

REPORTS OF THE COUNCIL ON MEDICAL SERVICE

The following reports, 1–8, were presented by Robert E. Hertzka, MD, Chair:

1. UPDATE ON PAYMENT MECHANISMS FOR PHYSICIAN-LED TEAM-BASED HEALTH CARE

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED

REMAINDER OF REPORT FILED

See Policies H-160.908, H-160.912, H-390.840 and D-160.933

At the 2013 Interim Meeting, the House of Delegates adopted as amended Council on Medical Service Report 1, “Payment Mechanisms for Physician-Led Team-Based Health Care.” The report was amended to ask that the American Medical Association (AMA) “report back to the House on issues, developments and AMA activity on payment mechanisms for physician-led team-based care by the 2015 Interim Meeting” (Policy D-160.933). The Board of Trustees referred the requested study to the Council on Medical Service for report back to the House at the 2015 Interim Meeting.

This report builds on the Council’s previous reports on physician-led team-based care, including one report focused on payment; outlines the transition of Medicare’s payment system to include value-based alternative payment models; acknowledges an increasing emphasis on team-based payment; highlights examples of specialty-specific team-based innovative payment models; summarizes AMA advocacy, activity and relevant policy; discusses avenues for AMA advocacy and policy development; and presents policy recommendations.

BACKGROUND

Established by Council on Medical Service Report 1-I-13, “Payment Mechanisms for Physician-Led Team-Based Health Care,” AMA Policy H-160.908 advocates that payment models for physician-led team-based care should be determined by physicians working collaboratively with hospital and payer partners to design models best suited for their particular circumstances. Physician team leaders should receive the payments from health insurers for services provided by the team and establish payment disbursement mechanisms that take into consideration each team member’s contribution. The policy also states that an effective payment system for team-based care should reflect the value, time, effort and intellectual capital provided by individual team members, be adequate to attract team members of high caliber, and be sufficient to sustain the team over the time frame that is needed.

REPEAL OF THE MEDICARE SUSTAINABLE GROWTH RATE (SGR) FORMULA

In April 2015, the AMA and other stakeholders were successful in lobbying to pass legislation eliminating Medicare’s SGR formula. The passage of H.R. 2, the “Medicare Access and CHIP Reauthorization Act,” (MACRA), is expected to potentially have great impact on the way physicians practice medicine and receive payments for services provided.

Alternative Payment Models (APMs)

Medicare fee-for-service payments will be retained under MACRA, although physicians are encouraged to participate in value-based Alternative Payment Models (APMs) through “alternative payment entities” in order to receive APM bonus payments. An “alternative payment entity” either: (a) bears financial risk under an APM for monetary losses that are in excess of a nominal amount; or (b) is a medical home expanded under the Centers for Medicare & Medicaid Services (CMS) Innovation Center’s authority. Physicians participating in APMs will receive annual bonus payments equal to five percent of their covered Medicare professional services provided during 2019 through 2024. To be eligible for these payments, physicians’ level of participation in the qualified APMs must reach certain threshold levels, starting with 25 percent of revenues in 2019 – 2020 and growing to 75 percent by 2023. Physician participation in APMs is voluntary.

APMs are designed to improve care coordination and professional collaboration, which foster team-based care. Under fee-for-service Medicare, team-based health care services are currently not billable. The option to participate in an APM allows physicians the opportunity to provide team-based care and receive payments for such services. For example, in an APM a surgeon who removes a patient's cancer and the surgeon who provides the reconstructive surgery could both receive payment when collaboratively working to avoid repeat operations.

Merit-based Incentive Payment Systems (MIPS)

Under MACRA, the current fee-for-service payment incentive programs – Meaningful Use, Physician Quality Reporting System and Value-Based Modifier – will be replaced with the new Merit-Based Incentive Payment System (MIPS) starting in 2019. MIPS will include measures from these programs as well as a new “clinical practice improvement activities” area that has not yet been developed. CMS has more flexibility to tailor MIPS to the needs of individual specialties. MACRA exempts physicians with low Medicare volume from MIPS and gives special considerations for practices that are small, rural or in underserved areas. Our AMA advocated for these provisions.

AMA Advocacy

In response to the passage of MACRA, the AMA developed a Federation task force made up of state and specialty societies to discuss the legislation and how physicians can successfully navigate the new law. The AMA has also developed Federation workgroups on the MIPS and APMs with the goal of determining innovations physicians are already engaged in, discussing implementation issues with CMS, and developing relevant policy recommendations.

TEAM-BASED PAYMENT

CMS recognizes the value of team-based care and is considering payment refinements to improve the accuracy of payments to physicians working in collaborative care practice arrangements. The AMA is providing input on improving payment accuracy for primary care and care management, including interprofessional services and consultations. In addition, the AMA Current Procedural Terminology (CPT[®]) Editorial Panel and the Relative Value Scale (RVS) Update Committee (RUC) are working with specialty societies on specific coding and valuation issues for collaborative care payments.

SPECIALTY-SPECIFIC TEAM-BASED ALTERNATIVE PAYMENT MODELS

The recent emphasis on APMs focuses mainly on delivering primary care services and hospital-based procedures. The primary care medical home model is a well-established team-based delivery model with a payment structure emphasizing value instead of volume. There has been rapid growth in accountable care organizations and many physicians now participate in this shared savings model. While many specialties are interested in developing APMs, at this time Medicare does not approve specialty models on a wide scale. Following are four examples of innovative payment models developed by non-primary care specialties:

Integrated Physical and Behavioral Health Care – Global Budget Payments

The Sustaining integrated Healthcare Across Primary care Efforts (SHAPE) initiative in Colorado is evaluating the use of a global budget payment model for the integration of physical and behavioral health care. SHAPE's global budget payment model allocates payments based on each practice's cost, panel size, panel complexity, and program design. The model includes shared risk and quality targets between a practice and payer. A comparison of the costs and outcomes in integrated practices using a global budget payment model and integrated practices using traditional payments will be published in late 2015.^{1,2}

Oncology – Patient-Centered Oncology Payment (PCOP)

PCOP is an innovative payment model designed by the American Society of Clinical Oncology (ASCO) to support higher quality cancer care at a lower cost. Practices are accountable for delivering high-quality care, such as following evidence-based use criteria for drugs, helping patients avoid and manage complications of treatment, and support patients' advanced care needs. Payments provide sufficient resources and flexibility for oncology practices to tailor health care services to meet each patient's unique needs.³

Transplant Surgery – Tiered Payments

The transplant community has used a tiering system for at least 20 years to pay providers involved in an episode of care. First or second tier providers are involved in 5 - 95 percent or more of the cases and receive a prospective payment based on an agreed upon percentage of each case's total payment according to historical payment data. Third tier providers are involved in less than five percent of the cases and are paid from funds set aside according to a pre-negotiated rate. For cases that do not necessitate third tier providers, the funds set aside are distributed to the first and second tier providers.⁴

American Society of Anesthesiologists (ASA) – Various Payments

The ASA has been developing the Perioperative Surgical Home (PSH) model of care for nearly four years as a cost-effective pathway to provide perioperative services. The PSH provides acute episode care that contributes to overall population health management, cost savings and improved quality of care. ASA is exploring feasible payment models given the challenges of providing perioperative services.⁵

AMA ADVOCACY AND ACTIVITIES

Professional Satisfaction and Practice Sustainability

Since 2013, the AMA strategic plan has included a focus on shaping payment and delivery models to enhance physician satisfaction. CMS Report 1-I-13 reported that as part of this focus area, the AMA collaborated with RAND Corporation to conduct in-depth field research on delivery and payment models. The 2013 AMA-RAND study, "Factors Affecting Physician Professional Satisfaction and their Implications for Patient Care, Health Systems, and Health Policy," aimed to better understand which payment models promote satisfaction and sustainability in different practice settings, and to identify critical factors of success.⁶

In 2015, the AMA again collaborated with RAND Corporation to research the impact that various payment models have on physician practices, their professional lives and the delivery of patient care. The 2015 AMA-RAND study, "Effects of Health Care Payment Models on Physician Practice in the United States," aimed to describe the effects that alternative health care payment models have on physicians and physician practices in the US.⁷

The results of the 2015 AMA-RAND study are guiding efforts to make improvements to current and future payment innovations and help physician practices succeed in these new payment models regardless of their mode of practice. The AMA is working with physicians, hospitals, commercial payers, employers, and federal and state policymakers to ensure the success and sustainability of payment models that improve patient care.

AMA Innovators Committee

In June 2011, the AMA formed the Innovators Committee, an advisory group of physicians with experience in the development and management of innovative delivery and payment models. The committee completed its charge by guiding the development of AMA resources to help physicians enact innovations that improve patient care and increase their professional satisfaction and success.

Council Report 1-I-13 noted that in July 2012, the Innovators Committee released a whitepaper entitled "Physician Payment Reform: Early Innovators Share What They Have Learned." In April 2014, the Innovators Committee released another whitepaper entitled "Where Do I Fit In? Dividing the Pie in New Payment Models." These whitepapers illustrate how payments might be appropriated to individual physicians and non-physician practitioners within a team.

RELEVANT AMA POLICY

The AMA will continue to monitor health care delivery and physician payment reform activities, and provide resources to help physicians understand and participate in these initiatives. The AMA will also continue to work with the Federation to identify, publicize and promote physician-led payment and delivery reform programs that can serve as models for others working to improve patient care and lower costs (Policy D-385.963).

In its work with CMS to shape the implementation of APMs, the AMA will advocate for physician leadership and accountability to deliver high quality and value to patient care; diversity of physician-led practice models; and opportunities for physicians to determine payment models that work best for their patients, practices, specialties and regions. The AMA will advocate that APMs consider physician readiness to assume up-side and down-side risk. The AMA will assist physician practices by offering support and guidance to optimize the quantity and content of physician work under APMs; address physicians' concerns about the operational details of APMs to improve their effectiveness; provide resources for data management and analysis; and coordinate key components of APMs across multiple payers, especially performance measures to help physician practices respond constructively. (Policies H-390.844 and H-450.931).

AMA Policy H-385.915 calls on the AMA to promote the development of sustainable payment models that could be used to fund the necessary services inherent in integrating behavioral health care services into team-based primary care settings. In addition, independent physician practices and small group practices are encouraged to consider opportunities to form health care teams such as through independent practice associations, virtual networks or other networks of independent providers (Policy H-160.912).

DISCUSSION

Team-based payment models should reflect the diversity of physician practices and provide opportunities for physicians to choose the payment mechanism or mechanisms that work best for their patients, practices, specialties and regions. The option to participate in a Medicare APM allows physicians to practice team-based care and receive payments for such services. To allow all sizes of physician practices to have the opportunity to participate in a Medicare APM, the Council recommends reaffirming Policy H-160.912, which encourages independent physician practices and small group practices to consider forming health care teams such as through independent practice associations, virtual networks or other networks of independent providers.

The Council also recommends reaffirming Policy H-160.908, which advocates that payment models for team-based care should be determined by individual physician practices working collaboratively with hospital and payer partners to design payment models that are best suited for their particular circumstances.

Established by Council on Medical Service Report 1-I-13, AMA Policy H-160.908 advocates that physician team leaders should receive the payments from health insurers for services provided by the team and establish payment disbursement mechanisms that take into consideration each team member's contribution. To assist in this endeavor, the Council suggests encouraging public and private health insurers to develop and offer a variety of value-based contracting options so that physician practices can select payment models that best suit their delivery models.

Physicians are understandably concerned about taking on financial risk that cannot be determined in advance. The Council suggests encouraging CMS to ensure that Medicare APMs do not require physicians to assume responsibility for costs they cannot control because it could potentially create an ethical conflict of interest. For example, non-compliant patients may require more services, which could result in lower incentive payments to their physicians.

The recent emphasis on APMs focuses mainly on delivering primary care services and hospital-based procedures. There has been rapid growth in accountable care organizations and many physicians now participate in this shared savings model. Bundled payment programs developed to date have focused almost exclusively on hospital episodes. While many specialties are interested in developing APMs linked to patient conditions instead of being tied to a hospitalization, at this time Medicare has not provided a pathway for approval and implementation of these types of models on a wide scale. The Council suggests that the AMA continue to advocate to CMS that physicians in all specialties and modes of practice must have at least one Medicare APM in which they can feasibly participate.

MACRA establishes a Physician-Focused Payment Model Technical Advisory Committee (TAC) to review proposed alternative payment models submitted by stakeholders and make recommendations to the Secretary of the Department of Health and Human Services on whether the models meet established criteria. The AMA nominated several individuals to serve on the TAC. The Council suggests advocating to CMS that any review process of APMs proposed by stakeholders be completed in a timely manner, include an administratively simple appeals process and access to an ombudsman.

Finally, the Council recommends rescinding Policy D-160.933[2], which calls for the update that has been accomplished by this report.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) reaffirm Policy H-160.912, which encourages independent physician practices and small group practices to consider opportunities to form health care teams such as through independent practice associations, virtual networks or other networks of independent providers.
2. That our AMA reaffirm Policy H-160.908, which advocates that payment models for physician-led team-based care should be determined by physicians working collaboratively with hospital and payer partners to design models best suited for their particular circumstances.
3. That our AMA encourage public and private health insurers to develop and offer a variety of value-based contracting options so that physician practices can select payment models that best suit their delivery of care.
4. That our AMA encourage the Centers for Medicare & Medicaid Services (CMS) to ensure that Medicare Alternative Payment Models (APMs) do not require physicians to assume responsibility for costs they cannot control because such a requirement could potentially create an ethical conflict of interest.
5. That our AMA continue to actively advocate to CMS that physicians in all specialties and modes of practice must have at least one Medicare APM in which they can feasibly participate.
6. That our AMA advocate to CMS that any review process of alternative payment models proposed by stakeholders be completed in a timely manner, include an administratively simple appeals process and access to an ombudsman.
7. That our AMA rescind Policy D-160.933[2], which was accomplished with this report.

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**2. PHARMACEUTICAL COSTS
(RESOLUTIONS 207-I-14 AND 228-I-14)**

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTIONS 207-I-14, 228-I-14, 806, 814 AND 817
REMAINDER OF REPORT FILED**

See Policies H-110.987, H-110.988, H-110.989, H-110.992, H-155.962 and D-330.954

At the 2014 Interim Meeting, the House of Delegates referred two resolutions on the issue of pharmaceutical costs. The Board of Trustees assigned these items to the Council on Medical Service for a report back to the House of Delegates at the 2015 Interim Meeting. Resolution 207-I-14, “Generic Pharmaceutical Pricing,” introduced by the Idaho Delegation, asked:

That our American Medical Association (AMA) advocate for prescription drug cost containment, and communicate concerns about the rapidly rising cost of generic prescription drugs to the US Food and Drug Administration.

Resolution 228-I-14, “High Cost of Drugs,” introduced by the Organized Medical Staff Section, asked:

(1) That our American Medical Association (AMA) advocate for a comprehensive federal government (e.g., CMS, etc.) study of the development and pricing practices of the pharmaceutical industry and inform the Congress of the United States if any questionable pricing practices are discovered; (2) That our AMA explore the rapidly escalating cost of generic drugs that are years past developmental costs; and (3) That our AMA report back to the House of Delegates at the 2015 Annual Meeting.

This report provides background on prescription drug spending and pricing; highlights contributors to drug pricing; assesses the impact of drug pricing on health plans, payers, physicians and patients; outlines relevant ongoing legislative activity; summarizes relevant AMA policy; and presents policy recommendations.

BACKGROUND

The most recent National Health Expenditure projections showed that prescription drug spending was estimated to have increased by 12.6 percent to \$305.1 billion in 2014, the highest rate of growth in the sector since 2002.¹ Drivers behind the high rate of growth in prescription drug spending include new specialty drugs, including those for hepatitis C, as well as increased utilization of prescription drugs. The projected annual growth in prescription drug spending is expected to average 6.3 percent from 2015 through 2024. Contributions to future growth in spending in the prescription drug sector include modifications in benefit management to improve drug adherence for individuals with chronic diseases, expected changes to clinical guidelines supporting drug therapies at earlier stages of treatment, identifying new drug targets and therapies based on expanded knowledge of genetic contribution to health and disease, and improving economic conditions.²

On the whole, prescription drugs account for more than nine percent of total health spending, and specialty drugs make up one-third of drug spending. Over the past five years, spending on specialty drugs, including biologics, has contributed to 73 percent of the overall growth in drug spending. In 2014 alone, spending on new brands increased by \$20.2 billion, which included four new hepatitis C treatments.³ The two hepatitis C treatments that have received significant attention over the past year due to their price include Sovaldi, which has an average wholesale price of \$1,000 per pill, amounting to \$84,000 per treatment regimen, and Harvoni, which has a list price of \$95,000 for a 12-week course of treatment. Outside of hepatitis C drugs, drivers of specialty spending growth include drugs for autoimmune diseases and oncology. The trend in growth in specialty drug spending is expected to continue, with 42 percent of the late-stage research and development pipeline consisting of specialty drugs.³ Many health plans and pharmacy benefit managers are concerned with the potential cost and impact of another new biologic which is a monoclonal antibody that inactivates a specific protein (proprotein convertase subtilisin kexin type 9, or PCSK9) in the liver, dramatically reducing the amount of harmful LDL cholesterol circulating in the bloodstream. At the time that this report was written, two PCSK9 inhibitors had been approved by the Food and Drug Administration (FDA), and had estimated annual wholesale acquisition costs between \$14,000 and \$15,000.⁴ Comparatively, evolocumab

costs \$6,800 per year in the United Kingdom, \$8,200 per year in Austria and \$8,800 per year in Finland.⁵ Unlike Sovaldi and Harvoni, which are time-limited treatments, patients could potentially take PCSK9 inhibitors for the duration of their lives. In addition, the target patient population for PCSK9 inhibitors could be significant.

Overall, annual price increases for prescription drugs are expected to average three percent from 2014 to 2024.¹ In 2013, the retail prices for 97 percent of the 227 most widely used brand name prescription drugs by older Americans increased. Prices for 96 percent of these drugs increased faster than the rate of inflation, with 87 percent of these drugs having annual retail price increases of more than three times the rate of inflation. Eighty-five of the 227 most widely used brand name drugs by older Americans had annual retail price increases of 15 percent or more.⁶

Approximately 4.3 billion outpatient prescriptions were dispensed in the US in 2014. Eighty-eight percent of prescriptions were dispensed as generics, an increase of two percent over 2013.³ Generic drugs, due to their historically significant savings over their brand-name counterparts, have contributed to health system savings over the past decade. However, there have been concerns whether savings from generics will continue to be achieved. There was a \$9.5 billion increase in generic drug spending in 2014. Recent patent expirations resulted in a \$11.9 billion reduction in drug spending in 2014, the lowest impact in five years.³ The average annual retail price of therapy for the most widely used generic drugs by older Americans was \$283 in 2013, approximately 78 cents per day. Twenty-seven percent of the 280 most widely used generic drugs by older Americans had price increases in 2013. Eleven of these generic drugs had price increases of 30 percent or more in 2013. From 2012 to 2013, doxycycline hyclate 100 mg capsule experienced a price increase of 1,961.5 percent, methotrexate 2.5 mg tablet had a 213.4 percent price increase, and divalproex sodium 500 mg tablet extended-release 24-hour experienced a 193.3 percent price increase.⁷

CONTRIBUTORS TO DRUG PRICING

Generic Drugs

Price increases for generic drugs may result from many factors, including drug shortages, supply disruptions, limits in manufacturing capacity, and generic drug industry mergers and acquisitions. In addition, generic drug companies may transition to manufacture drugs recently off patent to gain early market share, while others have chosen to manufacture generic drugs that have been on the market for some time and no longer have ample competition. To spur competition and expedite FDA review of generic drug applications, Congress passed the Generic Drug User Fee Amendments (GDUFA) of 2012. Effective October 2014, the GDUFA outlined new timelines for review of generic drug applications, the funding of which is supplemented by industry user fees. By 2017, the goal is for the FDA to take regulatory action on 90 percent of new generic drug applications within 10 months of submission. FDA's Office of Generic Drugs also expedites generic drug applications determined to be critical to public health or alleviate drug shortages. During the first three quarters of calendar year 2014, approximately 100 generic abbreviated new drug or supplemental applications had expedited review.⁸

Brand-Name Drugs

Several factors contribute to the pricing of brand-name drugs, including the number of individuals expected to use the drug, development costs, and competition in the marketplace. Brand-name drugs have 20 years of patent protection from the date of filing, and also enjoy a period of market exclusivity, depending on the type of drug. Orphan drugs – drugs to treat rare diseases or conditions affecting less than 200,000 individuals in the US, or affecting more than 200,000 individuals but for which there is not a reasonable expectation that the sales of the drug would recover the costs – have seven years of market exclusivity. Drugs deemed to be innovative products that include an entirely new active ingredient – a new chemical – have five years of market exclusivity. Six months of exclusivity are added to existing exclusivity periods once studies on the effects of a drug upon children are submitted for FDA review and meet the statutory requirements.⁹

Brand-name drug manufacturers have also used various techniques to delay competition in the marketplace or lengthen patent protection. In reverse-payment patent litigation settlements, also known as “pay-for-delay” settlements, a brand-name drug manufacturer pays a potential generic competitor to abandon its patent challenge and delay offering a generic drug product for a number of years. Pay-for-delay settlements do not always involve a direct cash payment to the generic manufacturer. For example, if a generic drug manufacturer agrees to delay its introduction of a generic drug into the marketplace, a brand-name manufacturer can agree not to offer an authorized

generic to compete with the generic competitor. In the case *Federal Trade Commission v. Actavis*, the US Supreme Court held that pay-for-delay settlements can violate antitrust laws.

Brand-name manufacturers can also attempt to effectively extend the term of patent protection for a single product by creating a patent portfolio, composed of patents with staggered terms for modified forms of the same drug, new delivery systems for that drug, or other variations of the original product, a practice known as “evergreening.” Examples of evergreening include reformulating a drug as extended release or changing the mix of chemical isomers. In situations where a newer version of an existing brand-name drug enters the marketplace, brand-name manufacturers can also choose to take the older drug off the market or restrict access to the older drug, including by limiting its distribution through select specialty pharmacies.

Biologics

Biologics include a range of products including vaccines, antitoxins, blood components, serums, allergenic extracts, and recombinant therapeutic proteins. Overall prices for biologics are higher resulting from the high risk and expense of manufacturing these products, the special handling and administration required, and an overall lack of competition in the marketplace. Currently, biologic manufacturers have 12 years of market exclusivity for innovator products. Innovator biologics also have additional patent protection that generally exceeds the market exclusivity period by a few years.

The Biologics Price Competition and Innovation Act (BPCIA), part of the Affordable Care Act, provided an expedited biosimilars approval pathway. In the case of biologics, biosimilar manufacturers do not have to show bioequivalence to the reference product. Instead, it needs to show that it is biosimilar; such products must be “highly similar to the reference product notwithstanding minor difference in clinically inactive components and exhibit “no clinically meaningful differences” in terms of safety, purity, and potency.”¹⁰ In order to meet the higher standard of interchangeability, the sponsor must demonstrate that the product “produces the same clinical result as the reference product in any given patient” and that switching between the reference biologic and the biosimilar does not result in additional risk in safety or efficacy for patients using only the reference biologic.¹¹ In March of this year, the FDA approved the first biosimilar in the United States, Zarxio, which is biosimilar to Neupogen (filgrastim).¹²

IMPACT ON HEALTH PLANS, PAYERS, PHYSICIANS AND PATIENTS

Health plans, payers, employers, physicians and patients are facing the increasing financial burden posed by prescription drugs, both brand name and generic. In the Medicare program, over the past eight years, Part D spending has seen an annual growth rate of approximately 6.5 percent, and amounted to \$78.1 billion in 2014.¹³ Under Medicare Part B, spending on covered prescription drugs was more than \$19 billion in 2013, with the drugs with the highest part B spending being biologics. Generic drugs accounted for 81 percent of all prescriptions filled in Part D in 2012.¹⁴ Medicare Parts B and D have also had to absorb the cost impact of the trend towards biologic products and specialty drugs. Specialty drug spending has been concentrated in conditions more prevalent in the Medicare population, including cancer, rheumatoid arthritis and multiple sclerosis. However, there has been a more limited use of specialty drugs among Part D beneficiaries thus far, as most plans have specialty tiers that require between 25 and 33 percent cost sharing. With the high reliance on generic drugs among Part D enrollees, the recent generic drug price increases can substantially impact the rate of growth in spending in Part D. In fact, the estimated average annual increase in spending for Part D is 10.9 percent over the next five years.¹³

Prescription drug costs are also consuming a greater share of Medicaid budgets, and state budgets overall. Under the Medicaid drug benefit, drug manufacturers pay rebates to states in return for Medicaid reimbursement for their prescription drugs. Drug manufacturers are required to pay an additional rebate amount if the average manufacturer price (AMP) for a brand-name drug rises faster than inflation. Medicaid spending on prescription drugs is projected to have increased by more than 23 percent in 2014.¹⁵ High growth in Medicaid drug spending is expected due to the increase in cost and utilization of specialty drugs; increases in enrollment; and fewer generic drugs entering the marketplace. Between 2010 and 2012, approximately one-quarter of total Medicaid drug spending before rebates was on specialty drugs, despite specialty drugs accounting for only two percent of total prescriptions. Overall, 28 percent of total Medicaid spending in 2012 was on specialty drugs.¹⁶ With the entrance of hepatitis C treatments including Solvaldi and Harvoni into the marketplace, specialty drugs are expected to consume a greater share of Medicaid budgets in future years.

Employer-sponsored health plans as well as health plans sold in the individual market have also had to absorb the higher costs of prescription drugs, which may translate to higher premiums, higher prescription drug cost-sharing, and additional prescription drug tiers to accommodate the higher costs of specialty and certain generic drugs. In 2014, 80 percent of employees were enrolled in plans with three, four or more cost-sharing tiers for prescription drugs.¹⁷ Like private health plans, Medicare Part D sponsors have started to move toward a five-tier formulary structure, placing higher-cost generics on a nonpreferred generic tier.

The higher costs of prescription drugs are expected in part to be passed down to health plan enrollees. Nonpreferred generic tiers in many cases have higher copayments than patients have become accustomed to for generic medications. In addition, plans with specialty drug cost-sharing tiers oftentimes require coinsurance amounts of 25 to 33 percent, versus requiring a fixed copayment. Considering the costs of many specialty medications, patients could quickly reach their deductibles and out-of-pocket maximums. The increased use and cost of specialty drugs in Medicare has the ability to cause the number of Part D enrollees who reach the out-of-pocket threshold to grow substantially, resulting in increases in Medicare spending for individual reinsurance and low-income cost sharing.

Increasing patient cost-sharing is associated with declines in medication adherence, which in turn can lead to poorer health outcomes.^{18,19,20} The higher costs of drugs and biologics can also impact the ability of physicians to place their patients on the best treatment regimen, due to the regimen being unaffordable for the patient, or being subject to coverage limitations and restrictions by the patient's health plan. In the worst-case scenario, patients entirely forego necessary treatments involving drugs and biologics due to their high cost.

The cost of drugs and biologics can also impact physicians participating in alternative payment models. For example, under the Oncology Care Model (OCM) developed by the Center for Medicare and Medicaid Innovation and starting in 2016, Medicare will continue to pay for Part B drugs administered within episodes of care at Average Sales Price plus six percent.²¹ However, bundled payment models also have the potential to pay physicians the same fee for drug administration regardless of the drugs administered to patients. Also, as providers under a bundled payment approach are paid a single payment amount for all services related to an episode of care, if the costs of care exceed the bundled payment, the providers assume financial liability. As such, if patients of physicians participating in shared savings models require higher cost drugs and biologics, the treating physicians may be portrayed as higher cost providers. The Council underscores that alternative payment models need to ensure that physicians and their patients can choose the drugs and biologics that are best for the individual patient. It is also important for physicians participating in alternative payment models to have the ability to change an episode's treatment regimen as new evidence on drug and biologic efficacy becomes available.

LEGISLATIVE ACTIVITY

There has been legislative activity on the state and federal levels addressing several of the factors contributing to the prices of generic and brand-name drugs, as well as biologics. On the state level, there have been bills introduced in states including California, Massachusetts, New York, North Carolina, Oregon and Pennsylvania to require prescription drug cost transparency. These bills propose to require pharmaceutical companies to disclose certain information, including development, manufacturing, marketing and advertising costs; a history of price increases; and the profit attributable to the drugs. Some state legislation would allow insurers and states to act on the information disclosed, ranging from allowing insurers to refuse to pay for a drug if its manufacturer did not file the required disclosure, to giving a state commission the authority to set a maximum price of a drug if the manufacturer's price was deemed to be too high after considering a range of factors.²² Legislation has also been introduced to cap the co-payments or coinsurance that patients could be required to pay for prescription drugs. In addition, state legislation has been introduced addressing state prescription drug discount programs, adverse drug tiering, as well as Medicaid and private insurer coverage of certain prescription drugs.

On the federal level, H.R. 6, the 21st Century Cures Act, sponsored by Representative Fred Upton (R-MI) passed the House of Representatives. H.R. 6, as passed in the House, would extend the marketing exclusivity period for drugs approved for a new indication that is a rare disease or condition, also known as orphan drugs, by six months. The bill also has provisions to support antibiotic drug development, and provide grants for studying continuous drug manufacturing. H.R. 6 would also make several revisions to the drug approval process, including allowing the FDA to expedite the development of certain drugs by relying upon data previously submitted for a different purpose, establishing a streamlined data review process for approving drugs for additional indications, and allowing patient experience data to be considered in the benefit-risk assessment of a new drug.

Patent reform legislation, including S. 1137, the PATENT Act and H.R. 9, the Innovation Act, has been introduced, which has the potential to impact pharmaceutical pricing practices as well as competition in the prescription drug marketplace. Perennial legislation has also been introduced on such topics as prescription drug price negotiation in Medicare and prescription drug importation.

The Obama administration, in its fiscal year 2016 budget proposal, also proposed shortening the market exclusivity period for biologics from 12 to seven years, which would require legislation. In addition, the budget included a proposal to stop companies from making anti-competitive deals intended to block or delay patient access to generic medications. The administration estimated that these proposals would save \$16 billion over 10 years.²³

AMA POLICY

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

- Work collaboratively with relevant federal and state agencies, policymakers and key stakeholders (e.g., the FDA, the US Federal Trade Commission [FTC], and the Generic Pharmaceutical Association) to identify and promote adoption of policies to address the already high and escalating costs of generic prescription drugs;
- Advocate with interested parties to support legislation to ensure fair and appropriate pricing of generic medications, and educate Congress about the adverse impact of generic prescription drug price increases on the health of our patients;
- Encourage the development of methods that increase choice and competition in the development and pricing of generic prescription drugs; and
- Support measures that increase price transparency for generic prescription drugs.

Policy H-110.998 urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. Policy D-110.993 states that our AMA will continue to meet with the Pharmaceutical Research and Manufacturers of America to engage in effective dialogue that urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. Policy H-110.992 states that the AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs. Policy H-110.997 supports programs to contain the rising costs of prescription drugs that meet certain criteria, and encourages physicians to consider prescribing the least expensive drug.

Policy H-155.962 opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services. However, AMA policy makes a departure from its market-based approach to pharmaceutical pricing in Policy D-330.954, which supports federal legislation that gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs. The policy also states that our AMA will work toward eliminating the Medicare prohibition on drug price negotiation.

Policies H-110.997 and H-110.996 support increasing physician awareness about the cost of drugs prescribed for their patients. Related, Policy H-125.979 supports physicians having accurate, real-time formulary data at the point of prescribing, as well as requiring insurance carriers making formulary information available to patients by October 1 of each year and forbidding insurers from making formulary deletions within the policy term. Policy H-110.990 supports physicians and patients being able to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions. The policy also states that cost-sharing requirements for prescription drugs should be based on considerations such as the unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance. Policy H-185.953 supports complete transparency of health care coverage policies related to specialty pharmaceuticals, including co-payment or co-insurance levels and how these levels are determined. Policy H-165.846 states that mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and lifetime benefit caps, and excluded services.

Policies H-100.980 and H-125.984 support a strong and adequately funded FDA to support effective drug approval processes. H-100.980 also states that our AMA will continue to work with the FDA on controversial issues concerning drugs, biologics and pharmaceuticals to try to resolve concerns of physicians. Policy D-110.994 states

that the AMA will continue to monitor the implementation of the newly enacted reforms to the Hatch-Waxman law to see if further refinements are needed that would prevent inappropriate extension of patent life of pharmaceuticals, and work accordingly with Congress and the Administration to ensure that AMA policy concerns are addressed. Policy H-125.978 states that our AMA will raise awareness among physicians of the strategy that could be used to limit the value to manufacturers of forced switching of brand formulations of prescription drugs; and advocate that the FDA and Congress ascertain the pervasiveness of this practice and advance solutions that strike an appropriate balance between innovation incentives and competition in order to support patient access to the newest treatments as well as those that are cost-effective. Policy H-110.989 supports the FTC in its efforts to stop “pay for delay” arrangements by pharmaceutical companies and federal legislation that makes tactics delaying conversion of medications to generic status, also known as “pay for delay,” illegal in the US.

DISCUSSION

The Council notes that AMA policy has long supported market-driven mechanisms to control pharmaceutical costs, as outlined in Policy H-155.962. However, policy also recognizes that improvements need to be made to ensure that the pharmaceutical marketplace operates efficiently and effectively, as evidenced in Policy H-110.989, which calls for making “pay-for-delay” agreements illegal, as well as Policy H-110.988, which encourages the development of methods that increase choice and competition in the development and pricing of generic prescription drugs. The Council believes that steps need to be taken to ensure that “evergreening” practices of brand-name drug manufacturers are not anticompetitive in nature. In that light, the AMA should encourage FTC actions to limit anticompetitive behavior by pharmaceutical companies attempting to ensure extended exclusivity for drugs and reduced competition from generic manufacturers through the filing of multiple patents on a single drug. Using controlled distribution channels for pharmaceuticals by limiting distribution through specialty pharmacies is sometimes necessary for reasons including safety considerations. However, the Council recognizes that controlled distribution can also be used to restrict patient access to a pharmaceutical, as well as limit market competition. As such, the AMA should also encourage Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.

Recent mergers and acquisitions in the pharmaceutical industry, especially in the generic drug industry, have reignited concerns that a consolidated pharmaceutical marketplace has the potential to increase drug prices. As such, the Council believes that our AMA needs to monitor pharmaceutical company mergers and acquisitions, as well as the impact of such actions on drug prices. In addition, patent reform continues to be a key area to monitor as policy-makers evaluate barriers to greater market-based competition. Brand and generic manufacturers are disputing whether the current statutory and regulatory framework for adjudicating patent disputes is adequate. Finally, while market exclusivity periods are important in ensuring pharmaceutical industry innovation, the 12-year exclusivity period currently enjoyed by biologics unduly delays entry of biosimilar competition in the marketplace. As such, the Council recommends that the market exclusivity period for biologics be shortened.

While AMA policy continues to promote market-based strategies to achieve the affordability of prescription drugs, policy also urges the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. The pricing of prescription drugs impacts state Medicaid budgets, Medicare spending, insurance premiums and prescription drugs tiers, and most importantly, patient access to these medications and medication adherence. To spur additional pricing restraint in the generic drug arena, the Council believes that generic drug manufacturers should be required to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation, as is currently required of brand-name drug manufacturers. The Council recognizes that the promotion of transparency in prescription drug pricing and costs will help patients, physicians and other stakeholders understand how drug and biologic manufacturers set prices. If there is greater understanding of the factors that contribute to prescription drug pricing, including the research, development, manufacturing, marketing and advertising costs borne by pharmaceutical companies, then the marketplace can react appropriately.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 207-I-14 and Resolution 228-I-14, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy H-155.962, which opposes the use of price controls in any segment of the health care industry, and continues to promote market-based strategies to achieve access to and affordability of health care goods and services.
2. That our AMA reaffirm Policy H-110.988, which supports efforts to ensure fair and appropriate pricing of generic medications.
3. That our AMA reaffirm Policy H-110.989, which supports the Federal Trade Commission (FTC) in its efforts to stop “pay for delay” arrangements by pharmaceutical companies and federal legislation that makes tactics delaying conversion of medications to generic status, also known as “pay for delay,” illegal in the United States.
4. That our AMA reaffirm Policy D-330.954, which states that our AMA will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs, and work toward eliminating Medicare prohibition on drug price negotiation.
5. That our AMA reaffirm Policy H-110.992, which states that our AMA will monitor the relationships between pharmaceutical benefits managers and the pharmaceutical industry and will strongly discourage arrangements that could cause a negative impact on the cost or availability of essential drugs.
6. That our AMA encourage Federal Trade Commission actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
7. That our AMA encourage Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
8. That our AMA monitor the impact of mergers and acquisitions in the pharmaceutical industry.
9. That our AMA continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
10. That our AMA encourage prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
11. That our AMA support legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
12. That our AMA support legislation to shorten the exclusivity period for biologics.
13. That our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
14. That our AMA generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.

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3. EMERGENCY PRESCRIPTION DRUG REFILLS (RESOLUTION 201-I-14)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 201-I-14
REMAINDER OF REPORT FILED**
See Policy H-120.933

At the 2014 Interim Meeting, the House of Delegates referred Resolution 201, “Short-Term Urgent Refills,” which was sponsored by the Indiana Delegation. Resolution 201-I-14 asked:

That our American Medical Association (AMA) develop a policy that short-term urgent refills should be allowed once a month for certain critical medications when authorization for refill is not readily available after hours, on weekends and on holidays, and that this recommendation be sent to the Food and Drug Administration and other vested parties, and ask that the same parties generate a list of critical medications qualifying for a short-term urgent refill; and

That our AMA generate model state legislation to allow short-term urgent refills for certain critical medications as often as once a month.

This report provides background on state laws addressing emergency refills of prescription drugs; highlights the issue of emergency dispensing of Schedule II controlled substances; summarizes relevant AMA policy; and presents policy recommendations.

BACKGROUND

Many states already permit emergency refills under their state pharmacy practice acts, thereby enabling pharmacists to dispense a certain quantity of a prescription drug on an emergency basis if in the pharmacist's professional judgment, the prescription drug is critical to continue a therapeutic regimen or otherwise maintain a patient's health status. Situations under which emergency refills may be permitted under state law include when a refill is immediately needed and the prescriber cannot be reached, and when prior authorization cannot be obtained in a timely manner by the patient's health insurance plan. Some state laws also specifically address emergency prescription drug refills in the event of a state of emergency.

According to the Centers for Disease Control and Prevention, 28 states and the District of Columbia require day or hour limits for prescription drugs dispensed on an emergency basis. Twenty-two states allow emergency dispensing when a prescription drug is needed but prior authorization required by a patient's health plan has not been obtained.¹ There is variation in the day and hour limits outlined in state law for emergency refills. For example, numerous states, including Alabama, Colorado, Florida, Kentucky, Louisiana, Mississippi, New Mexico, Rhode Island, Texas and Utah have laws authorizing pharmacists to dispense an emergency refill of up to a 72-hour supply of prescription medication if such dispensing meets all other parameters outlined in law.² Other states allow for larger supplies of emergency refills, ranging from a seven-day supply as provided for in Kansas law, to up to a 30-day supply of prescription medication as authorized in North Carolina law.³ However, the state laws of Delaware, Idaho and Montana do not specify a specific day or hour limit for emergency refills; their laws authorize pharmacists to dispense sufficient medication to maintain the prescribed treatment until prescriber authorization can be achieved.⁴

While some states do not differentiate in their laws concerning the emergency supply allowed as a result of a state of emergency versus an individual medical emergency, other states only allow emergency refills in a state of emergency, or authorize a larger emergency supply of a prescription drug in the context of a state of emergency or in the event of a natural or manmade disaster. In states including Florida and Texas, for example, while state law permits pharmacists to dispense emergency refills of up to a 72-hour supply, pharmacists can be authorized to dispense up to a 30-day emergency refill of a prescription drug in the event of a natural or manmade disaster, or when an emergency order or proclamation of a state of emergency is declared by the governor.⁵ The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy outline model rules for refill dispensing during a state of emergency issued pursuant to a public health emergency. The model rules state that a pharmacist may dispense a prescription drug refill of no greater than a 30-day supply without prescriber authorization if certain conditions are met. The rule also explicitly states that the practitioner and pharmacist shall not incur any liability resulting from such emergency dispensing.⁶

EMERGENCY DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES

Eleven states have laws permitting dispensing of prescription drugs on an emergency basis, with language that specifically excludes schedule II drugs.¹ Substances in schedule II, determined to have a high potential for abuse which may lead to severe psychological or physical dependence, include methodone; oxycodone; fentanyl; morphine; codeine; hydrocodone and methylphenidate.⁷ While refills for schedule II controlled substances are prohibited, there is a mechanism allowing for the emergency dispensing of schedule II controlled substances. In the case that a prescriber is not able to provide a written prescription, a prescriber may call in a schedule II prescription

to a pharmacist, who may then dispense the prescription. The prescriber must provide a written and signed prescription to the pharmacy within seven days and meet other outlined requirements in the law.⁸

RELEVANT AMA POLICY

Policy H-120.987 advocates notification by the American Pharmacists Association (APhA) of its members that prescriptions should be refilled only on the physician's order. Policy D-35.987 opposes federal and state legislation allowing pharmacists to independently prescribe or dispense prescription medication without a valid order by, or under the supervision of, a licensed doctor of medicine, osteopathy, dentistry or podiatry; and opposes federal and state legislation allowing pharmacists to dispense medication beyond the expiration of the original prescription.

To prevent the need for emergency refill requests, Policy D-120.984 states that the AMA will work with the APhA, the National Community Pharmacists Association, and the National Association of Chain Drug Stores to streamline the process for prescription refills in order to reduce administrative burdens on physicians and pharmacists and to improve patient safety. Policy H-120.952 encourages relevant organizations, including but not limited to insurance companies and professional pharmacy organizations, to develop a plan to implement prescription refill schedule strategies so that patients requiring multiple prescription medications may reduce the need for multiple renewal requests and travel barriers for prescription acquisition. Specifically addressing public health emergencies and disasters, Policy H-120.942 states that it is reasonable and prudent for patients with chronic medical conditions to maintain an emergency reserve of their prescription medications, and that patients with chronic medical conditions should discuss options with their physician for ensuring that they have an adequate supply of prescription medications in the event of a disaster or other potential emergency.

DISCUSSION

While many states already permit emergency refills under their state pharmacy practice acts, the Council believes that principles are needed to guide future legislation, regulations and protocols addressing emergency refills. The Council recognizes that mechanisms to allow for emergency refills of prescription medications are necessary to prevent the interruption of a therapeutic regimen, as well as patient suffering. However, only a minimum sufficient quantity should be dispensed as an emergency refill until authorization can be obtained from a prescriber, or in the case of prior authorization, a patient's health plan. However, larger emergency supplies of prescription medications may be needed following a natural or manmade disaster, when a state of emergency or emergency order is issued. If an emergency order or proclamation of a state of emergency is declared by a state's governor, an executive order can be used to allow pharmacists to dispense up to a 30-day supply of a prescription medication, or other amount as provided for under existing state law.

Emergency refills of prescription drugs should not be a regular occurrence. It is essential for the pharmacist to inform the patient or the patient's agent at the time of dispensing that the refill is being provided without the prescriber's authorization and that authorization of the prescriber is required for a future refill. In addition, the pharmacist should notify the patient or the patient's agent of any cost-sharing responsibilities prior to dispensing. Within 72 hours of dispensing, the pharmacist should notify the prescriber of the emergency refill. As emergency refills require pharmacists to dispense prescription medication without prescriber authorization, a prescriber should not be liable for any damages resulting from an emergency refill.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 201-I-14, and the remainder of the report be filed:

That our American Medical Association (AMA) advocate the following principles to guide the dispensing of emergency refills of prescription drugs:

- a) Emergency refills should only be authorized if, in the pharmacist's professional judgment, failure to refill the prescription might result in an important interruption of a therapeutic regimen that could cause patient harm.
- b) Emergency refills should only be dispensed if the pharmacy is unable to readily obtain refill authorization from the prescriber; prior authorization cannot be obtained in a timely manner from the patient's health

- plan; or when an emergency order or a proclamation of a state of emergency is declared by a state's governor.
- c) Schedule II controlled substances can be dispensed on an emergency basis as allowed under Drug Enforcement Administration protocol.
 - d) In general, the pharmacist may dispense a sufficient supply of the medication to maintain the prescribed treatment until prescriber authorization can be achieved.
 - e) If an emergency order or proclamation of a state of emergency is issued by a state's governor, an executive order may allow pharmacists to dispense up to a 30-day supply of a prescription drug, or other amount as provided for under existing state law.
 - f) The dispensing pharmacist should notify the prescriber of the emergency refill within 72 hours of dispensing.
 - g) Emergency refills should not be a regular occurrence.
 - h) The pharmacist should inform the patient or the patient's agent at the time of dispensing that the refill is being provided without the prescriber's authorization and that authorization of the prescriber is required for a future refill.
 - i) The pharmacist should notify the patient or the patient's agent of any cost-sharing responsibilities prior to dispensing.
 - j) A prescriber should not be subject to liability for any damages resulting from an emergency refill of a prescription drug by a pharmacist.

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4. PARITY OF PAYMENT FOR ADMINISTERING BIOLOGIC MEDICATIONS (RESOLUTION 218-I-14)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 218-I-14
REMAINDER OF REPORT FILED
*See Policies H-70.919, H-330.883 AND H-390.921***

At the 2014 Interim Meeting, the House of Delegates referred Resolution 218, "Parity of Payment for Administration of Medications within the Same Category of Drug," which was sponsored by the American College of Rheumatology, American Academy of Allergy, Asthma and Immunology, and the American Gastroenterological Association. Resolution 218-I-14 asked:

That our American Medical Association (AMA) use its influence and resources to secure Congressional outreach to the Centers for Medicare and Medicaid Services (CMS) with the objective that CMS issue guidance requiring parity of payment for administration of medications within the same category of drug.

This report provides background on the concerns raised in Resolution 218-I-14, explains Medicare's process for developing local and national coverage determinations (NCDs), outlines the development of current procedural

terminology (CPT[®]) codes for the administration of biologics, reviews CPT Editorial Panel activities, summarizes relevant AMA policy, discusses the appropriate avenue for addressing payments by Medicare for biologics, and provides policy recommendations.

BACKGROUND

Resolution 218-I-14 states that several Medicare Administrative Contractors (MACs) do not cover all biologics as complex injections or infusions when administered to patients with rheumatic diseases, while other MACs do. In separate communication with the Council, the resolution's sponsors assert that inconsistent payments by MACs for biologics result in geographic disparities in access to care and are seeking a NCD directing Medicare Administrative Contractors (MACs) to uniformly pay for all biologics for rheumatic conditions under the complex chemotherapy administration codes (96401-96549).

At the 2014 Interim Meeting, the reference committee recommended that Policy H-390.921 be reaffirmed in lieu of Resolution 218. Policy H-390.921 advocates for uniformity of business policies and procedures among MACs. While some testimony agreed that Policy H-390.921 addresses the concerns raised by Resolution 218-I-14, it was referred due in part to disagreement about whether all biologics could be considered equal with respect to administration and payment. Of additional concern is that the outcome of requesting CMS to review and possibly issue a NCD is uncertain. Payments for the administration of biologics could be uniformly increased or decreased.

MEDICARE ADMINISTRATIVE CONTRACTORS

Medicare uses an evidence-based process to make NCDs. If a national coverage policy does not exist or if there is a need to further define NCDs, MACs are responsible for developing local coverage determinations (LCDs). Since there is no national coverage policy for the administration of biologics to patients with rheumatic conditions, MACs have developed LCDs, resulting in inconsistent payments among MACs for these medications.

CODING AND PAYMENT FOR BIOLOGICS

In the AMA's 2015 CPT codebook, administration codes for biologics include three categories: hydration, therapeutic and chemotherapy.¹ These codes are intended to reflect differences in the physician work and other resources needed to administer biologics depending on the therapeutic need. Specifically, the CPT Editorial Panel has defined the differences in each category in terms of physician work, staff work and training, and patient risk. In general, the degree to which these factors impact the administration of biologics is less for hydration infusion services and progressively increases for therapeutic infusions and chemotherapy infusions. Preceding each category of infusions in the AMA's 2015 CPT[®] codebook, introductory text defines the physician work, staff training and work, and patient risk, to assist users in applying the codes. Therefore, payment is dependent on the factors impacting the administration of the infusion or injection and cannot be determined uniformly for a specific drug.

Current CPT codes for the administration of infusions and injections were developed by the CPT Editorial Panel in 2004. A CPT Editorial Panel Drug Infusion Workgroup (Workgroup), which included representatives from the sponsor organizations of Resolution 218-I-14, developed CPT code revisions and clarifications over the course of six years. During the Workgroup's May 2006 conference call, it was decided that a revision would be proposed to the CPT Editorial Panel for review by the specialties that chemotherapy administration guidelines in the CPT codebook should clarify the difference between the therapeutic injection codes and the chemotherapy administration codes. To make this distinction, the CPT Editorial Panel decided to add the word "certain" to the guidelines to convey that not all monoclonal antibodies, only certain ones, require use of the complex infusion administration codes.

The biologics identified in Resolution 218-I-14, Rituximab and Infliximab, are monoclonal antibodies that the resolution's sponsors have found to be considered complex injections or infusions by MACs, and therefore covered as such. Other monoclonal antibodies may not be considered complex if a MAC has made a determination that the infusion does not require complex services and instead belongs in the therapeutic infusion services category.

CPT EDITORIAL PANEL ACTIVITIES

Board of Trustees Report 10-A-07, “Development of a Drug Classification Advisory Panel,” considered the development of an AMA-sponsored drug classification advisory panel to facilitate appropriate use of CPT drug administration codes.² Through a feasibility study conducted by an outside consultant, it was determined that an AMA-sponsored drug classification advisory panel would present legal risk to the AMA, largely because the development of drug products is a high-stakes venture in which classification decisions potentially have million-dollar ramifications. Of specific concern was that a drug manufacturer could potentially seek judicial review if it does not agree with a classification decision.

Board Report 10-A-07 established Policy D-70.956, directing the AMA to ask the CPT Editorial Panel to develop educational material to assist users in the application of CPT drug administration codes. This directive was accomplished by the CPT Editorial Panel publishing numerous articles in the CPT Assistant Newsletter, a publication that provides in-depth information on how to code accurately and efficiently. Policy D-70.956 also directed the AMA to request the CPT Editorial Panel to consider revisions to the existing drug administration codes to add enhanced section and subsection headings, guidelines and parenthetical references, with the intention of assisting users in the application of the codes. The suggested revisions were made. The AMA continues to monitor the issue of drug classification within CPT drug administration code categories for physician billing and claims problems.

The AMA identifies the CPT Editorial Panel as the proper forum for addressing CPT codeset maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetical statements and modifiers (Policy H-70.919).

The AMA continues to support taking all appropriate measures, including meetings if necessary, to ensure that no CPT Editorial Panel updating process proceeds without providing for input from knowledgeable physicians and other stakeholders, including a cross-section of affected and related specialties, to allow these physicians to carefully review all changes suggested for inclusion in CPT prior to their acceptance (Policy H-70.998).

It is the policy of the AMA that the CPT Editorial Panel continue its policy of not making coding decisions that are influenced by economic or budgetary considerations. It is the responsibility of the AMA/Specialty Society Relative Value Scale Update Committee (RUC) to consider implementation issues such as economic factors when it recommends work values for new and revised CPT codes (Policy H-70.966).

ADDITIONAL RELEVANT AMA POLICY

The Council addressed payment for biologics and pharmacologic agents in its Report 3-I-08, “Payment for Biologics and Pharmacologic Agents,” which established policy supporting Medicare payments for drugs to fully cover the physician’s acquisition, inventory, carrying cost, administration and related services, and to be adequate to ensure continued patient access to biologic and pharmacologic agents³ (Policy D-330.960).

In accordance with Policy H-390.921, the AMA supports uniformity of business policies and procedures among MACs and monitors differences in payment to physicians by MACs. The AMA works to identify outdated coverage decisions that create obstacles to clinically appropriate patient care and advocates that NCDs and LCDs should reflect available scientific evidence and contemporary practice. The AMA encourages the Federation to report problems with MACs, or other Medicare contractors, to the AMA (Policy D-330.943).

DISCUSSION

The Council agrees with the concerns raised in Resolution 218-I-14 that access to care can be compromised if biologics for rheumatic diseases are not uniformly paid for by all MACs.

The Council notes, however, that the CPT codebook considers only certain biologics administered for rheumatic diseases to require the use of the chemotherapy administration codes. The Council suggests reaffirming Policy H-70.919, which directs interested stakeholders to use the CPT Editorial Panel process to request revisions in CPT codes, descriptors, guidelines, parenthetical statements and modifiers.

Submitting a request to CMS for a NCD that directs MACs to uniformly pay for all biologics used for rheumatic diseases under the complex chemotherapy administration codes, as requested by Resolution 218-I-14, is a formal process outlined in the notice issued by CMS concerning the revised process for making national coverage determinations.⁴ The request must clearly identify the statutorily defined benefit category to which the requester believes the service applies and contain enough information for Medicare to make a benefit category determination; be accompanied by sufficient, supporting evidentiary documentation; address relevance, usefulness or the medical benefits of the service to the Medicare population; and fully explain the design, purpose and method of using the service for which the request is made.⁵

The formal submission process requires detailed clinical and specialty-specific knowledge of the requested services, which the AMA cannot provide. Accordingly, the Council supports and encourages interested national medical specialty societies and other stakeholders to submit a request to Medicare for a NCD directing MACs to consider all biologics as complex injections or infusions for rheumatic conditions.

The Council also recommends reaffirming Policy H-390.921, indicating that the AMA supports uniformity of business policies and procedures among MACs.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 218-I-14 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-390.921, which advocates for uniformity of business policies and procedures among Medicare Administrative Contractors.
2. That our AMA reaffirm Policy H-70.919, which identifies the Current Procedural Terminology (CPT®) Editorial Panel process as the proper forum for the development of new and revised CPT codes, descriptors, guidelines, parenthetical statements and modifiers.
3. That our AMA support and encourage interested national medical specialty societies and other stakeholders to submit a request to Medicare for a national coverage determination directing Medicare Administrative Contractors to consider all biologics as complex injections or infusions.

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5. PHYSICIAN EMPLOYMENT TRENDS AND PRINCIPLES

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policies H-225.947 AND H-385.926

At the 2014 Interim Meeting, the House of Delegates adopted Resolution 607, which established Policy D-225.976 directing the American Medical Association (AMA) to examine the potential long-term effects of trends in

physician employment on patients and on the medical profession, and report back at the 2015 Interim Meeting. Policy D-225.976 specifies that the study should consider questions such as but not necessarily limited to:

- a) What factors have contributed most to increases in the proportion of physicians who are employed?
- b) How do employment and concomitant increases in rates of physician “turnover” affect continuity of care and patients’ perceptions that the physicians who treat them are dedicated to their long-term well-being?
- c) In what other ways might a physician’s employment status potentially affect the patient-physician relationship, and how might these effects, if problematic, be mitigated?
- d) How do increasing rates of employment affect the physician-hospital/health system relationship?
- e) How does employment affect physicians’ understanding of and will to engage in advocacy on issues that have historically been of significant importance to physicians, such as medical liability reform and physician reimbursement issues (e.g., SGR)? What effect will employment ultimately have on the collective voice of the medical profession?

The study directed in Policy D-225.976 was subsequently assigned to the Council on Medical Service. The literature often distinguishes between employment and independent practice, although independent practices can have both owner and employed physicians. The Council has focused this report on physicians employed by hospitals and health systems. This report provides background that speculates about physician employment and notes some incentives that drive physician employment opportunities; outlines extensive AMA activity to understand and improve physician employment; explores the questions posed in Policy D-225.976; summarizes relevant AMA policy; and provides policy recommendations.

BACKGROUND

There is widespread interest in physician practice choices, fueled by research that predicts a widespread trend toward physician employment and the purchase of physician practices by hospitals and health systems.¹

The AMA’s 2014 Physician Practice Benchmark Survey² (Benchmark Survey), which is a nationally representative sample of non-federal physicians who provide care to patients at least 20 hours per week, involves periodic censuses of physician practice. It confirms a shift toward hospital employment of physicians, but finds that this shift may not be as large as some articles have suggested. The 2014 survey found that 26 percent of physicians worked in practices that were at least partially owned by a hospital and another seven percent were directly employed by a hospital. In contrast, 57 percent of physicians worked in practices that were wholly owned by physicians. The Benchmark Survey has also asked about ownership and employee status and practice type. The percent of physicians who are owners of their practices declined from 76.1 percent in 1983 to 50.8 percent in 2014. Also in 2014, 43 percent of physicians were practice employees and 6.2 percent were practice contractors. The Benchmark Survey finds younger and female physicians more likely to be employed by their practice than older and male physicians.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), was signed into law on April 16, 2015. This bipartisan legislation permanently repealed the sustainable growth rate (SGR) formula and provides positive updates for Medicare payments for physician services from July 1, 2015, through the end of 2019, and again in 2026 and beyond. The legislation, like the Affordable Care Act (ACA), includes incentives to work in accountable teams, which in turn may encourage physician employment with hospitals and health systems, including insurers. The goals of accountable care organizations and other forms of team-based care are to provide better value by coordinating care and improving quality. AMA resources for physicians who are navigating these new delivery models are available online.³

AMA ACTIVITY

The AMA supports the ability of physicians to choose their mode of practice. The aforementioned AMA Benchmark Survey provides an evidence base for AMA activity. In addition, more recently, the AMA has partnered with RAND Corporation to study physician professional satisfaction. In addition, the AMA has numerous resources to help employed physicians and those considering employment by hospitals or other corporations to preserve independent decision-making, avoid conflicts of interest and protect patient relationships.

In 2013, the AMA and RAND studied professional satisfaction and found that physicians in physician-owned practices were more satisfied than physicians in other ownership models (e.g., hospital or corporate).⁴ Work controls

and opportunities to participate in strategic decisions were found to mediate the effect of practice ownership on overall professional satisfaction. In 2015, the AMA and RAND collaborated again to focus on the effects of health care payment models on physician practices.⁵

The AMA and the American Hospital Association (AHA) held a joint leadership conference in October 2013 on new models of care to initiate discussions about integrating the administrative and clinical aspects of health care delivery. The conference, which was the first formal meeting between these two organizations in more than 35 years, was an opportunity to better understand how physicians and hospitals interact and the ways in which they can become more collaborative. Conversations centered on the need for greater physician-hospital collaboration to move toward a reformed system and to achieve the Triple Aim of better health, better health care and lower costs. These discussions laid the foundation for identifying solutions to aid physicians and hospital executives in working together and in adapting to an ever changing health care environment, including financial, cultural and operational changes. In 2015, the AMA and AHA jointly released “Integrated Leadership for Hospitals and Health Systems: Principles for Success”.⁶ These principles provide a guiding framework for physicians and hospitals that choose to create an integrated leadership structure but are unsure how to best achieve the engagement and alignment necessary to collaboratively prioritize patient care and resource management.

As more physicians became employed by hospitals and health systems, the AMA developed the Annotated Model Physician-Hospital Employment Agreement and the Annotated Model Physician-Group Practice Employment Agreement⁷ to assist in the negotiation of employment contracts. AMA Principles for Physician Employment (Policy H-225.950) address some of the more complex issues related to employer-employee relationships. Conflicts of interest, advocacy for patients and hospital/medical staff relations are some of the topics addressed in these principles. Further guidance on conflicts of interest can also be found in Conflict of Interest Guidelines for Organized Medical Staffs and the AMA *Code of Medical Ethics*.

The AMA is developing a leadership program for physicians regardless of career stage or practice setting. Under development in 2015, the program will aim to prepare physicians to lead successfully and to manage in a strategic and efficient manner, with the goal of creating a better health care system for patients and physicians alike.

LONG TERM EFFECTS OF PHYSICIAN EMPLOYMENT

Policy D-225.976 specified five questions to include in the study the potential long-term effects of trends in physician employment on patients and on the medical profession. Accordingly, the Council identified and reviewed available data related to the questions and found a paucity of data.

- a) What factors have contributed most to increases in the proportion of physicians who are employed?

The AMA Benchmark Survey queried physicians about their motivations for recent hospital ownership and found that, among physicians in hospital-owned practices where the practice was acquired in 2005 or later, “improve practice financial stability” was listed as a very important motivator by 59 percent of respondents, and “prepare for payment and delivery reform” was indicated by 43 percent of respondents. In comparison to 2012, 2014 data showed an increased mention of being approached by a hospital (41 percent) and the desire to better implement HIT (35 percent) as very important motivators. Additional motivators included: “achieve a better work/life balance” (31 percent); “improve quality of care” (24 percent); “improve clinical care coordination” (23 percent); and “access to more patients” (21 percent).

Results from the 2015 AMA-RAND study on the effects of health care payment models on physician practice identified similar factors contributing to practice mergers and hospital ownership: the need for capital investment under new payment models; seeking improved negotiating positions with health plans; and the perception of a greater sense of security in changing or unfamiliar payment models.

- b) How do employment and concomitant increases in rates of physician “turnover” affect continuity of care and patients’ perceptions that the physicians who treat them are dedicated to their long-term well-being?

Empirical findings delineating these effects on continuity and patient well-being could not be located. A report under development by the AMA Council on Ethical and Judicial Affairs (CEJA) has begun looking at the

challenges of providing continuity of care in complex health systems, which may identify effects on the patient experience of, for example, seeing different providers at each visit.

- c) In what other ways might a physician's employment status potentially affect the patient-physician relationship, and how might these effects, if problematic, be mitigated?

The Council is well aware of longstanding concerns among physicians about preserving professional autonomy under employment models and the rippling effects that limited autonomy could have on their patients. The forthcoming CEJA report may provide insights on this question as well.

- d) How do increasing rates of employment affect the physician-hospital/health system relationship?

Although studies delineating this relationship could not be located, the AMA and AHA are currently developing guidance on collaborations and partnerships between physicians and hospital or health system executives, including key attributes that would foster successful, integrated leadership. Physician and hospital integrated leadership supports a change in the management structure of hospitals and health systems by having more physicians in the boardroom and in key roles at the executive level so hospitals can succeed in the reformed models for health care delivery and payment.

- e) How does employment affect physicians' understanding of and will to engage in advocacy on issues that have historically been of significant importance to physicians, such as medical liability reform and physician reimbursement issues (e.g., SGR)? What effect will employment ultimately have on the collective voice of the medical profession?

Data regarding the effect of employment on physicians' understanding of and willingness to engage in advocacy, could not be found. However, AMA Policy H-225.950[2] asserts that employed physicians should be free to engage in volunteer work outside of, and which does not interfere with, their duties as employees.

AMA POLICY

The AMA has substantial policy on physician employment. Policy H-385.926[2] affirms AMA support for the freedom of physicians to choose their method of earning a living. Policy D-225.977 directs the AMA to continue to assess the needs of employed physicians, ensuring autonomy in clinical decision-making and self-governance; and promote physician collaboration, teamwork, partnership, and leadership in emerging health care organizational structures, including but not limited to hospitals, health care systems, medical groups, insurance company networks and accountable care organizations. Furthermore, Policy H-285.954 states that certain professional decisions critical to high quality patient care should always be the ultimate responsibility of the physician regardless of the practice setting. Policy H-285.910 endorses the insertion into physician employment agreements of language guaranteeing physician independence.

The inviolability of the patient-physician relationship is a recurrent theme throughout the AMA *Code of Medical Ethics*. Opinion 8.131 in the *Code of Medical Ethics* states that physicians in leadership positions within health care organizations have an ethical responsibility to ensure that practices for financing and organizing the delivery of care recognize physicians' primary obligation to their patients. It is also the policy of the AMA to strongly condemn any interference by outside parties that causes a physician to compromise his or her medical judgment (Policy H-5.989). Policies H-285.910 and H-285.951 promote independent patient advocacy as fundamental to the patient-physician relationship and thereby free from interference.

AMA Principles for Physician Employment (Policy H-225.950) are intended to help physicians, those who employ physicians, and their respective advisors identify and address some of the unique challenges employment presents to professionalism and the practice of medicine. Conflicts of interest are addressed in these principles, which make clear that patient welfare must always take priority over an employer's economic interests.

The AMA has also established policy addressing payment variations across outpatient sites of service, most recently through the adoption of the recommendations contained in Council on Medical Service Report 3-A-13 (Policy D-240.994), which advocated equal or lower coinsurance for lower-cost sites of service; and Council on Medical Service Report 4-A-14, which modified Policy H-330.925 to advocate that CMS use the hospital market basket

index to annually update ambulatory surgical center payment rates, rather than the Consumer Price Index for all Urban Consumers. Based on the policy established with these reports, an advocacy briefing document entitled “Payment variations across outpatient sites of service” was that can be downloaded from the Council’s website: ama-assn.org/go/cms.

The AMA has equally strong policy on organized medical staff affairs (e.g.: Policies H-235.963, H-235.990, H-235.992, H-235.999), including a physician’s right to exercise independent judgment in all matters regarding patient care, the profession, health care in the community and medical staff matters, and to incorporate the independent exercise of medical judgment into physician employment and contracting agreements (Policy D-225.978). Policy H-225.957 outlines principles for strengthening physician-hospital relationships. Finally, AMA Policy H-285.983 supports the establishment of self-governing medical staffs in other health care delivery systems, similar to those that exist in hospitals.

DISCUSSION

The Council concurs with the premise of Resolution 607-I-14, the genesis of Policy D-225.976, which expresses caution regarding the unknown consequences of physician employment. The preamble of Resolution 607-I-14 acknowledges that increased employment among physicians is a result of their choosing to do so. The Council recommends reaffirming Policy H-385.926[2], which supports the freedom of physicians to choose their method of earning a living,

In this report, the Council has summarized a variety of AMA resources that aim to help employed physicians and those considering employment by hospitals or other corporations to preserve independent decision-making, avoid conflicts of interest and protect patient relationships.

For those physicians who choose employment with a hospital or health system, the Council recommends a series of guiding principles regarding characteristics of the employment arrangement. The recommended principles reflect the joint AMA/AHA document “Integrated Leadership for Hospitals and Health Systems: Principles for Success.”

In its examination of the enumerated effects of long-term employment provided by Policy D-225.976, the Council found a lack of empirical data and published research. The delivery reforms promoted by the ACA and MACRA are likely to influence the ways hospitals and physicians work together in the future. The Council believes that these alternative models of payment and delivery provide a natural experiment and a rich body of data that should continue to be studied for their effects on patients and the medical profession. Acknowledging the ongoing changes in physician employment, the Council looks forward to data on emerging models (e.g., physician cooperatives, independent physician associations, and specialty-specific physician practice management companies).

Finally, the Council recommends rescinding Policy D-225.976, which calls for the study that has been accomplished by development of this report. Acknowledging the rapid emergence of payment and delivery innovations, the Council will continue to study new models.

RECOMMENDATIONS

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

1. That our American Medical Association (AMA) reaffirm Policy H-385.926[2], which supports the freedom of physicians to choose their method of earning a living.
2. That our AMA encourage physicians who seek employment as their mode of practice to strive for employment arrangements consistent with the following principles:
 - a. Physician clinical autonomy is preserved.
 - b. Physicians are included and actively involved in integrated leadership opportunities.
 - c. Physicians are encouraged and guaranteed the ability to organize under a formal self-governance and management structure.
 - d. Physicians are encouraged and expected to work with others to deliver effective, efficient and appropriate care.

- e. A mechanism is provided for the open and transparent sharing of clinical and business information by all parties to improve care.
 - f. A clinical information system infrastructure exists that allows capture and reporting of key clinical quality and efficiency performance data for all participants and accountability across the system to those measures.
3. That our AMA encourage continued research on the effects of integrated health care delivery models (that employ physicians) on patients and the medical profession.
 4. That our AMA rescind Policy D-225.976, which requested this report.

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6. HEARING AID COVERAGE (RESOLUTIONS 812-I-14 AND 817-I-14)

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTIONS 812-I-14 AND 817-I-14 REMAINDER OF REPORT FILED

See Policies H-165.846, H-185.929 and H-245.970

At the 2014 Interim Meeting, the House of Delegates referred two resolutions addressing hearing aid coverage. Resolution 812-I-14, “Health Plan Coverage for Hearing Aid Devices,” which was introduced by the American Academy of Pediatrics, asked:

That our American Medical Association (AMA) support state advocacy efforts that would mandate universal health plan coverage of hearing aid devices to patients with hearing loss, regardless of age, to help them realize the potential benefits from appropriate amplification that is properly fit, adjusted and used as part of a comprehensive intervention plan. Coverage should also recognize the need for replacement of hearing aids due to maturation, change in hearing ability, and normal wear and tear.

Resolution 817-I-14, “Medicare Coverage of Hearing Aids,” which was introduced by the Florida Delegation, asked:

That our AMA support Medicare coverage of hearing aid devices, including external and implantable hearing aid devices.

The Board of Trustees assigned these resolutions to the Council on Medical Service for report back to the House of Delegates at the 2015 Interim Meeting. This report provides background on hearing loss and hearing aid coverage for people of all ages; summarizes relevant AMA policy; and makes policy recommendations.

BACKGROUND

Hearing loss can occur at any age, although its prevalence increases exponentially with age. According to statistics compiled by the National Institute on Deafness and Other Communication Disorders, two to three of every 1,000 children in the US are born with a detectable level of hearing loss. Approximately 15 percent of adults aged 18 and over, or 37.5 million Americans, report some degree of hearing loss. Disabling hearing loss is experienced by two percent of adults aged 45 to 54, 8.5 percent of adults aged 55-64, nearly a quarter of adults aged 65 to 74, and half of adults who are 75 and older.¹

Hearing loss reduces a person's sound awareness and ability to listen and understand speech, and can diminish one's quality of life. Among older adults, empirical studies have identified associations between hearing loss and frailty, lower levels of physical activity, social isolation, depression, health care expenditures and even earlier mortality.²

Hearing aids are amplifying devices that compensate for mild to profound hearing loss experienced by people of all ages. They range in price from hundreds to several thousand dollars; the average cost is estimated to be about \$2,500. Out-of-pocket expenses for a pair of hearing aids (most people experience hearing loss in both ears) ranges from about \$4,000 to \$6,000, a considerable expense that is not covered by Medicare or most insurance plans and that is beyond the means of many patients who could benefit from them.

Children's Coverage

Hearing loss profoundly affects the social development of children, their ability to communicate and their speech development. The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program, which is the child health component under Medicaid, requires hearing aid coverage for children up to age 21. The EPSDT benefit is more robust than the Medicaid benefit for adults and is designed to assure that hearing loss is detected and treated in children as early as possible. That being said, several barriers limit children's access to hearing aid devices under Medicaid, including low payment rates and limited availability of pediatric hearing health professionals in some areas.

According to the American Academy of Pediatrics, 20 states have health insurance mandates requiring some private health plan coverage for hearing aids for children. However, the type of coverage varies by criteria such as ages covered, coverage amounts and benefit period. For example, Colorado requires insurance carriers to cover hearing aids for children under 18 when medically necessary, and must include new hearing aids at least every five years, whereas Connecticut requires coverage for children up to age 12 and allows policies to limit the benefit to \$1,000 every two years.³

A recent study on the Affordable Care Act's pediatric essential health benefit (EHB) found that 24 states include hearing aid coverage for children.⁴ EHBs provide coverage standards for non-grandfathered health plans sold in individual and small-group markets, including plans sold via state health insurance marketplaces. Under federal regulations, pediatric EHBs must include oral health care and vision coverage. States may add hearing aid coverage to their pediatric benchmark plans but it is not a federal requirement.

Early intervention through the Individuals with Disabilities Education Act (IDEA) also provides coverage for certain costs associated with audiology services and hearing devices for children. These services are provided through local school districts or health departments, depending on the state, and vary with regard to degrees of hearing loss required to obtain assistance under the program.

Adult Coverage

According to the Hearing Loss Association of America, approximately 20 state Medicaid programs provide coverage of hearing aids and related services.⁵ Coverage in some states is quite limited with additional barriers such as prior authorization requirements and low Medicaid payment rates.

The US Department of Veterans Affairs provides hearing aids and related services to qualified military veterans and is the country's largest purchaser of hearing aids. In 2013, the VA purchased 617,000 hearing aids, or about 20 percent of the US market.⁶

Few private insurance plans cover hearing aids for adults, and among those that do, most coverage is limited. The American Speech-Language-Hearing Association lists 20 states that currently require health care plans to include some payment for hearing aids. Most of these mandate coverage for children, and only three states—Arkansas, New Hampshire and Rhode Island—require insurers to provide hearing aid coverage to adults.⁷

Private insurance policies that provide coverage of hearing aids typically only cover a portion of the cost. For example, a health plan may pay a specified amount—such as \$500 or \$1,000—toward a hearing aid purchase, or the plan may provide discounts with contracted hearing aid providers. In addition, private health plans may offer hearing-aid coverage riders on their policies for an additional premium cost to members who select the rider option. Those who enroll in a rider are generally given discounts on hearing aids and batteries for themselves and covered family members under specific parameters as described in the rider, such as contracted vendors where devices must be purchased.

Medicare

Medicare's Initial Preventive Physical Examination, also known as the "Welcome to Medicare Preventive Visit" requires physicians to review the patient's functional ability and level of safety. As part of this once-per-lifetime visit, physicians are directed to use appropriate screenings that are recognized by national professional medical associations to review certain functional areas, including hearing impairment. However, Section 1862(a)(7) of the Social Security Act explicitly excludes hearing aids and related exams from Medicare coverage.⁸ A diagnostic hearing exam ordered because of recent illness or injury may be covered by Medicare Part B, but if a hearing aid is prescribed during such an exam, it is not covered. Some Medicare Advantage (Part C) plans cover hearing exams and hearing aids, although this coverage varies and may not be available in all areas.

Certain prosthetic devices that are indicated for patients who cannot use or do not benefit from hearing aids—such as cochlear implants, auditory brainstem implants and osseointegrated implants—are covered by Medicare. However, the primary treatment for most hearing loss, which is a properly fitted hearing aid, is prohibited by law from being paid for by Medicare. The Medicare Hearing Aid Coverage Act of 2015 would remove the provisions in the Social Security Act that prohibit Medicare from covering hearing aids.

RELEVANT AMA POLICY

AMA policy supports hearing aid coverage for children via Policy H-165.846[2], which advocates that the EPSDT program be used as the model for any essential health benefits package for children. Policy H-245.970 supports early hearing detection and intervention for infants, and supports federal legislation that provides statewide programs for hearing screening of newborns and infants, prompt evaluation and diagnosis of children referred from screening programs, and appropriate interventions and follow-up for children with hearing loss.

However, Policy H-185.964 opposes new health benefit mandates unrelated to patient protections, which jeopardize coverage to currently insured populations. Similarly, under Policy H-165.856, the AMA supports the principle that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options.

AMA policy is silent with regard to adult and Medicare coverage of hearing aids.

DISCUSSION

The Council recognizes that access to hearing aids by people with hearing loss improves health outcomes, and that a lack of access to these devices can adversely impact the quality of life of people of all ages. In its recommendations, the Council seeks to balance the value of hearing aid coverage with concerns over costs and new benefit mandates.

The Council is particularly concerned that many children with hearing loss may not receive hearing aids and appropriate related services due to a lack of coverage or limitations on existing coverage under the patchwork of

public and private insurance mandates described in this report. Accordingly, the Council recommends reaffirmation of Policies H-245.970 and H-165.846. Consistent with these policies, and to further minimize negative outcomes on children with hearing loss who would benefit from hearing aid devices but lack adequate coverage, the Council suggests adopting new policy that explicitly affirms the AMA's support for children's hearing aid coverage. The Council recommends that the AMA support public and private health insurance coverage that provides all infants and children with hearing loss access to appropriate hearing health professionals, services and devices, including digital hearing aids. The Council further recommends that this coverage should, at minimum, recognize the need for replacement of hearing aids due to maturation, change in hearing ability and normal wear and tear.

With regard to adult coverage, the Council considered whether AMA support for state benefit mandates would conflict with existing AMA policy that generally opposes new benefit mandates and supports the minimization of new benefit mandates. The Council concluded that a recommendation supporting adult hearing aid coverage mandates would conflict with Policies H-185.964 and Policy H-165.856. In an effort to increase access to hearing aids and related services among adults with hearing loss, the Council recommends encouraging private health plans to offer optional riders allowing their members to add hearing benefits to existing policies which offset the costs of hearing aid purchases, hearing-related exams and related services. Regarding Medicare, the Council notes that Medicare managed care plans (Part C) are private plans that could offer riders.

The Council also discussed whether to recommend that the AMA support Medicare coverage or partial coverage of hearing aids and related services. Prevalence of hearing loss increases with age, and the incidence of hearing loss among Medicare patients is expected to increase exponentially in the coming years. The Medicare population is projected to increase from 55 million enrollees today to over 81 million people by 2030 as baby boomers age into the program.⁹ The cost of hearing aid coverage for several million eligible enrollees would be considerable. The Council is mindful that the goal of the Medicare program is to ensure patient access to high-quality services while encouraging efficient use of government resources. The Council also notes that supplemental insurance and Medicare Advantage plans, which pay for some hearing aid expenses, are available to a subset of Medicare patients with hearing loss. For these reasons, the Council does not recommend that the AMA support Medicare coverage of hearing aids.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolutions 812-I-14 and 817-I-14, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy H-245.970, which supports early hearing detection and intervention to ensure that all infants receive proper hearing screening, diagnostic evaluation, intervention and follow-up in a timely manner.
2. That our AMA reaffirm Policy H-165.846, which advocates that the Early Periodic Screening, Diagnostic, and Treatment (EPSDT) program be used as the model for any essential health benefits package for children.
3. That our AMA support public and private health insurance coverage that provides all hearing-impaired infants and children access to appropriate physician-led teams and hearing services and devices, including digital hearing aids.
4. That our AMA support hearing aid coverage for children that, at minimum, recognizes the need for replacement of hearing aids due to maturation, change in hearing ability and normal wear and tear.
5. That our AMA encourage private health plans to offer optional riders that allow their members to add hearing benefits to existing policies to offset the costs of hearing aid purchases, hearing-related exams and related services.
6. That our AMA support coverage of hearing tests administered by a physician or physician-led team as part of Medicare's benefit.

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7. INCORPORATING COMMUNITY HEALTH WORKERS INTO THE US HEALTH CARE SYSTEM (RESOLUTION 805-I-14)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 805-I-14
REMAINDER OF REPORT FILED
*See Policies H-373.994 and H-440.828***

At the American Medical Association's (AMA) 2014 Interim Meeting, the House of Delegates referred Resolution 805, "Incorporating Community Health Workers into the US Health Care System," submitted by the AMA Medical Student Section. Resolution 805-I-14 asked "that the AMA: 1) encourage the incorporation of community health workers into the US health care system and support legislation that integrates community health workers into care delivery models especially in communities of economically disadvantaged, rural, and minority populations; and 2) support appropriate stakeholders to define community health workers in order to define their required level of training and scope of practice and to legitimize their role as health care providers." The Board of Trustees referred this issue to the Council on Medical Service (CMS) for a report back to the House at the 2015 Interim Meeting.

The following report discusses the diverse roles that community health workers assume in the community and broader health care system, provides examples of community health worker programs and ethical guidelines, outlines the current funding structure of community health worker programs, and recommends policy to help define the appropriate role of community health workers as part of a patient's health care team.

BACKGROUND

Community health workers (CHWs) are known as peer advocates, community health representatives, and patient navigators, among many terms, and are broadly defined as "community members who work almost exclusively in community settings and who serve as connectors between health care consumers and providers to promote health among groups that have traditionally lacked access to adequate health care."¹ The Council is defining CHWs as public health workers serving as intermediaries between health services and the community. This definition encompasses non-clinical workers serving the community including those serving as patient navigators. The scope of CHWs varies greatly depending on the sector and state in which they work. CHWs are uniquely qualified as intermediaries between the populations they serve and the health care system, because they live in, and speak the language of the community, and recognize and understand cultural issues. CHW expertise is based on shared life experiences with those they serve. The community health worker model has its origins in antipoverty programs and

in efforts to address health care disparities and improve health outcomes among underserved populations. Since the 1960s, CHWs have helped patients navigate the health care system by decreasing socioeconomic barriers to care. The US recently has seen increased attention to these non-traditional health care workers and their potential value due to evidence that some interventions involving CHWs have produced positive outcomes for management of diabetes, hypertension, asthma, cancer, and HIV/AIDS.

In 2002, the Institute of Medicine (IOM) recognized that CHWs offer promise as a resource to increase racial and ethnic minorities' access to care while liaising between health care providers and the community.² Subsequently, in 2010, both the US Department of Labor (DOL) and the Affordable Care Act (ACA) expressly recognized both patient navigators and the broader profession of CHWs.³ The DOL created a unique occupational code for CHWs, and the ACA identified CHWs as members of the health care workforce who may be used to provide outreach, promote positive health behaviors, and guide underserved populations to appropriate health care resources. The ACA authorized the Centers for Disease Control and Prevention (CDC) to issue grants to organizations utilizing CHWs although Congress never appropriated funding for the grants.

CURRENT ROLE OF COMMUNITY HEALTH WORKERS

Consistent with the ACA's emphasis on community-based prevention, health care teams, and the growing recognition of disparities in health outcomes across ethnic groups, CHWs represent a developing resource to assist in providing care that is accessible and culturally competent. Literature generally recognizes seven core roles of CHWs: those promoting cultural mediation between communities and the health care system; those providing culturally appropriate and accessible health education and information; those ensuring that people get the services they need; those providing informal counseling and social support; those advocating for individuals and communities; those providing direct services and administering health screening tests; and those building individual and community capacity.⁴ These categories are not mutually exclusive, and many CHW programs exhibit a number of these core values, which continue to guide the field.

Hundreds of programs across the country utilize CHWs in a variety of ways, and, when providing services as an integrated member of the primary health care team, CHWs can have a positive effect on the health outcomes of patients.⁵ CHWs serve as intermediaries between clinical services and the community. The information CHWs gather about patients' health status and unique socioeconomic barriers to health are relayed to the health care team to tailor the patient's care plan.

The Mississippi Delta Health Collaborative (MDHC), a state Department of Health initiative, aims to provide leadership and guidance in the Delta region to improve the population's cardiovascular health by using CHWs.⁶ All CHWs in the program are from the Delta region, are state health department employees, and receive initial and ongoing competency and clinic-based training. MDHC's CHWs are integrated into and receive referrals of patients with elevated blood pressure from various sites such as health care providers at federally qualified health centers (FQHCs) and rural clinics.⁷ CHWs follow an approach intended to establish and maintain links to the health care system and maintain adherence to treatment protocol. CHWs help physicians with care coordination by conducting home visits to monitor cardiovascular risk factors, helping patients schedule appointments, and linking patients with transportation services to access health care.

A University of Pennsylvania Medicine program at two clinics incorporates CHWs into the primary care team to improve the health of vulnerable patients dealing with chronic conditions.⁸ The CHWs are part of the Individualized Management for Patient-Centered Targets (IMPACT) program where trained CHWs provide social support and health care system navigation assistance to socioeconomically vulnerable patients. At the clinic, patients dealing with chronic conditions discuss a specific health goal with their primary care provider, and CHWs help the patient carry out that goal. Over a six-month time frame, patients work with a CHW to create a plan to achieve the goal. Goals may include addressing food insecurity, economic issues like affording basic utilities, creating a plan to increase medication adherence, or addressing addiction. The framework allows for patients to receive holistic care and empower the patient to follow-through on their care plans by addressing barriers to health that may be non-medical.

As part of the CDC Division of Diabetes Translation, the CDC partnered with Marshall University to create the Appalachian Diabetes Control and Translation Project (ADCTP), which is aimed at reducing the impact of diabetes on people living in high-risk counties in the Appalachian Region.⁹ As part of the ADCTP, groups of CHWs

throughout the Appalachian Region are developing partnerships and collaborating with community organizations to develop ways to promote healthier lifestyles and increase prevention efforts. The ADCTP specifically targets economically distressed adult populations disproportionately affected by type 2 diabetes.¹⁰ CHW-led projects include education on healthy eating and exercise habits, health fairs, and support groups. CHWs also provide instruction to patients on diabetes self-management.

FUNDING

While some CHWs are volunteers, the majority of CHW programs rely on paid CHW positions.¹¹ Because the profession lacks broad recognition and acceptance, there is difficulty establishing and maintaining CHW program funds. Current CHW program funding sources vary and many are mixed. About two-thirds of all CHW programs use multiple funding streams from a combination of both public and private sources.¹² Generally, funding sources are grouped into one of three categories: time-limited grants, state and local funds, and public or private insurance.

Time-Limited Grants

Most programs rely, at least in part, on time-limited grants. Time-limited grants may be as short as a year or as long as three years, and come from sources like private foundations and government agencies. Many grant programs target a specific condition or population, such as asthmatic children in an underserved community. While there is relative availability of grants, most are not renewable, so CHW programs are at high risk of disruption and termination when the grant terminates.

State and Local Funds

CHW programs funded through state and local funds are allocated each budget cycle and make funding of CHWs directly available.¹³ Under this model, the funds may either pay CHW salaries directly or be designated to an organization that administers the program. Of course, the nature of these funds makes them susceptible to budget restrictions and cuts. Additionally, such funding is highly dependent on each state and locality's budget and political situation.

Private or Public Insurance

Both private and public insurance have played a role in the funding of CHW positions.¹⁴ Insurance plans may fund CHW positions in a number of ways either through direct reimbursement, indirect payment, or capitation. Some health plans are paying CHWs via capitation as part of the health care team. Public insurance such as Medicaid has been used by a number of states to fund their CHW programs and has emerged as relatively stable since it accesses an existing health care financing mechanism. Medicaid managed care organizations may use capitated payments to employ CHWs or organizations such as federally qualified health centers can be reimbursed for Medicaid administrative costs performed by CHWs.¹⁵ Also, Medicaid Section 1115 waivers permit states to implement demonstration projects to further the goals of Medicaid, and a number of states have utilized section 1115 waivers as a means of financing their CHW initiatives.¹⁶

COMMUNITY HEALTH WORKERS PROGRAMS AND STANDARDS

The community health worker's role varies considerably and depends on the sector in which they work. The skills and competencies for a CHW working to promote nutrition and immunization differ from those of a CHW working to connect patients with clinical services. Because each community's needs differ and the skills required for any particular CHW program vary, it is a challenge developing standardized training or certification. A 2002 IOM report identified barriers to the effective use of CHWs in multidisciplinary health care teams including inconsistent CHW scope of practice, training, and qualifications.¹⁷

As the role of CHWs in the health care system increases, so too does interest in formalizing and standardizing workforce training requirements. Five states have laws or regulations establishing a certification program, seven states have no law but have established a state-led training or certification program, while others have remained silent on the issue altogether leaving requisite training or certification requirements the responsibility of the CHW program.¹⁸

Texas enacted legislation requiring the Department of State Health Services (DSHS) to establish a CHW training program, which is mandatory for those CHWs who are compensated for their services.¹⁹ To become a certified CHW, an individual must be at least 18 years old and complete a DSHS-approved 160 hour competency-based training program or prove the completion of at least 1,000 hours of CHW services within the last 6 years.²⁰ The established core competencies include communication skills, interpersonal skills, organizational skills, and knowledge of specific health issues. Certified CHWs are required to renew their certification and complete continuing education biannually.²¹

Indiana does not have legislation establishing CHW certification; rather, certification is department-established. The Indiana Division of Mental Health and Addiction and the Department of Health jointly established a training and certification program for CHWs. In order to be eligible, individuals must be at least 18 years old and have a high school diploma or equivalent. The training program is three-days and ends with a final exam. The program is module-based and covers topics such as communication skills, cultural understanding, prevention, chronic illness, behavioral health, and outreach. Upon completion of the training, certified CHWs may serve in a variety of settings including hospitals, clinics, and community centers.

Kentucky lacks legislation establishing CHW certification and does not require CHW certification. Any CHW certification largely occurs at individual CHW programs. For example, the Kentucky Homeplace Program, a CHW program delivering education on prevention and disease self-management, requires certification to work in the program. Certification requires CHWs to have a high school diploma or equivalent and complete 40 hours of training on chronic disease management, cancer prevention, in-home visiting safety, communication, and liability and legal instruction.²² Additionally, the certification requires three months of shadowing an experienced CHW wherein CHWs meet the community providers with whom they will work.²³ After the certificate is earned, there are continual trainings on various topics such as communicable diseases and child abuse.²⁴

Ethical Standards

The Community Health Worker Code of Ethics is based on and supported by the core values adopted by the American Association of Community Health Workers (AACHW), a national professional CHW group. The Code of Ethics provides a framework for CHWs, supervisors, and employers of CHWs to guide the discussion of ethical issues facing the profession. Not only are employers encouraged to consider this Code when creating CHW programs, but also, numerous states, including Indiana and Massachusetts, have developed ethical standards using the CHW Code as a model.

The CHW Code of Ethics is based upon commonly understood principals that apply to all health and social service professionals including the promotion of social justice, improved health, and dignity. The core of the CHW Code is that the responsibility of all CHWs is to strive for excellence by providing quality service and the most accurate information available to individuals, families, and communities. It includes sections on confidentiality, equitable relationships, rights and responsibilities, and the scope of ability and training. The CHW Code specifically directs CHWs to disclose qualifications, training, experience, and credentials. The CHW Code, however, does not address all ethical issues facing CHWs and states that the absence of a rule does not imply that there is no ethical obligation present. As professionals, CHWs are encouraged to reflect on the ethical obligations that they have to the communities that they serve.

RELEVANT AMA POLICY

Policy D-165.975 directs the AMA to highlight the need for improved access to quality health care for all disadvantaged, working with the private sector and government at all levels to improve health care access for this population.

Policy H-373.994, established with CMS Report 7-I-11, addresses patient navigators, who are non-clinical patient advocates whose role is encompassed in the broader term of community health workers. The Council's concerns and expectations with patient navigators mirror those regarding CHWs. Policy H-373.994 recognizes that patient navigator services may help improve access to care and help patients manage aspects of the health care system and that information provided by the patient navigator enhances a patient's ability to make appropriate health care choices. The policy provides guidelines to patient navigator programs to ensure patient navigators foster patient empowerment while explicitly refraining from any activity that could be construed as clinical in nature. Policy states

patient navigator programs should establish procedures to ensure direct communication between the navigator and the patient's health care team. The policy emphasizes that patient navigators should fully disclose relevant training, experience, credentials, and potential conflicts of interest. The policy also calls for the AMA to work with other organizations to ensure patient navigators are free of bias and do not usurp the physician's role or responsibility for patient education or treatment planning.

The AMA has extensive policy related to individuals who work with patients as part of a health care team. Several policies reinforce the concept of physicians bearing the ultimate responsibility for care and advocate that allied health professionals such as nurses and physician assistants function under the supervision of a physician (e.g. Policies H-35.970, H-45.973, H-35.989). Policy H-160.912 advocates that all members of a physician-led team be enabled to perform medical interventions that they are capable of performing according to their education, training and licensure, and the discretion of the physician team leader. Policy H-160.938 promotes a physician-led team approach to disease-specific patient care and self-management programs. Policy H-35.996 states that hospital medical staffs should have the authority to determine what functions and services should be made available for patient care by members of "emerging or expanding health professions." Policy H-160.906 defines "physician-led" in the context of team-based health care as the consistent use by a physician of the leadership, knowledge, skill, and expertise necessary to identify, engage, and elicit from each team member the unique set of training, experience, and qualifications needed to help patients achieve their care goals, and to supervise the application of those skills.

DISCUSSION

The general concept of community health workers is consistent with the patient-centered medical home model, which emphasizes physician-led, team-based care that is coordinated and integrated across all elements of the health care system and the patient's community (Policy H-160.919). Providing open communication and serving between health systems and communities facilitates access to and improves the quality and cultural competence of care. Conversely, to the extent CHW services have the potential to restrict care or interfere with the patient-physician relationship by interfering with and contradicting treatment plans, it is important that our AMA be prepared to confront this potential intrusion. To mitigate risk of interference, the Council believes CHWs should work under a protocol developed by the physician-led health care team regarding any activity relating to clinical matters. Because CHWs encompass the role of patient navigators, the Council recommends Policy H-373.994, Patient Navigator Programs, be amended and apply to community health workers.

Because of the diversity of roles and responsibilities of community health workers, it is challenging to identify a single set of guidelines applicable to all CHWs. The Council believes that the CHW Code of Ethics, supported by the AACHW, provides a strong framework for ensuring CHWs work properly to enhance and supplement the work of the physician-led health care team. The CHW Code specifically calls for cooperation among other health care providers and recognizes limitations on the services they can provide. The Council finds these principles imperative, and believes it is important the CHWs refrain from any activity that could be construed as clinical in nature, including interpreting test results, diagnosing illness or disease, or making treatment recommendations. Where appropriate, CHWs may use clinical experience or training to help patients better understand information provided by their physician or other members of their health care team.

The CHW Code directs that all CHWs be truthful and forthright in presenting their background and training to health care providers and be truthful about qualification and competencies to individuals, families, and communities. Though not stated in the CHW Code, the Council believes it is in the interest of patients for CHWs to be subject to background checks as they will have contact with patients and may have access to personal and medical information. The role of the CHW is built on trust, and full disclosure of background and training allows patients to determine which services the CHW is qualified to perform.

CHWs serve in a wide variety of roles within the health care system, and there is a lack of specificity regarding distinct roles and responsibilities. The Council believes the current absence of standardized core competencies and standardized training contributes to this lack of professional acceptance. The Council believes that appropriate stakeholders must work to establish not only a set of defined core competencies and skills but also establish clear training and continuing education requirements. CHWs have the capacity to be valuable members of the health care team. To do so, their roles and responsibilities must be clarified, and their training must be standardized as appropriate for the services they provide.

The lack of sustainable funding disrupts the services CHWs provide and prevents health care teams from realizing their full potential. The expanding evidence base for CHW programs suggests their strong potential for improving health outcomes; however, programs are often not sustained due in large part to limited and time-sensitive funding mechanisms. Establishing sustainable funding mechanisms supports the integration of CHWs into the care team. In particular, public and private insurance payers could provide pathways to a sustainable financing structure. The Council believes sustainable funding mechanisms that do not come out of that allocated physician payment should be pursued.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 805-I-14 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) amend Policy H-373.994 by addition of a new recommendation that specifies that the policy provisions for patient navigators are also relevant for community health workers and other non-clinical public health workers.
2. That our AMA encourage states and other appropriate stakeholders to establish that community health workers work under a strict protocol for any activity that relates to clinical matters and that this protocol be developed by the physician-led health care team.
3. That our AMA encourage states and other appropriate stakeholders to conduct background checks on community health workers prior to the community health worker providing services and take the background check results into appropriate consideration.
4. That our AMA encourage states and other appropriate stakeholders to develop a set of defined core competencies and skills of community health workers.
5. That our AMA encourage states to support or establish the training, certification, and continuing education of community health workers that allow for multiple points of entry into the profession.
6. That our AMA encourage health insurers and other appropriate stakeholders to promote sustainable funding mechanisms such as public and private insurance to finance community health worker services and that this funding not be part of funds allocated for physician payment.
7. That our AMA encourage states and other appropriate stakeholders to engage in collaborative efforts with community health workers and their professional organizations in the development and implementation of policies related to community health workers.
8. That our AMA encourage states to consider privacy and liability issues related to the inclusion of community health workers in the physician-led health care team.

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8. HEALTH INSURANCE AFFORDABILITY (RESOLUTION 120-A-15)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 120-A-15
REMAINDER OF REPORT FILED**
See Policy H-165.828

The American Medical Association (AMA) proposal to cover the uninsured and expand choice, used in AMA advocacy leading up to and following the enactment of the Affordable Care Act (ACA) and highlighted in AMA's Voice for the Uninsured campaign, is based on a number of policies developed and/or refined by the Council on Medical Service, and adopted by the House of Delegates, during the 1990s and 2000s. The proposal removes the bias towards employment-based insurance and promotes a system of individually selected and owned health insurance coverage, using tax credits, individual responsibility, and other market regulations to maximize coverage gains, make coverage affordable, and ensure patient choice of health plan and physicians.

With the implementation of the ACA well underway, the Council spent the past year reviewing the substantial body of AMA policy pertaining to the AMA proposal for reform. The Council has concluded that the preponderance of AMA policy regarding coverage, choice and access remains relevant. However, in its review, the Council identified policy gaps with respect to affordability of coverage.

At the 2015 Annual Meeting, the House of Delegates referred Resolution 120, "High Deductible, High Coinsurance Policies," which was introduced by the Wisconsin Delegation and assigned to the Council for study. Resolution 120-A-15 asked:

That our American Medical Association study how high deductible, high maximum out-of-pocket insurance policies affect health care costs in the immediate and distant future so that we may learn whether this actually increases total cost of care over time by delaying early treatment and secondary prevention efforts.

This report outlines policy gaps and opportunities with respect to defining affordability as well as the affordability of exchange coverage, summarizes relevant AMA policy and presents policy recommendations.

DEFINING AFFORDABILITY

The definition of affordable coverage is not consistent within the ACA, with noteworthy differences existing between the definition of affordable coverage pertaining to exemption from the individual mandate, and eligibility for premium and cost-sharing subsidies. The inconsistencies in how affordable coverage has been defined in ACA implementation have left millions of Americans ineligible for premium tax credits to purchase coverage through health insurance exchanges. In addition, opportunities exist to improve the affordability of coverage purchased through health insurance exchanges, especially regarding exchange plan deductibles and cost-sharing.

Exemption from the Individual Mandate

Beginning in 2014, the ACA required most individuals to obtain minimum acceptable coverage for themselves and their dependents or pay a tax penalty. Exemptions from the requirement to purchase health insurance are available to those who qualify for a religious exemption, American Indians, those who have been uninsured for less than three months, undocumented immigrants, incarcerated individuals, and those deemed unable to afford health insurance. Individuals are exempt from the individual mandate if the lowest-priced coverage available to them would cost more than 8.05 percent of their household income in 2015, the threshold over which coverage is determined to be unaffordable. Dependents are exempt from the individual mandate as well if the premium of the lowest cost family coverage, including employer-sponsored coverage, is more than 8.05 percent of their household income.

Eligibility for Premium and Cost-Sharing Subsidies

Individuals eligible for premium and cost-sharing subsidies to purchase coverage on health insurance exchanges include US citizens, legal immigrants, and employees who are offered an employer plan that does not have an actuarial value of at least 60 percent or if the employee share of the premium exceeds 9.56 percent of income in 2015. As such, individuals offered employer-sponsored coverage with premiums for self-only coverage equaling 9.25 percent of household income would be exempt from the individual mandate because their coverage would be deemed unaffordable with respect to application of the individual mandate, but at the same time they would not be eligible to receive premium and cost-sharing subsidies to purchase exchange coverage because their premium contribution for self-only coverage through their employer would be considered affordable. This affordability misalignment prevents a segment of workers from accessing coverage that would in many instances be more affordable on health insurance exchanges, considering roughly 17 million workers who are offered employer coverage have incomes low enough to qualify for cost-sharing subsidies if they would be otherwise eligible.¹

Family Glitch

In determining eligibility for premium tax credits, coverage for family members of an employee is considered to be affordable as long as employee-only coverage is affordable. Defining the affordability of employer coverage based on the premium contribution for employee-only coverage, and not family-based coverage, is rooted in ambiguity within the ACA as to how affordability is defined for family members of employees offered employer-sponsored coverage. As a result, the Joint Committee on Taxation interpreted the law to base the definition of employer-sponsored coverage solely on the cost of employee-only coverage; this interpretation was ultimately adopted in regulations issued by the Internal Revenue Service. The employee-only definition of affordable coverage pertaining to employer-sponsored coverage, commonly referred to as ACA's "family glitch," does not take into consideration the cost of family-based coverage, which commonly is much more expensive than employee-only coverage. The average employee contribution for self-only coverage is estimated to be \$1,290 in 2015, while the average contribution for family-based coverage is estimated to be \$4,874.² The "family glitch" leaves many workers and their families ineligible to receive premium and cost-sharing subsidies to purchase coverage on health insurance exchanges, even though in reality they would likely have to pay well over 9.56 percent of their income for family coverage. There is also the potential for workers and families affected by the glitch to remain uninsured, especially considering that low-income families are disproportionately affected. The Agency for Healthcare Research and Quality has estimated that 10.5 million adults and children may fall within the "family glitch."³

AFFORDABILITY OF EXCHANGE COVERAGE

Consistent with longstanding AMA policy supporting the provision of refundable and advanceable tax credits that are inversely related to income, eligible low-income individuals and families qualify for subsidized coverage offered

on health insurance exchanges. Individuals and families with incomes just above Medicaid levels to 250 percent of the federal poverty level (FPL) qualify for both premium tax credits and cost-sharing subsidies, while individuals and families with incomes between 250 and 400 percent FPL qualify only for premium tax credits. In 2015, the federal poverty level is \$11,770 for an individual and \$24,250 for a family of four.⁴ In 2016, approximately 13.8 million individuals will be eligible for both premium and cost-sharing subsidies, with an additional 9.4 million individuals eligible solely for premium tax credits.⁵

Premium Tax Credits

Eligible individuals and families with incomes between 100 and 400 percent FPL (133 and 400 percent in Medicaid expansion states) are being provided with refundable and advanceable premium credits to purchase coverage on health insurance exchanges. The size of premium credits is based on household income relative to the cost of premiums for the reference plan, which is the second-lowest-cost silver plan offered on the exchange. The premium credit as such caps the percentage of income that an individual pays for their premiums. Examples of maximum monthly health insurance premiums for the second-lowest-cost silver plan in federally facilitated and partnership exchanges for single adults include \$20 for an adult at 100 percent FPL, \$123 for an adult at 200 percent FPL, and \$279 for an adult at 300 percent FPL.⁶

However, individuals eligible for premium subsidies can also choose to purchase other levels of coverage. The bronze plan, which represents minimum creditable coverage, covers 60 percent of benefit costs including out-of-pocket limits that cannot be more than \$6,600 for individuals and \$13,200 for families in 2015. The percentage of benefit costs covered increases to 70 percent in the silver plan, 80 percent in the gold plan, and 90 percent in the platinum plan. If individuals eligible for premium subsidies choose a higher-level plan (gold, platinum), they would be responsible for paying the difference between the costs of the higher-level plan and the second-lowest cost silver plan. All subsidy-eligible individuals can also choose to pay less for a bronze plan, which would have higher deductibles and cost-sharing.

Cost-Sharing Subsidies

In addition, individuals and families with incomes between 100 and 250 percent FPL (133 and 250 percent FPL in Medicaid expansion states) also qualify for cost-sharing subsidies to purchase coverage on health insurance exchanges. Individuals eligible for cost-sharing subsidies must be enrolled in a silver plan. Cost-sharing subsidies effectively raise the actuarial value (percent of benefit costs covered) of the silver plan, leading patients to face lower deductibles, out-of-pocket maximums, copayments and other cost-sharing amounts. The average annual value of cost-sharing subsidies per eligible individual is projected to be \$479 in 2016, ranging from an average of \$217 for those with incomes between 200 and 250 percent FPL, to an average of \$693 for those with incomes above Medicaid levels but below 150 percent FPL.⁵ However, individuals eligible for cost-sharing subsidies forego such subsidies if they enroll in a bronze plan to save on premiums. More than 2 million individuals enrolled in exchange plans in 2015 who are eligible for cost-sharing subsidies are not receiving them because they did not select a qualifying silver plan.⁷

Average Deductibles and Out-of-Pocket Limits by Plan Type
Federally Facilitated and Partnership Exchanges^{8,9}

	Standard Silver Plan	Silver Plan – by Income			Bronze Plan
		Above Medicaid to 150% FPL	150-200% FPL	200-250% FPL	
Deductible	\$2,556	\$229	\$737	\$2,077	\$5,328
Out-of-Pocket Limit	\$5,826	\$881	\$1,692	\$4,624	\$6,359

High-Deductible Health Plans

Related to the intent of referred Resolution 120-A-15, the Council recognizes that low-income individuals who enroll in bronze plans may have difficulties affording the medical care they need. However, individuals with higher incomes are more likely to be able to absorb the costs associated with high-deductible health plans. Overall, from January to March of 2015, 4.4 percent of the US population failed to obtain needed medical care due to cost, a decline from 5.9 percent in 2013.¹⁰ Forty percent of health plan enrollees in the non-group market (both ACA-

compliant and non-compliant plans) have a plan with a deductible of \$1,500 or more for an individual or 3,000 or more for a family.¹¹ Fourteen million Americans ages 19 to 64 who were insured all year in 2014 had deductibles equal to five percent or more of their income. These individuals with deductibles equal to five percent or more of their income were more likely to report not getting needed medical care because of cost, as well as having issues with medical bills than those with lower or no deductibles.¹² Among households with incomes between 100 and 250 percent FPL, the income eligibility range for cost-sharing subsidies, only 32 percent have enough liquid financial assets to meet deductible amounts of \$1,200 for individuals and \$2,400 for families, while one in five can meet deductible amounts of \$2,500 for individuals and \$5,000 for families.¹³ According to the Commonwealth Fund Health Care Affordability Tracking Survey conducted September to October 2014, approximately two-thirds of privately insured individuals with incomes between 100 percent and 199 percent FPL reported it was difficult to afford their deductibles, with half of those with incomes between 200 percent and 399 percent FPL reporting difficulties. Almost half of privately insured adults with incomes below 200 percent FPL reported avoiding medical care when sick, avoiding necessary specialist visits, not filling prescriptions and skipping medical tests due to their copayments and coinsurance.¹⁴

RELEVANT AMA POLICY

Policy H-165.841 supports the overall goal of ensuring that every American has access to affordable high quality health care coverage. Policy H-165.845 states that health insurance coverage should be equitable, affordable, and sustainable. Policy H-165.838 supports insurance market reforms that expand choice of affordable coverage. Policy H-165.865 states that the size of tax credits should be large enough to ensure that health insurance is affordable for most people. Policy H-373.998 states that health reform plans should effectively provide universal access to an affordable and adequate spectrum of health care services, maintain the quality of such services, and preserve patients' freedom to select physicians and/or health plans of their choice.

Policy H-165.839 states that health insurance exchanges should maximize health plan choice for individuals and families purchasing coverage, with participating health plans providing an array of choices, in terms of benefits covered, cost-sharing levels and other features. Policy H-165.852 strongly supports HSAs maintaining their role in the health insurance marketplace as an option for patients. Policies H-165.845, H-373.998, H-165.838, H-165.846, H-320.968 and H-165.985 support patient choice of health plan, as well as the provision of full and clear information to consumers on the provisions and benefits offered by health plans. Policy H-373.994 outlines guidelines for patient navigator programs. Policy H-165.846 states that mechanisms must be in place to educate patients and assist them in making informed choices, including ensuring transparency among all health plans regarding covered services, cost-sharing obligations, out-of-pocket limits and excluded services. The policy also states that provisions must be made to assist individuals with low-incomes or unusually high medical costs in obtaining health insurance coverage and meeting cost-sharing obligations, which aligns with Policy H-165.865, which states that the size of premium credits should be large enough to ensure that health insurance is affordable for most people.

Policy H-165.920 supports a replacement of the present federal income tax exclusion from employees' taxable income of employer-provided health insurance coverage with tax credits for individuals and families. Policy H-165.851 supports incremental steps toward financing individual tax credits for the purchase of health insurance, including but not limited to capping the tax exclusion for employment-based health insurance. The Council notes that capping the tax exclusion for employment-based insurance is different from the excise tax on high cost employer-sponsored coverage that was included in the ACA, also known as the "Cadillac tax." Starting in 2018, employer-sponsored health benefits will be subject to the excise tax if their total value—including employers' and employees' tax-excluded contributions for health insurance premiums and contributions made through health reimbursement arrangements (HRAs), flexible spending accounts (FSAs), or HSAs—is greater than \$10,200 for single coverage and \$27,500 for other than self-only coverage in 2018.¹⁵ The amount of the excise tax will be equal to 40 percent of the difference between the total cost of health benefits for an employee and the applicable threshold amount. Rather, capping the tax exclusion for employment-based coverage would impose a limit to which employer and worker contributions for an employee's health insurance and other health care costs (FSAs, HRAs, and HSAs) could be excluded from an employee's taxable income.

DISCUSSION

As millions of Americans have enrolled in coverage offered through health insurance exchanges, the Council affirms that progress has been made on a long-time policy priority of the AMA—expanding access to affordable, quality health insurance coverage. According to Census Bureau findings released in September 2015, the uninsured rate decreased from 13.3 percent, or 41.8 million individuals in 2013 to 10.4 percent, or 33 million individuals in 2014.¹⁶ However, there is an opportunity to provide millions of workers and their families with access to premium credits and cost-sharing subsidies to purchase affordable coverage on health insurance exchanges, who are currently not eligible for subsidized exchange coverage due to how affordable coverage has been defined as the ACA has been implemented. First, aligning the definitions of affordability of coverage with respect to being exempt from the individual mandate (premium > 8.05 percent of income), and eligibility for premium tax credits if offered employer-sponsored coverage (premium > 9.56 percent of income), will prevent situations in which workers are ineligible for subsidized exchange coverage, despite only having access to employer-sponsored coverage with premiums high enough to make them exempt from the individual mandate. In addition, the ACA’s “family glitch” has left many children and other family members being considered ineligible for premium tax credits to purchase coverage on health insurance exchanges, because the affordability of employer-sponsored coverage is only based on the cost of employee-only coverage, ignoring the cost of family coverage. Without fixing the “family glitch,” families will continue to be in the position of choosing between unaffordable employer-sponsored coverage or face a penalty under the individual responsibility requirement for failing to have coverage. While the cost of fixing the “family glitch” depends on the actual regulatory or legislative approach selected, the Urban Institute has estimated that the cost of its proposed approach to address the “family glitch” through regulatory changes would be \$78 billion over 10 years.²

The intent of health insurance exchanges is to provide a patient-friendly market for patients to purchase health insurance, as well as increase the competition among plans based on quality and price. In general, patients have to navigate through many health plans to make the right choice that responds to their health care needs and budgetary realities. A Department of Health and Human Services study that analyzed the exchange market in 35 states showed that patients have an average of 40 health plans to choose from for 2015 coverage, including catastrophic plans. On average, there are 15 silver plans available, 12 bronze, 9 gold, 2 platinum and 2 catastrophic.¹⁷ However, there is notably wide variation in the number of health plans to choose from in each rating area; some rating areas offer very limited health plan choice, whereas there are some rating areas with well over 100 plans available. Realizing that navigating health plan choices available on health insurance exchanges may be potentially difficult for patients, the Council supports efforts to ensure clear and meaningful differences between plans offered on health insurance exchanges. There should also be clear labeling of exchange plans that are HSA eligible with information on how to set up an HSA.

The Council believes that additional assistance is needed during the health plan enrollment process to ensure patients are able to base their enrollment decision not solely on the cost of the premium, but rather on the total cost of care. At the time that this report was written, the Centers for Medicare & Medicaid Services was developing an Out-of-Pocket Cost Comparison Tool to show patients looking for coverage in federally facilitated exchanges estimates of total spending (to include premiums and cost-sharing) across the health insurance plans available to them. While the Council believes that such a tool is a key first step, there is also a need for additional education regarding deductibles and cost-sharing at the time of enrollment, including through the use of online prompts and the provision of examples of patient cost-sharing responsibilities for common procedures and services. With additional education, patients will have a greater understanding of the impact of enrolling in plans with higher deductibles, co-payments and co-insurance.

Individuals and families with incomes between 100 and 250 percent FPL (133 and 250 percent FPL in Medicaid expansion states) – the population eligible for cost-sharing subsidies – have a choice when selecting a health plan on the exchange. They can purchase a subsidized silver plan that due to cost-sharing subsidies has lower deductibles, out-of-pocket maximums, copayments and other cost-sharing amounts than would otherwise be available. Or, they can forego the cost-sharing subsidy and enroll in a bronze plan, which may have a lower premium, but higher deductibles. The Council is concerned that patients who forego cost-sharing subsidies by enrolling in a bronze plan may have difficulties affording any care they need, which can result in them avoiding or delaying needed care. While the Council does not want to limit health plan choice, the Council recognizes that there may be a role for HSAs to assist patients who forego cost-sharing subsidies by enrolling in a bronze plan. The AMA should encourage the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these

subsidies by enrolling in a bronze plan, to have access to an HSA partially funded by an amount determined to be equivalent to the cost-sharing subsidy. Therefore, in cases when individuals forego cost-sharing subsidies by enrolling in a bronze plan, they would have some contributions in their HSAs to help finance the medical care they need. Unspent HSA funds will rollover from year to year, creating greater protection against high deductibles.

Existing policy has supported capping the tax exclusion for employment-based insurance as an incremental step toward financing individual tax credits for the purchase of health insurance – a key provision of the AMA proposal for reform. The Council notes that in some proposals released to date, capping the tax exclusion would effectively replace the “Cadillac tax” of the ACA. Building off of existing policy that recognizes that providing affordable health insurance to individuals in the US has a cost, the Council believes that, as ACA implementation moves forward, capping the employee tax exclusion for employment-based insurance can be used as a funding stream to improve health insurance affordability, including for individuals impacted by the “family glitch,” individuals who forego cost-sharing subsidies despite being eligible, and individuals impacted by the inconsistency in affordability definitions.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 120-A-15, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered employer-sponsored coverage by lowering the threshold that determines whether an employee’s premium contribution is affordable to that which applies to the exemption from the individual mandate of the Affordable Care Act (ACA).
2. That our AMA support legislation or regulation, whichever is relevant, to fix the ACA’s “family glitch,” thus determining the affordability of employer-sponsored coverage with respect to the cost of family-based or employee-only coverage.
3. That our AMA encourage the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to a health savings account (HSA) partially funded by an amount determined to be equivalent to the cost-sharing subsidy.
4. That our AMA support capping the tax exclusion for employment-based health insurance as a funding stream to improve health insurance affordability, including for individuals impacted by the inconsistency in affordability definitions, individuals impacted by the “family glitch,” and individuals who forego cost-sharing subsidies despite being eligible.
5. That our AMA support additional education regarding deductibles and cost-sharing at the time of health plan enrollment, including through the use of online prompts and the provision of examples of patient cost-sharing responsibilities for common procedures and services.
6. That our AMA support efforts to ensure clear and meaningful differences between plans offered on health insurance exchanges.
7. That our AMA support clear labeling of exchange plans that are eligible to be paired with a Health Savings Account (HSA) with information on how to set up an HSA.

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