriate facility" to allow full payment for transport to the most appropriate facility based on the patient's needs and the determination made by physician medical direction. The policy goes on to state that the AMA will work with CMS to pay emergency medical service providers for the evaluation and transport of patients to the most appropriate site of care not limited to the current CMS defined transport locations.

To promote the safety of emergency medical service helicopters, Policy D-130.967 highlights the importance of the Federal Aviation Administration's Helicopter Medical Service Operations and Safety Alert for Operators and its role as a critical component of Helicopter Emergency Medical Services in assuring the safety of patients and medical providers. The policy goes on to advocate that its members contract with or implement a Helicopter Emergency Medical Service that is

compliant with risk reduction systems/programs established in standards set forth in the Federal Aviation Administration's Helicopter Medical Service Operations and Safety Alert for Operators.

DISCUSSION

Air ambulances serve to reduce the transit time for critically ill patients in emergent circumstances. Due to the nature of air ambulance services, patients typically have little or no choice over their mode of transportation and the provider of such transportation and can face significant air ambulance bills.

To address the appropriate provision of emergency care and consistent with ethical delivery of care, the Council recommends amending Policy H-130.954 not only to support the education of physicians and the public, but also first responders, about the costs associated with inappropriate use of emergency patient transportation systems and encouraging the development of non-emergency patient transportation systems that are affordable to the patient, thereby ensuring cost effective and accessible health care for all patients.

Many aspects of the air ambulance market and the extent patients are balance-billed are unclear due to lack of available data. There is a void in data on ownership, revenue, and service capabilities. Similarly, data on the costs to provide service, the number of transports, and provider information are not readily available. For example, it is unclear whether price increases are tied to market concentration or whether providers adjust prices to receive sufficient revenue from private insurance to account for lower-paid transports, such as those paid for by Medicare. Moreover, there is evidence that in markets with predominantly hospital-owned air ambulance providers, patients are balance-billed at lower rates and face lower costs. However, because these data cannot be verified at this time, the Council believes it is most appropriate to support increased data collection and data transparency of air ambulance providers and services, particularly increased price transparency. Subsequently, the Council recommends supporting consumer disclosures that include price variation among air ambulance providers and the potential limits of insurance coverage.

As previously discussed, the ADA preempts state-level regulation of air ambulance prices, routes, and services. Due to a profound void in air ambulance data, the Council believes that calling for an amendment to the ADA is premature. Before such a recommendation could even be considered, the Council believes that requisite information is needed on air ambulance command and control practices as well as additional data to determine the root cause of the issue at hand, and whether it is a result of market failure or other causes. Therefore, the Council strongly calls for additional data collection and transparency on air ambulances and sees merit in working with relevant stakeholders to evaluate the ADA as it applies to air ambulances.

The AMA believes that access to affordable emergent health care services must be preserved and strengthened. In that spirit, the Council recommends supporting the sharing of industry best practices among stakeholders across various regions. The Council's recommendations build upon the AMA's work to improve safe and affordable air ambulance access and protect patients in life-threatening emergencies.

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) amend Policy, H-130.954, "Non-Emergency Patient Transportation Systems," by addition as follows:
The AMA: (1) supports the education of physicians, first responders, and the public about the costs associated with inappropriate use of emergency patient transportation systems; and (2) encourages the development of non-emergency patient transportation systems that are affordable to the patient, thereby ensuring cost effective and accessible health care for all patients. (Modify Current HOD Policy)

2. That our AMA support increased data collection and data transparency of air ambulance providers and services to the appropriate state and federal agencies, particularly increased price transparency. (New HOD Policy)

3. That our AMA work with relevant stakeholders to evaluate the Airline Deregulation Act as it applies to air ambulances. (New HOD Policy)

4. That our AMA support stakeholders sharing air ambulance best practices across regions. (New HOD Policy)

5. That our AMA rescind Policy D-130.964, which directed the AMA to conduct the study herein. (Rescind AMA Policy)

Fiscal Note: Less than $500.

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[12] *Supra* note 1.
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[14] *Id.*

[15] *Id.*

REPORT 4 OF THE COUNCIL ON MEDICAL SERVICE (I-18)
The Site-of-Service Differential
(Resolution 817-I-17)
(Reference Committee J)

EXECUTIVE SUMMARY

The site-of-service differential is a longstanding payment policy issue stemming from the Medicare program's use of separate payment systems in its rate-setting calculations. This report addresses disparities in Medicare Part B payment for covered items and services across outpatient care settings, including the offices of physicians and other health professionals, hospital outpatient departments (HOPDs), and ambulatory surgical centers (ASCs). Most outpatient procedures can be provided across multiple clinical settings, and although the choice of outpatient site for many services has no discernible effect on patient care, it significantly impacts Medicare's payment for such services and patient cost-sharing expenses. Generally speaking, Medicare pays higher rates for outpatient services performed in hospital facilities than to physician offices or ASCs for furnishing the same service to similar patients. The scope of the payment differential varies, depending on the procedure.

This report describes ongoing disparities in Medicare payment for outpatient procedures across care settings, explains how Medicare determines payments for outpatient services in each setting, compares Medicare physician payment updates to inflation, and summarizes relevant American Medical Association (AMA) policy and activity. The Council recommends reaffirmation of existing AMA policy as well as new policy addressing the site-of-service differential. The Council recommends that the AMA support Medicare payment policies for outpatient procedures that are site-neutral without lowering total Medicare payments. The Council further recommends that the AMA support Medicare payments for the same service routinely and safely provided in multiple outpatient settings (e.g., physician offices, HOPDs, and ASCs) that are based on sufficient and accurate data regarding the real costs of providing the service in each setting.

While the focus of this report is the site-of-service differential, the Council recognizes that broader physician payment issues must also be addressed. To help build the case for future Medicare payment reforms that support site-neutrality without lowering total Medicare payments, the Council recommends that the AMA collect data and conduct research both: a) to document the role that physicians have played in reducing Medicare spending; and b) to facilitate adjustments to the portion of the Medicare budget allocated to physician services that more accurately reflects practice costs and changes in health care delivery.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-I-18

Subject: The Site-of-Service Differential (Resolution 817-I-17)

Presented by: James G. Hinsdale, MD, Chair

Referred to: Reference Committee J (Steven Chen, MD, Chair)

At the 2017 Interim Meeting, the House of Delegates referred Resolution 817-I-17, "Addressing the Site of Service Differential," introduced by the New Mexico Delegation, for report back at the 2018 Annual Meeting. The Board of Trustees assigned this item to the Council on Medical Service. Resolution 817-I-17 asked the American Medical Association (AMA) to:

> 1) Study the site-of-service differential with a report back no later than the 2018 Interim Meeting, including: a) the rising gap between independent practice expenses and Medicare reimbursement, taking into account the costs of the regulatory requirements; b) the increased cost of medical personnel and equipment, including electronic health record (EHR/EMR) purchase, software requirements, and ongoing support and maintenance; c) the expense of maintaining hospital-based facilities not common to independent practices, such as burn units and emergency departments, and determine what payment should be provided to cover those explicit costs; and d) the methodology by which hospitals report their uncompensated care, and the extent to which this is based on actual costs, not charges; and
>
> 2) Advocate for a combined health care payment system for patients who receive care that is paid for by the Centers for Medicare & Medicaid Services (CMS), that: a) follows the recommendation of MedPAC to pay "site-neutral" reimbursement that sufficiently covers practice expenses without regard to whether services are performed under the Hospital Outpatient Prospective Payment System (OPPS) or the Physician Fee Schedule (PFS); b) pays appropriate facility fees for both hospital owned facilities and independently owned non-hospital facilities, computed using the real costs of a facility based on its fair market value; and c) provides independent practices with the same opportunity to receive reimbursement for uncompensated care as is provided to hospital owned practices.

This report describes ongoing disparities in Medicare payment for outpatient procedures across care settings, summarizes relevant AMA policy and activity, and presents policy recommendations addressing the outpatient site-of-service differential.

BACKGROUND

The site-of-service differential is a longstanding payment policy issue stemming from the Medicare program's use of more than a dozen separate payment systems—some of which are based on the location where services are provided—in its rate-setting calculations. Several of these payment systems base payments on the location where services are provided. This report addresses disparities in Medicare Part B payment for covered items and services across outpatient care

settings, including the offices of physicians and other health professionals, hospital outpatient departments (HOPDs), and ambulatory surgical centers (ASCs). Most outpatient procedures can be provided across multiple clinical settings, and although the choice of outpatient site for many services has no discernible effect on patient care, it significantly impacts Medicare's payment for such services and patient cost-sharing expenses. Generally speaking, Medicare pays higher rates for outpatient services performed in hospital facilities than to physician offices or ASCs for furnishing the same service to similar patients. The scope of the payment differential varies, depending on the procedure, and in some cases may be difficult to ascertain because units of payment differ across payment systems. Furthermore, the payment differential may extend beyond primary services to entire episodes of care. One analysis found that payments for cardiovascular imaging, colonoscopy, and evaluation and management services are higher when furnished in HOPDs, and that the higher payments extend to related services provided to patients as part of episodes of care associated with these procedures.[1] The variations in payment persisted after controlling for patient demographic and severity differences, thereby attributing a substantial portion of the pay disparities to the payment systems themselves.[2]

The Council previously studied aspects of the site-of-service differential—and confirmed that Medicare payments for many procedures are higher when furnished in HOPDs—during the development of Council Report 3-A-13, "Payment Variations across Outpatient Sites of Service," and Council Report 3-A-14, "Medicare Update Formulas Across Outpatient Sites of Service." Council Report 3-A-13 compared Medicare payments for five common procedures performed across outpatient settings, and built upon the AMA's substantial policy supporting site neutrality by encouraging private payers to incentivize outpatient care delivery in lower-cost settings. Council Report 3-A-14 found that existing Medicare payment formulas have contributed to growth in the volume of outpatient services provided in hospitals and hospital-owned facilities, even when these services can be safely performed in lower-cost settings. Council Report 3-A-14 focused primarily on equalizing payments between HOPDs and ASCs because payments to these settings are based on the same Medicare payment system (OPPS), with ASCs paid at lower rates. Developing policy addressing payment disparities between hospital-owned facilities and independent physician practices is more complex because, under current statute, the rate-setting for items and services in these outpatient sites is based on separate Medicare payment systems that calculate payments for different units of service.

Medicare Payment Rates for Off-Campus Provider-Based Hospital Departments

For many years, higher payments to HOPDs likely incentivized the sale of physician practices and ASCs to hospitals because acquired facilities meeting certain criteria (eg, located within 35 miles of the hospital) were routinely converted to HOPDs and allowed to charge higher OPPS rates for services performed at these off-campus facilities. However, a provision in the Bipartisan Budget Act of 2015 (BBA) disallowed provider-based billing by hospitals for newly acquired physician practices and ASCs. The Congressional Budget Office estimated in 2015 that this provision would save $9.3 billion over 10 years.[3] Beginning in 2017, off-campus entities acquired after enactment of the BBA—in November 2015—were no longer permitted to bill for services under the OPPS, and instead required to bill under the applicable payment system (PFS). Since 2017, CMS has paid for services at non-excepted off-campus provider-based hospital departments using a PFS relativity adjuster that is based on a percentage of the OPPS payment rate. Currently, CMS regulations stipulate that these services be paid 40 percent of OPPS payment rates,[4] although provider-based departments acquired prior to November 2015 continue to bill under the OPPS. In July 2018, CMS proposed extending site-neutral payments to include clinic visits provided at off-campus provider-based hospital departments acquired prior to November 2015, that were excepted from the BBA provision.[5] CMS proposed to reduce payment rates for clinic visits at hospital-owned physician

practices located off the hospital campus from $116 with $23 cost-sharing to $46 with $9 cost-sharing.[6] At the time this report was written, the CMS proposal had not been finalized.

Hospital Employment of Physicians

It is possible that Medicare payment reductions for services provided at off-campus provider-based hospital departments acquired after November 2015 have contributed to a leveling off of hospital acquisitions of physician practices. Data from the AMA's 2012, 2014, and 2016 Physician Practice Benchmark Surveys, which yield nationally representative samples of non-federal physicians who provide care to patients at least 20 hours per week, demonstrate recent stability in the ownership structure of physician practices. Analyses of the surveys found that the share of physicians who worked directly for a hospital or in practices that were at least partially owned by a hospital remained unchanged between 2014 and 2016—at 33 percent.[7] This percentage represented an increase from 29 percent in 2012. Although detailed information on practice ownership structure is not available for years prior to 2012, research suggests that in 2007-2008, only 16 percent of physicians worked directly for a hospital or in practices that were at least partially owned by a hospital.[8]

Medicare Payment Systems for Outpatient Services

The separate methodologies used for rate-setting under the OPPS and the PFS are at the root of the outpatient site-of-service differential (see Table 1). Under current law, Medicare's payment systems do not account for the fact that many outpatient services can be provided safely and at lower cost to Medicare and patients outside of the hospital setting. Because there is no linkage between OPPS and PFS payment systems, Medicare may pay dramatically different rates for the same services based on whether they are provided in hospital facilities or physician offices.

Table 1: Medicare Payment Systems for Physician Offices, Hospital Outpatient Departments, and Ambulatory Surgical Centers

Site	**Physician Office**	**Hospital Outpatient Department**	**Ambulatory Surgical Center**
Payment System	Physician fee schedule (non-facility rate)	Physician fee schedule (facility rate) plus OPPS rate	Physician fee schedule (facility rate) plus ASC payment system (based on relative weight under the OPPS)
Basis for Updates	Medicare Access and CHIP Reauthorization Act (MACRA)	Hospital market basket	Consumer price index for all urban consumers
Unit of Payment	Individual service	Ambulatory payment classification	Ambulatory payment classification

For services furnished in physician and other practitioner offices, Medicare pays for units of service billed under the PFS. There is a single payment for each service which amounts to 80 percent of the PFS rate, with the patient responsible for cost-sharing that covers the remaining 20 percent. For procedures provided in hospital outpatient departments, Medicare pays a reduced physician fee under the PFS plus a facility fee established under the OPPS. Patients are responsible for cost-sharing associated with both the physician fee and the facility fee. Whereas providers generally receive separate payments for each service under the PFS, services paid under the OPPS

are grouped together into ambulatory payment classifications based on clinical and cost similarities.

Formulas unique to each payment system are then used to annually adjust payment rates for inflation, which may actually widen existing payment disparities. HOPD updates are based on the hospital market basket, and annual updates to the PFS were established by MACRA. The Medicare program currently uses the consumer price index for all urban consumers (CPI-U) to annually update ASC payment rates, although—consistent with AMA policy—CMS recently proposed updating ASC rates using the hospital market basket instead of the CPI-U for a five-year period. If this proposal is finalized, CMS will examine whether the change incentivizes a migration of services to lower-cost ASC settings over the five-year period.

Medicare Physician Payment Updates Compared to Inflation

Medicare payments for physician services have for many years failed to keep pace with the actual costs of running a practice. From 2001 to 2017, Medicare physician pay rose just six percent (0.4 percent per year on average), although Medicare's index of inflation in the cost of running a practice increased 30 percent (1.7 percent per year on average). Economy-wide inflation, as measured by the Consumer Price Index, has increased 39 percent over this time period.[9] Adjusted for inflation in practice costs, Medicare physician pay has declined 19 percent from 2001 to 2017, or by 1.3 percent per year on average.

During the same time period, Medicare hospital pay has increased roughly 50 percent, with average annual increases of 2.6 percent per year for inpatient services, and 2.5 percent per year for outpatient services. Medicare skilled nursing facility pay has increased 51 percent between 2001 and 2017, or 2.6 percent per year.[10] There are some significant differences between hospitals and physician practices that may lead to higher costs of providing care in HOPDs. For example, hospitals maintain operations 24/7, and also standby capacity for handling emergencies, although payment for standby costs is included in Medicare's payment for emergency department services.[11]

Uncompensated/Inadequately Compensated Physician Practice Expenses

The need for sustainable physician payments under the Medicare program is compounded by numerous uncompensated administrative tasks that are extremely costly to practices and reduce time spent with patients, yet increase the work necessary to provide medical services. CMS alone publishes thousands of pages of regulations affecting physician practices every year, including rules governing the reporting of quality measures, the Recovery Audit Contractor (RAC) Program, MACRA implementation, and Medicare's numerous payment systems. Utilization management has become so burdensome that in 2017 the average physician reported completing 29 prior authorizations per week, a process that required 14.6 hours of work or the equivalent of two business days.[12] In addition to navigating a plethora of payer protocols and utilization management requirements, physician practices have to purchase, manage and update electronic health records (EHRs) to document the care they are providing. Incorporating EHR technology into practice workflows is costly and consumes a significant amount of physician time that could otherwise be spent with patients. Notably, a 2016 *Annals of Internal Medicine* study found that, for every hour of clinic time spent with patients, physicians spend approximately two hours per day during office hours, and another one to two hours outside of office hours, on EHR and desk work.[13] According to a 2016 *Health Affairs* study, physician practices across four common specialties spend over $15.4 billion annually to report quality measures, with physicians on average spending 2.6 hours per week on these measures.[14] Many physician practices also provide high-technology outpatient

services (ie, infusions and/or imaging) that were once the domain of hospitals and for which practices are not adequately compensated under the PFS.

Hospitals that treat a disproportionate share of low-income patients receive additional payments to offset the financial effects of treating these patients. Traditionally, disproportionate share hospital (DSH) payments were based on hospitals' share of Medicaid patients and Medicare patients with Social Security Disability Insurance. Beginning in 2014, DSH payments were calculated as 25 percent of that payment amount, and hospitals also began receiving uncompensated care payments from a pool of funds equal to 75 percent of the DSH payment received under the traditional formula, minus an amount that increases in proportion to decreases in the uninsured population.[15] Part of this pool is distributed to hospitals based on the share of uncompensated care they provide.[16] Physician practices are not eligible for either DSH or uncompensated care payments, despite the fact that most physicians (89 percent) treat Medicare patients and, in 2016, most also had Medicaid (82.6 percent) and uninsured (75.6 percent) patients.[17] There have been questions as to whether Medicare DSH and uncompensated care payments are appropriate proxies for the amount of uncompensated care provided by hospitals, and Medicare Payment Advisory Commission (MedPAC) has recommended that uncompensated care payments to hospitals be based on actual uncompensated care data.

Expert Policy Recommendations for Reducing Payment Variations

To address shifts in outpatient care to higher cost sites-of-service (eg, hospital-owned facilities), which increase costs to the Medicare program and its patients, several policy options have been proposed to equalize payments across settings for certain services. After the MedPAC found that payments to HOPDs for 15-minute evaluation and management visits were 80 percent higher than payments to physician offices for the same service, it recommended in 2012 that HOPD payments for these services be reduced to physician office rates.[18] In 2014, MedPAC recommended that differences in payment rates between HOPDs and physician offices be eliminated by reducing HOPD rates for 66 ambulatory payment classifications. These groups of services were selected by MedPAC based on patient severity being similar in HOPDs and physician offices, and because they are frequently furnished in physician offices.[19]

A 2011 RAND Health analysis examined several policy options for addressing Medicare payment differentials across outpatient sites, such as increasing uniformity in the units of service across payment systems, and basing payment rates on the least costly setting. This analysis concluded that basing payment differentials on justifiable cost differences would promote payment equity across outpatient sites-of-care and value-based care, but would also be administratively burdensome. Determining justifiable cost differences would also be impractical.[20]

The Office of the Inspector General (OIG) has also recommended reductions in HOPD payment rates to those of less costly settings, and has even recommended pursuing legislative changes to OPPS budget neutrality provisions so that payment rates to HOPDs could be reduced without offsetting those reductions with payment increases.[21] Several administrations have also proposed equalizing payment variations via budget proposals, and President Trump's budget published in February 2018 proposed applying physician office rates to all hospital-owned physician offices located off the hospital campus. As stated previously, CMS has proposed extending site-neutral payments to include clinic visits provided at off-campus hospital-owned facilities.

It is clear that most of the policy options identified to date have recommended leveling the site-of-service playing field by reducing payment rates to the amounts payable in the least costly outpatient setting. Although CMS has not implemented the MedPAC or OIG recommendations, in

2014 the agency identified approximately 200 services for which physician office payments were higher than HOPD or ASC rates and proposed lowering physician fees for these services. Most experts, including MedPAC, believe that Medicare payments to physician offices, HOPDs and ASCs will continue to be based on the program's current payment systems for the foreseeable future. The combined payment system called for in the second resolve of Resolution 817-I-17 would require legislative changes that would face significant obstacles in a Congress that is hamstrung by partisanship and budgetary concerns. Opponents, including hospitals and other stakeholders whose payment rates would be affected, are likely to counter that physicians' facility costs are already covered through the practice expense component of the PFS.

Moreover, convincing Congress to redesign Medicare's payment systems would be extremely difficult. Given existing pressures to reduce health care costs, there is also a risk that advocating for a combined payment system could encourage Congress or CMS to design a system that lowers payments to all providers and/or does not provide relief for independent physician practices. CMS could also choose to impose the OPPS payment system, on which HOPD and ASC payments are based, on physician practices. Doing so would mean that units of service currently paid separately under the PFS would be grouped together into an ambulatory payment classification, which is the unit of payment under the OPPS.

Updating Physician Practice Expenses Paid under the PFS

Alternatively, the Council considered requesting that CMS update the inputs used to calculate the indirect practice expense component of the PFS, which is analogous to OPPS facility fees and which is based in part on 10-year-old survey data that no longer reflect current practice arrangements or the relative costs of running a practice. Updated data are urgently needed to ensure that practice expenses under the PFS more accurately reflect the costs to physician practices of furnishing office-based services. However, it is important to recognize that any practice expense changes under the current system will need to be budget neutral.

Payments under the PFS are required by statute to be based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service.[22] In brief, RVUs are established for work, practice expense, and malpractice expense categories, which are adjusted for geographic cost variations. These values are multiplied by a conversion factor to convert the RVUs into payment rates. Statutory budget neutrality provisions require that annual adjustments to the RVUs that increase by more than $20 million must be offset by cuts in other RVUs or through a cut in the conversion factor.[23]

CMS establishes separate facility-and nonfacility-based practice expense RVUs for services furnished in facility settings (eg, HOPD or ASC) and in nonfacility settings (eg, physician offices). Facility-based RVUs are generally lower than nonfacility-based RVUs, so that HOPDs and ASCs receive facility payments under the OPPS whereas physician offices receive a facility fee under the PFS. Nonfacility practice expense RVUs are intended to reflect all of the direct and indirect practice expenses associated with furnishing a service in a physician office.

Direct expenses include cost inputs related to clinical labor, medical equipment and supplies. Indirect expenses include administrative labor, rent, billing services, and other office-related expenses that cannot be directly attributed to a service. In its proposed rule for CY 2019, CMS proposed updated pricing recommendations for 2,017 supply and equipment items currently used as direct practice expense inputs. The proposal is based on a report from a CMS contractor that used market research resources and methodologies to determine the updated prices.[24] As described in the following section, survey data are used by CMS to determine the indirect practice expenses

incurred per hour worked.[25] Each procedure is then assigned practice expense RVUs that are supposed to reflect the practice expenses required to provide the service relative to those required to provide other procedures.

The need for accurate data on practice costs is significant, considering many of the points raised in Resolution 817-I-17. Physician practices have experienced significant increases in practice expenses due to cumbersome regulations, quality measure requirements, EHRs (purchases, software upgrades, ongoing support and maintenance), complex payment and utilization management protocols, costly equipment used to provide, for example, imaging or infusions, and other costs that have changed dramatically since practice expense survey data was collected a decade ago. It may also be challenging for many independent and small group practices to accurately determine their total practice expenses when completing surveys about the costs of running a practice.

The Physician Practice Information Survey (PPI Survey)

In 2010, CMS began basing indirect practice expenses on the PPI Survey, a multispecialty, nationally representative survey of both physicians and non-physician practitioners paid under the PFS that was administered by the AMA over a period of time in 2007 and 2008. The PPI Survey collected data from 3,656 respondents across 51 medical specialties and health care professional groups.[26] Participating practices were asked to fill out expense worksheets that itemized expenses such as payroll, supplies and equipment. They were also asked about the costs of managing a practice, charity care, time spent on quality improvement activities, and the acquisition, operating and maintenance costs associated to EHRs. PPI Survey data were used by CMS to confirm the accuracy of PFS practice expense data. As required by statute, CMS uses medical oncology supplemental survey data from 2003 for practice expenses per hour for oncology drug administration services. For specialties that did not participate in the PPI Survey, CMS develops proxy practice expense values by crosswalking practice expense data from specialties providing similar services.[27]

Section 220 of the Protecting Access to Medicare Act of 2014, allocates funds for CMS "…to collect and use information on physicians' services in the determination of relative values in the formulae for setting physician's fees."[28] The AMA/Specialty Society RVS Update Committee and other entities have encouraged CMS to use these funds to conduct an updated survey on practice expense data. Even CMS has expressed concerns regarding the accuracy of the outdated data used to determine practice expense RVUs but, lacking other sources, the agency continues using PPI Survey data to inform physician payments under the PFS. The collection of physician practice expense data is a necessary first step which will enable comparisons to hospital cost and payment metrics and provide insight into the costs of care provided in hospital-owned and independently-owned practices.

AMA POLICY

The AMA has substantial and long-standing policy supporting equitable payments across outpatient sites of service. Policy H-240.993 calls for equity of payment between services provided by hospitals on an outpatient basis and similar services in physicians' offices. AMA policy also supports defining Medicare services consistently across settings and encouraging the CMS to adopt payment methodologies that assist in leveling the playing field across all sites of service (Policy D-330.997).

Policy H-330.925 encourages CMS to fairly pay physicians for office-based procedures and adopt a site-neutral payment policy for hospital outpatient departments and ambulatory surgical centers; advocates for the use of valid and reliable data in the development of any payment methodology for the provision of ambulatory services; advocates that in place of the CPI-U, CMS use the hospital market basket index to annually update ASC payment rates; and encourages the use of Current Procedural Terminology (CPT) codes across all sites of service as the only acceptable approach to payment methodology.

Policy H-400.957 encourages CMS to expand the extent and amount of reimbursement for procedures performed in the physician office, to shift more procedures from the hospital to the office setting, which is more cost effective, and to seek to have practice expense RVUs reflect the true cost of performing office procedures. Policy H-400.966 directs the AMA to aggressively promote the compilation of accurate data on all components of physician practice costs, and the changes in such costs over time, as the basis for informed and effective advocacy concerning physician payment under Medicare.

Policy D-240.994 directs the AMA to work with states to advocate that third-party payers be required to assess equal or lower facility coinsurance for lower-cost sites of service; publish and routinely update pertinent information related to patient cost-sharing; and allow their plan's participating physicians to perform outpatient procedures at an appropriate site of service as chosen by the physician and the patient. Furthermore, AMA policy urges private third-party payers to implement coverage policies that do not unfairly discriminate between hospital-owned and independently owned outpatient facilities with respect to payment of facility costs (Policy H-240.979). Policy H-390.849 directs the AMA to advocate for the adoption of physician payment reforms that promote improved patient access to high-quality and cost-effective care, do not require budget neutrality within Medicare Part B, and are based on payment rates that are sufficient to cover the full cost of sustainable medical practices.

AMA ACTIVITY

Enhancing Practice Efficiency and Promoting Physician Satisfaction

A strategic focus area within the AMA is working diligently to help physicians succeed in a rapidly changing health care environment. From advancing health care delivery and payment reforms that promote affordable care to restoring and preserving physician professional satisfaction, the AMA is driving practice transformation by translating regulatory requirements into actionable information; developing and disseminating practice improvement strategies and tools; establishing national benchmarks for physician burnout, leading to organizational level changes; and producing evidence-based research. To accelerate advancements in—and support for—physician and care team well-being, the AMA sponsors conferences that bring top investigators and thought leaders together to debate and advance health policies.

Encouraging Value-Based Payment

The AMA has been working for several years to encourage the development and implementation of Medicare payment models that will improve the financial viability of physician practices in all specialties, and help independent practices of all sizes remain independent; give physicians more resources and greater flexibility to deliver appropriate care to their patients; minimize administrative burdens that do not improve the quality of patient care; enable physicians to help control aspects of health care spending that they can influence, rather than having Medicare use inappropriate mechanisms to control costs such as payment cuts, prior authorization or non-

coverage of services. Since the passage of MACRA, the AMA has been accelerating its efforts to help national medical specialty societies and other physician organizations to develop, refine and implement alternative payment models (APMs) that will achieve these goals. Ideally, payment under these models should extend across sites of care.[29] AMA policy (Policy H-385.913) recognizes that APMs should provide adequate resources to support the services physician practices need to deliver to patients. The AMA has urged the US Department of Health and Human Services to reconsider testing a number of APMs as recommended by the Physician-Focused Payment Model Technical Advisory Committee.[30]

Improving Price Transparency

As the health care market evolves, patients are increasingly becoming active consumers of health care services rather than passive recipients of care in a market where price is often unknown until after the service is rendered. Achieving meaningful price transparency can help lower costs and empower patients to make informed care decisions, including decisions about where to receive certain outpatient services. Many patients may not be able to readily distinguish between hospital-owned and independent practices, and may not understand how choice of outpatient setting impacts their cost-sharing expenses. The AMA supports measures to expand the availability of health care pricing information that allows patients and their physicians to make value-based decisions when patients have a choice of provider or facility.

DISCUSSION

The AMA has long supported and advocated for fair, equitable and adequate Medicare payments across outpatient sites of service, as well as payment policies that support value-based care and encourage use of the most cost-effective care setting. The policy priority established by the Council in previous reports addressing the site-of-service differential has been to ensure patient access to services in the most clinically appropriate setting, depending on their needs and the severity of their conditions. While an HOPD may be the appropriate setting for certain medically complex patients, the migration of many services from physician offices to hospital-owned facilities is of significant concern not only because of increased costs to the Medicare program, but also because it has become increasingly difficult for practices in certain specialties to remain competitive or even sustain operations because of declining payment rates and the increased costs to practices of dealing with regulatory and administrative burdens. The Council continues to be concerned for independent physician practices, and for Medicare patients who incur higher cost-sharing expenses for outpatient services provided in hospital facilities whose care could have been safely provided in lower-cost settings. The Council believes that policy proposals addressing the site-of-service differential must be patient-centric and ensure adequate payment that supports the costs of providing high-quality, high-value physician services.

Accordingly, the Council recommends reaffirming four existing policies that guide AMA advocacy regarding the site-of-service differential: Policy H-240.993, which calls for equity of payment between services provided by hospitals and similar services provided in physician offices; Policy D-330.997, which supports defining Medicare services consistently across settings and encouraging CMS to adopt payment policies that assist in leveling the playing field across all sites of service; Policy H-400.957, which encourages CMS to expand the extent and amount of payment for procedures performed in physician offices, to shift more procedures from the hospital to the office setting, and to seek to have practice expense RVUs reflect the true cost of performing office procedures; and Policy H-400.966, which promotes the compilation of accurate physician practice cost data as the basis for informed and effective advocacy concerning Medicare physician payment.

Building on these policies, the Council recommends that the AMA support Medicare payment policies for outpatient services that are site-neutral without lowering total Medicare payments. This policy recommendation enables ongoing AMA advocacy in support of site-neutral payments while at the same time seeking solutions that do not simply lower payments for services to amounts paid to the least costly setting. The Council is mindful that there is the potential for physicians to be adversely affected as Congress and the Administration promote site-neutrality based solely on cost as a means of reining in health care spending.

The site-of-service differential impedes the provision of high-value care because it incentivizes payment based on the location where a service is provided. Payment should be based on the service itself, and not the location where it is provided. Accordingly, the Council recommends that the AMA support Medicare payments for the same service routinely and safely provided in multiple outpatient settings (eg, physician offices, HOPDs, and ASCs) that are based on sufficient and accurate data regarding the real costs of providing the service in each setting.

After extensive exploration of the "combined health care payment system" described in the second resolve of Resolution 817-I-17, the Council concludes that the practice expense component of the PFS is analogous to the facility fee paid under the OPPS, and that the valuation of the practice expense component needs to be updated to accurately reflect the costs of running a practice. The Council further believes that if physicians are paid a facility fee as called for in the second resolve, that fee is likely to be smaller than the current one and might not make up for the probable elimination of the practice expense differential in the current system. Rather than seeking the statutory changes to implement a combined payment system that pays facility fees for both hospital-owned and independent physician practices—which would be extremely challenging to accomplish in a Congress hamstrung by partisanship and a trillion-dollar deficit—the Council recommends urging CMS to update the data used to calculate the practice expense component of the PFS. The Council believes that CMS should conduct a survey similar to the PPI Survey to confirm the accuracy of practice expense data, given the many changes that have occurred since the survey was administered in 2007 and 2008, and that this survey should be administered every five years to ensure that timely data are used to inform PFS calculations. The Council believes that CMS should collect data to ensure that all physician practice costs are captured. Examples of data that must be collected by CMS include administrative and other costs that cannot be directly attributed to a service, costs of managing the practice, costs of providing uncompensated care, costs of navigating payer protocols and utilization management requirements, costs of purchasing, managing and updating EHRs, and costs related to quality measures and improvements.

Advocating for regular ongoing collection of physician practice expense data that more accurately reflect the costs of sustaining a practice is a viable option that could be impactful in the nearer term although, under Medicare's current system, PFS payments would be redistributed rather than increased overall. The updated data could be used to help measure differences in the costs of providing services in physician offices and hospital settings, and would inform future AMA advocacy on broader payment reforms.

To address concerns regarding the methodology used for DSH and uncompensated care payments to hospitals and the care provided by many physicians for which they are not fully compensated, the Council recommends that the AMA encourage CMS to both: a) base DSH and uncompensated care payments to hospitals on actual uncompensated care data; and b) study the costs to independent physician practices of providing uncompensated care.

While the focus of this report is the site-of-service differential, the Council recognizes the need to address broader physician payment issues. The Council further recognizes that achieving site-

neutral payments for outpatient procedures will require increases in Medicare payment for physician services so that physician practices can be sustained and patient choice of care setting is safeguarded. To help build the case for future Medicare payment reforms, the Council recommends that the AMA collect data and conduct research both: a) to document the role that physicians have played in reducing Medicare spending; and b) to facilitate adjustments to the portion of the Medicare budget allocated to physician services that more accurately reflects practice costs and changes in health care delivery.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 817-I-17, and the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-240.993, which urges more aggressive implementation by the US Department of Health and Human Services of existing provisions in federal legislation calling for equity in payment between services provided by hospitals on an outpatient basis and similar services in physician offices. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy D-330.997, which encourages the Centers for Medicare & Medicaid Services (CMS) to define Medicare services consistently across settings and adopt payment methodology for hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) that will assist in leveling the playing field across all sites-of-service. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy H-400.957, which encourages CMS to expand the extent and amount of reimbursement for procedures performed in the physician office, to shift more procedures from the hospital to the office setting, which is more cost effective, and to seek to have practice expense relative value units reflect the true cost of performing office procedures. (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-400.966, which directs the AMA to aggressively promote the compilation of accurate data on all components of physician practice costs, and the changes in such costs over time, as the basis for informed and effective advocacy concerning physician payment under Medicare. (Reaffirm HOD Policy)

5. That our AMA support Medicare payment policies for outpatient services that are site-neutral without lowering total Medicare payments. (New HOD Policy)

6. That our AMA support Medicare payments for the same service routinely and safely provided in multiple outpatient settings (eg, physician offices, HOPDs, and ASCs) that are based on sufficient and accurate data regarding the real costs of providing the service in each setting. (New HOD Policy)

7. That our AMA urge CMS to update the data used to calculate the practice expense component of the Medicare physician fee schedule by administering a physician practice survey (similar to the Physician Practice Information Survey administered in 2007-2008) every five years, and that this survey collect data to ensure that all physician practice costs are captured. (New HOD Policy)

8. That our AMA encourage CMS to both: a) base disproportionate share hospital payments and uncompensated care payments to hospitals on actual uncompensated care data; and b) study the costs to independent physician practices of providing uncompensated care. (New HOD Policy)

9. That our AMA collect data and conduct research both: a) to document the role that physicians have played in reducing Medicare spending; and b) to facilitate adjustments to the portion of the Medicare budget allocated to physician services that more accurately reflects practice costs and changes in health care delivery. (Directive to Take Action)

Fiscal Note: $100,000 to $200,000

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 801
(I-18)

Introduced by: Medical Student Section

Subject: Encourage Final Evaluation Reports of Section 1115 Demonstrations at the End of the Demonstration Cycle

Referred to: Reference Committee J
(Steven Chen, MD, Chair)

Whereas, Under Section 1115 of the Social Security Act, the Secretary of Health and Human Services may approve state waivers for demonstration projects that are experimental in nature;[1] and

Whereas, Section 1115 demonstrations allow states to use federal Medicaid funds for costs that would not otherwise be covered, amounting to approximately one-third (over $100 billion) of Medicaid spending in 2015;[1,2] and

Whereas, States have used these waivers to expand coverage, change delivery systems, alter benefits and cost sharing, modify provider payments, and extend coverage in emergency situations;[3] and

Whereas, Final evaluations of demonstrations have historically been required by the Centers for Medicare & Medicaid Services (CMS) only after the final expiration of the demonstration, rather than at the end of each three-to five-year demonstration cycle;[3] and

Whereas, Demonstrations may be renewed for multiple three-to five-year demonstration cycles, resulting in demonstrations running for decades without proper analyses and data reporting;[3] and

Whereas, An interim report submitted by the state of Massachusetts to CMS in 2016 regarding a demonstration initially approved in 1997 lacked data measuring the effectiveness of nearly $700 million used to create and fund new hospital Medicaid payment delivery systems;[3] and

Whereas, Massachusetts currently spends approximately 40% of its state budget on Medicaid services, and CMS has previously encouraged the state to move to more aggressive accountability measures;[4,5] and

Whereas, Recent interim evaluations of demonstrations in Arkansas and Arizona lacked important information necessary for proper assessment of those demonstrations as well;[3] and

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[4]Testimony: Joint Hearing of the House & Senate Committees on Ways & Means and the Joint Committee on Health Care Financing. *The Commonwealth of Massachusetts.* 2017:1.
[5] Sanchez, Jeffrey. Tackling Medicaid in Massachusetts. *Health Affairs Blog.* 2015; https://www.healthaffairs.org/do/10.1377/hblog20150622.048691/full/ Accessed April 4, 2018.

Whereas, In ten states, including Arizona, over 75% of the Federal Medicaid Expenditures go towards Section 1115 demonstrations;[3] and

Whereas, The U.S Government Accountability Office (GAO) published a study in January 2018 showing that state-led evaluations of demonstrations had limited usefulness for federal decision-making due to the temporal gaps in comprehensive results, and CMS officials acknowledge this fact;[3] and

Whereas, The GAO has made the following recommendations to CMS: (1) establish written procedures for requiring final evaluation reports at the end of each demonstration cycle, (2) issue criteria for when it will allow limited evaluations of demonstrations, and (3) establish a policy for publicly releasing findings from federal evaluations of demonstrations;[3] and

Whereas, CMS officials have said that the agency plans to require appropriate evaluation at the end of each demonstration cycle, but still lacks any written procedures for implementing these requirements;[3] therefore be it

RESOLVED, That our American Medical Association encourage the Centers for Medicare & Medicaid Services to establish written procedures that require final evaluation reports of Section 1115 Demonstrations at the end of each demonstration cycle, regardless of renewal status. (New HOD Policy)

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

Date Received: 9/21/18

RELEVANT AMA POLICY:

Medicaid Waivers for Managed Care Demonstration Projects H-290.987
(1) Our AMA adopts the position that the Secretary of Health and Human Services should determine as a condition for granting waivers for demonstration projects under Section 1115(a) of the Medicaid Act that the proposed project: (i) assist in promoting the Medicaid Act's objective of improving access to quality medical care, (ii) has been preceded by a fair and open process for receiving public comment on the program, (iii) is properly funded, (iv) has sufficient provider reimbursement levels to secure adequate access to providers, (v) does not include provisions designed to coerce physicians and other providers into participation, such as those that link participation in private health plans with participation in Medicaid, and (vi) maintains adequate funding for graduate medical education. (2) Our AMA advocates that CMS establish a procedure which state Medicaid agencies can implement to monitor managed care plans to ensure that (a) they are aware of their responsibilities under EPSDT, (b) they inform patients of entitlement to these services, and (c) they institute internal review mechanisms to ensure that children have access to medically necessary services not specified in the plan's benefit package.
Citation: (BOT Rep. 24, A-95; Reaffirmation A-99; Reaffirmation A-00; Reaffirmation I-04; Modified: CMS Rep. 1, A-14)

Opposition to Medicaid Work Requirements H-290.961
Our AMA opposes work requirements as a criterion for Medicaid eligibility.
Citation: Res. 802, I-17; Reaffirmation: A-18

Medicaid Expansion Options and Alternatives H-290.966
1. Our AMA encourages policymakers at all levels to focus their efforts on working together to identify realistic coverage options for adults currently in the coverage gap.
2. Our AMA encourages states that are not participating in the Medicaid expansion to develop waivers that support expansion plans that best meet the needs and priorities of their low income adult populations.
3. Our AMA encourages the Centers for Medicare & Medicaid Services to review Medicaid expansion waiver requests in a timely manner, and to exercise broad authority in approving such waivers, provided that the waivers are consistent with the goals and spirit of expanding health insurance coverage and eliminating the coverage gap for low-income adults.
4. Our AMA advocates that states be required to develop a transparent process for monitoring and evaluating the effects of their Medicaid expansion plans on health insurance coverage levels and access to care, and to report the results annually on the state Medicaid web site.
Citation: CMS Rep. 5, I-14; Reaffirmed: CMS Rep. 02, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 802
(I-18)

Introduced by:	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Subject:	Due Diligence for Physicians and Practices Joining an ACO with Risk Based Models (Up Side and Down Side Risk)
Referred to:	Reference Committee J (Steven Chen, MD, Chair)

Whereas, Recent presentations by CMS Secretary Verma have stressed moving Medicare Shared Savings ACO's to reduce the number of upside only Medicare Shared Savings ACO's (MSSP ACO's) by moving them to a two-track model and reducing the length of time that existing MSSP ACO's can remain in the program to two years and lowering their share of savings to 25%. Telemedicine initiatives were offered as a way to offset the risks. The rationale is that new risk based ACO's will be able to move to Value Based Care as outlined in MACRA. The risk based ACO's will have to remain in the program for 5 years starting in 2020; and

Whereas, Given that 15 of the 18 Next Gen (risk based ACO's) have prior MSSP experience and are huge organizations with prior experience with integration and cost reductions, the fact that they only saved 1.7% is alarming. Eliminating the MSSP prevents new organizations from acquiring the experience in a lower risk environment. (Infrastructure costs, etc. for an ACO). It reinforces the fact that smaller organizations and private practitioners will have no access to APM's and the bonuses related to Value Based Care; and

Whereas, Recent results from CMS MSSP ACO's viewed on the whole do not show consistent "significant savings" for many organizations, and many others show no savings. Thus, making the losses associated with the move to involve "downside risk" even more likely and the pathway more treacherous. (CMS Report 2017).[3] This will limit the number of risk-based organizations to only very large previously integrated and well capitalized healthcare systems; and

Whereas, Recent publications (NEJM 9/5/18), four which have done subgroup analyses of the results, have shown a differential in savings when MSSP ACO's owned by physicians are reviewed versus hospital integrated systems. The physician owned systems have substantially greater savings; and

Whereas, Risk based ACO's require prior ACO experience, organizational infrastructure, linked health information technology (HIT), and business resources. Large amounts of capital are necessary to form and run a given system. The necessary funds are only available to large well capitalized health care systems. These requirements create a vulnerability which will lead to further consolidation of medical practices given the need for capital needed to allow them to participate in Advance Payment Models (APM's). Thus, it will also expose integrated healthcare systems to takeovers by financial firms or other larger systems; and

Whereas, consolidation of physicians' practices has not led to greater savings. Further consolidation forced by eliminating the MSSP ACO program may cause some systems to drop out of the MSSP program. This will likely further raise costs while making it impossible for smaller groups of physicians and rural physicians to participate in ACO's. The opportunity to participate in value-based care (APM's) to receive bonuses in MACRA will not be accessible. Elimination and/or modification of MIPS makes the opportunity for bonuses based on superior physician performance impossible; therefore be it

RESOLVED, That our American Medical Association advocate for the continuation of up side only risk Medicare Shared Savings ACO (MSSP ACO) program as an option from the Centers for Medicare and Medicaid Services, particularly for physician owned groups (New HOD Policy); and be it further

RESOLVED, That our AMA develop educational resources and business analytics to help physicians complete due diligence in evaluating the performance of hospital integrated systems before considering consolidation. Specific attention should be given to the evaluation of transparency on past savings results, system finances, quality metrics, physician workforce stability and physician job satisfaction, and the cost of clinical documentation software (Directive to Take Action); and be it further

RESOLVED, That our AMA evaluate the characteristics of successful physician owned MSSP ACOs and participation in alternative payment models (APMs) to create a framework of the resources and organizational tools needed to allow smaller practices to form virtual ACOs that would facilitate participation in MSSP ACOs and APMs. (Directive to Take Action)

Fiscal Note: Estimated cost of $30,000 to implement resolution.

Received: 09/25/18

References

1. Announcing the Next Gen ACO Results
2. AMA Accountable Care Principles 2017
3. Was the Medicare Accountable Care Savings Program Successful in 2017
4. Medicare Spending over 3 year of the shared savings program McWilliam, J M, et. al., N Engl J Med. 2018 Sept. 5
5. Ready or not for Quality Based Re-imbursement
6. Use of EHR's does not reduce Administrative Costs
7. Hospital Consolidation linked to higher healthcare costs
8. MACRA
9. How the Next Gen ACO's compared on savings in 2016
10. The Impact of Hospital Consolidation on Medical Costs
11. The Hidden Cost of Provider Consolidation
12. Next Gen Model Saves 62 Million
13. Scholarly Articles on Consolidation of Medical Practices

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 803
(I-18)

Introduced by: Resident and Fellow Section

Subject: Insurance Coverage for Additional Screening Recommended in States with Laws Requiring Notification of "Dense Breasts" on Mammogram

Referred to: Reference Committee J
(Steven Chen, MD, Chair)

Whereas, "Dense breast" tissue makes it harder to identify cancer on a mammogram, especially if there are no calcifications present within the cancer[i]; and

Whereas, Patients with "dense breast" tissue are also associated with an increased risk of breast cancer (i.e., the risk is estimated to be four times greater for women with extremely dense breasts versus women with fatty breasts)[i]; and

Whereas, A "negative" screening mammography result does not reliably rule out cancer in women with dense breasts[i]; and

Whereas, These women with "dense breast" tissue often have higher stage cancers upon detection due to the fact that they are not discovered until they are larger and symptomatic[i]; and

Whereas, Ultrasound and MRI have been shown to reduce interval cancers in women with "dense breasts"[i]; and

Whereas, Approximately 30 states have adopted laws requiring notification to patients with "dense breasts"[ii]; and

Whereas, The decision to pursue additional screening should be a result of the conversation between individual patients and their physician-led health care team[i]; and

Whereas, Insurance companies are not required to pay for additional screening[iii]; therefore be it

RESOLVED, That our American Medical Association support insurance coverage for supplemental screening recommended for patients with "dense breast" tissue following a conversation between the patient and their physician (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for insurance coverage for and adequate access to supplemental screening recommended for patients with "dense breast" tissue following a conversation between the patient and their physician. (New HOD Policy)

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

Received: 09/27/18

RELEVANT AMA POLICY

Screening Mammography H-525.993

Our AMA:
a. recognizes the mortality reduction benefit of screening mammography and supports its use as a tool to detect breast cancer.
b. recognizes that as with all medical screening procedures there are small, but not inconsequential associated risks including false positive and false negative results and overdiagnosis.
c. favors participation in and support of the efforts of professional, voluntary, and government organizations to educate physicians and the public regarding the value of screening mammography in reducing breast cancer mortality, as well as its limitations.
d. advocates remaining alert to new epidemiological findings regarding screening mammography and encourages the periodic reconsideration of these recommendations as more epidemiological data become available.
e. believes that beginning at the age of 40 years, all women should be eligible for screening mammography.
f. encourages physicians to regularly discuss with their individual patients the benefits and risks of screening mammography, and whether screening is appropriate for each clinical situation given that the balance of benefits and risks will be viewed differently by each patient.
g. encourages physicians to inquire about and update each patient's family history to detect red flags for hereditary cancer and to consider other risk factors for breast cancer, so that recommendations for screening will be appropriate.
h. supports insurance coverage for screening mammography.
i. supports seeking common recommendations with other organizations, informed and respectful dialogue as guideline-making groups address the similarities and differences among their respective recommendations, and adherence to standards that ensure guidelines are unbiased, valid and trustworthy.
j. reiterates its longstanding position that all medical care decisions should occur only after thoughtful deliberation between patients and physicians.
Citation: (CSA Rep. F, A-88; Reaffirmed: Res. 506, A-94; Amended: CSA Rep. 16, A-99; Appended: Res. 120, A-02; Modified: CSAPH Rep. 6, A-12)

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[i] Berg WA. Supplemental Breast Cancer Screening in Women with Dense Breasts Should be Offered with Simultaneous Collection of Outcomes Data. *Annals of internal medicine*. 2016;164(4):299-300. doi:10.7326/M15- 2977.
[ii] Breast Density Notification Laws by State — Interactive Map. Available at http://www.diagnosticimaging.com/breast-imaging/breast-density-notification-laws-state--interactive-map.
[iii] Dense Breast Info. Available at http://densebreast-info.org/legislation.aspx.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 804
(I-18)

Introduced by: Alaska

Subject: Arbitrary Documentation Requirements for Outpatient Services

Referred to: Reference Committee J
(Steven Chen, MD, Chair)

Whereas, Onerous administrative requirements can reduce practice efficiency and contribute to physician burnout, without improving patient care; and

Whereas, Fee for service payers including Medicare and Medicaid have historically advised that clinical documentation for outpatient services should be completed in a "timely manner" (or within some other non-specific timeframe); and

Whereas, A new Alaska Medicaid regulation arbitrarily imposes a "72 hour" rule, prohibiting payment for any outpatient claim unless documentation for the provided service had been substantively completed within three days of the visit (including weekends/holidays); and

Whereas, Neither government nor private health insurers should unilaterally impose burdensome documentation requirements without at least some evidence that the new rules will improve patient outcomes; and

Whereas, Alaska's new regulation also includes a provision that the three day requirement shall be waived if a provider's professional body has adopted policy specifying that a longer time period for documentation is appropriate; therefore be it

RESOLVED, That our American Medical Association agree that documentation for outpatient physician services should be completed in a timely manner (New HOD Policy); and be it further

RESOLVED, That for circumstances in which more specific definitions of timeliness are required, AMA policy is that documentation for outpatient services should be completed, when possible, within 14 days of a provided service (New HOD Policy); and be it further

RESOLVED, That our AMA work with government health plans and private insurers to help them better understand the unintended consequences of imposing documentation rules with unrealistically short timeframes, and that our AMA oppose the use of such rules or regulations in determining whether submitted claims are valid and payable. (Directive to Take Action)

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

Received: 09/28/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 805
(I-18)

Introduced by: Florida

Subject: Prompt Pay

Referred to: Reference Committee J
(Steven Chen, MD, Chair)

Whereas, Current AMA policy declares that it is a top priority to seek regulatory and legislative relief to ensure that all health insurance and managed care companies pay for clean claims submitted electronically within fourteen days (H-190.959); and

Whereas, The AMA is still working to ensure that the 14-day prompt payment objective is achieved; and

Whereas, Advances in automation and technology enable insurance companies and managed care plans to pay clean claims on the day received; therefore be it

RESOLVED, That American Medical Association policy H-190.959 be amended by addition and deletion to read as follows:

> Physician Reimbursement by Health Insurance and Managed Care Companies
> 1. Our AMA shall make it a top priority to seek regulatory and legislative relief to ensure that all health insurance and managed care companies pay for clean claims submitted electronically within ~~fourteen~~ three days.
> 2. When electronic claims are deemed to be lacking information to make the claim complete, the health insurance and managed care companies will be required to notify the health care provider within ~~five~~ one business day~~s~~ to allow prompt resubmission of a clean claim.
> 3. Our AMA shall advocate for heavy penalties to be imposed on health insurance and managed care companies, including their employees, that do not comply with laws and regulations establishing guidelines for claims payment. (Modify Current HOD Policy)

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

Received: 09/27/18

RELEVANT AMA POLICY

Physician Reimbursement by Health Insurance and Managed Care Companies H-190.959
1. Our AMA shall make it a top priority to seek regulatory and legislative relief to ensure that all health insurance and managed care companies pay for clean claims submitted electronically within fourteen days.
2. When electronic claims are deemed to be lacking information to make the claim complete, the health insurance and managed care companies will be required to notify the health care provider within five business days to allow prompt resubmission of a clean claim.
3. Our AMA shall advocate for heavy penalties to be imposed on health insurance and managed care companies, including their employees, that do not comply with laws and regulations establishing guidelines for claims payment.
Citation: (Sub. Res. 713, A-02; Modified: Res. 714, A-03; Reaffirmation I-04; Reaffirmed: CMS Rep. 1, A-14; Reaffirmed: Res 132, A-14; Reaffirmed: Sub. Res. 715, A-15)