

REPORTS OF THE COUNCIL ON MEDICAL SERVICE

The following reports, 1–8, were presented by Paul A. Wertsch, MD, Chair.

1. COUNCIL ON MEDICAL SERVICE SUNSET REVIEW OF 2008 AMA HOUSE POLICIES

Reference committee hearing: see report of Reference Committee A.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

In 1984, the House of Delegates established a sunset mechanism for House policies (Policy G-600.110). Under this mechanism, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to re-establish it.

The objective of the sunset mechanism is to help ensure that the American Medical Association (AMA) Policy Database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the sunset mechanism contributes to the ability of the AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of House deliberations.

Modified by the House on several occasions, the policy sunset process currently includes the following key steps:

- Each year, the House policies that are subject to review under the policy sunset mechanism are identified, and such policies are assigned to the appropriate AMA Councils for review.
- Each AMA Council that has been asked to review policies develops and submits a separate report to the House that presents recommendations on how the policies assigned to it should be handled.
- For each policy under review, the reviewing Council recommends one of the following alternatives: (a) retain the policy; (b) rescind the policy; or (c) retain part of the policy.
- For each recommendation, the Council provides a succinct but cogent justification for the recommendation.
- The Speakers assign the policy sunset reports for consideration by the appropriate reference committee.

RECOMMENDATION

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

That our American Medical Association (AMA) policies listed in the appendix to this report be acted upon in the manner indicated.

APPENDIX - Recommended Actions on 2008 Socioeconomic Policies

Policy #	Policy Title	Recommended Action and Rationale
D-70.955	Postoperative Care of Surgical Patients	Retain. Still relevant.
D-70.969	Discriminatory Payment Policies	Retain. Still relevant.
D-70.999	Diagnostic Procedural Coding System	Rescind. Directive accomplished. By CMS reporting mandate, this work was required to be, and in fact was, completed Oct 1, 2015. The recommendations in the policy were completed in the necessary timeframe to complete the physician roll-out of the new diagnostic code set.
D-125.995	Health Plan Coverage of Prescription Drugs	Rescind. Superseded by Policy D-120.988.
D-125.999	Health Plan Coverage for Over-the-Counter Drugs	Rescind. Superseded by Policy H-125.990.

Policy #	Policy Title	Recommended Action and Rationale
D-155.992	Appropriate Hospital Charges	Rescind. Directive accomplished. Also superseded by Policy H-155.958, which was adopted via a 2009 Council on Medical Service report. The AMA sent a letter to the American Hospital Association with regard to the second Resolve.
D-160.944	Recognizing Transitions of Care for Performance Improvement	Rescind. Directive accomplished. The Physician Consortium for Performance Improvement (PCPI), in collaboration with the American College of Physicians, Society for Hospital Medicine, and the American Board of Internal Medicine Foundation, developed measures focusing on care transitions between the inpatient and outpatient settings. Additionally, the AMA participated in the AMDA task force to develop guidelines for transitional care in the long-term care continuum. Current guidelines are available at: https://paltc.org/product-store/transitions-care-cpg .
D-165.959	State-Based Demonstration Projects to Expand Health Coverage to the Uninsured	Rescind. Section 1332 of the Affordable Care Act established a new waiver supporting state innovation in order to enable states to experiment with and implement different models to provide health insurance coverage to their residents, with federal pass-through funding provided. As such, superseded by Policy H-165.826.
D-165.999	The Impact of Rapidly Developing Biotechnology on the Delivery of Medical Care	Rescind. Section 2 was accomplished via AMA advocacy in support of the Affordable Care Act. Section 1 was superseded by Policies H-450.938, D-478.966, D-478.976, H-478.985, D-478.977 and D-478.991.
D-180.984	Payer Measures for Private and Public Health Insurance	Retain. Still relevant.
D-180.987	Elimination of Federal Government Discrimination Against Individuals Who Purchase Health Insurance	Rescind. Superseded by Policy H-165.920.
D-190.986	Provision of Payment Schedules and Methodology of Payment as Part of the Contracting Process	Rescind. Directive accomplished. The AMA added a category to the attorney expertise sheet for "Hospital Medical Staff Issues/Bylaws." It was provided to all members of AMA. Consulting link to indicate that they have this expertise. In addition, an updated Web site allowed physicians to search for attorneys and consultants by expertise. Now any new attorney member can indicate that they have expertise in this area.
D-210.997	Home Infusion Therapies	Retain. Still relevant.
D-220.972	Expanding Physician and Medical Staff Participation in Accreditation Surveys	Retain. Still relevant.
D-235.990	<u>The Joint Commission Standard MS.01.01.01 JCAHO Standard MS.1.20</u>	Retain-in-part. Rescind (1) and (2), as superseded by the adoption of Standard MS.01.01.01. Amend (3[a]) as follows: Our AMA Commissioners to The Joint Commission: (1) introduce and support language before the full JCAHO board such that Standard MS.1.20 clearly states there is a single document known as the "Medical Staff Bylaws" which must be approved by the voting members of the medical staff; (2) introduce and support language before the full JCAHO board such that JCAHO Standard MS.1.20 clearly states that the following components are to be an integral part of the medical staff bylaws: a. Application, reapplication, credentialing and privileging b. Fair hearing and appeal processes c. Selection, election and removal of medical staff officers d. The clinical criteria and standards which manage quality assurance and improvement, and utilization review e. Criteria and processes for privileging f. Qualification for appointment g. The structure of the medical staff h. The duties and privileges of medical staff categories i. The right to develop and adopt medical staff policies, procedures, rules, and regulations j. The right and ability of the medical staff as a group to retain and be represented by independent legal counsel at the medical staff's expense

Policy #	Policy Title	Recommended Action and Rationale
		<p>k. The right and ability to assess dues and to utilize the dues as the medical staff sees fit; and</p> <p>(3 1) continue to advocate:</p> <p>a. Any element of performance of Standard MS.1-20 01.01.01 must be retained in the medical staff bylaws and not in other documents such as rules and regulations or policies...</p>
D-275.965	Optional Use of Social Security Numbers During the Council for Affordable Quality Health Care Credentialing Process	Retain. Still relevant.
D-330.926	Herpes Zoster Vaccines and Medicare Payment for the Vaccine and for Physician Administration of the Vaccine	Rescind. Directive accomplished. The AMA advocated with CMS as directed. Medicare Part D prescription drug plans and Medicare Advantage plans now provide coverage and payment for herpes zoster vaccines and its administration by physicians. Also superseded by Policies D-440.981 and H-440.875.
D-330.951	Medicare Cost-Sharing	Retain. Still relevant.
D-335.984	Medicare Part B Contractor Changes	Retain.
D-340.999	Ensuring the Accuracy of Statistics Related to Physician Billing	Retain. Still relevant.
D-385.968	Support for Appropriate Billing and Payment Procedures by Physicians	Retain. Still relevant.
D-390.962	National Care Project Physician Input	Rescind. Directive accomplished. The AMA has had discussions with CMS about the importance of physician input into the Post Acute CARE Project which evaluates costs and outcomes in post acute care provided in various facilities, including Skilled Nursing Facilities, Inpatient Rehabilitation Facilities and Home Health. We have also sent a letter urging the participation of physicians.
D-390.999	Universal Explanation of Medical Benefits Forms	Rescind. Superseded by Policy H-390.865 and AMA re-focus on adoption of the standard transaction for electronic remittance advice (a focus on encouraging an electronic version of a paper explanation of benefits). The AMA has undertaken significant activity to further the goal of adoption of the standard transaction for electronic remittance advice, including the development and publication of an educational toolkit available on the AMA website to help practices implement the standard electronic remittance advice transaction
D-400.986	The RUC: Recent Activities to Improve the Valuation of Primary Care Services	Retain. Still relevant.
D-406.994	Safeguard National Provider Identifier and Physician Privacy	Rescind. Directive accomplished. The AMA implemented a complaint form for physicians to register problems stemming from Medicare Administrative Contractor reforms and forwarded this information to CMS. The AMA also asked the states and specialties to forward any concerns they hear from the field so these issues can be tracked. The AMA continues to raise these concerns to CMS.
D-475.997	Postoperative Care of Surgical Patients	Retain. Still relevant.
H-25.998	Policy Recommendations in the Field of Aging	Retain. Still relevant.
H-70.938	Certified Professional Coders	Retain. Still relevant.
H-70.940	AMA Program to Readily Retrieve Billing Code Data by Payee within a Practice	Rescind. No longer relevant and superseded by Policy H-190.978.
H-70.946	Rebundling of Vaccine Codes	Retain. Still relevant.
H-70.948	Exclusion of Preoperative Services from Surgical Global Fee	Retain. Still relevant.

Policy #	Policy Title	Recommended Action and Rationale
H-70.962	Changes in the Bundling of Medical Services by Managed Care Plans	Retain. Still relevant.
H-70.982	Primary Health Care Reimbursement Coding	Retain. Still relevant.
H-70.993	Uniform Use of CPT Coding	Retain. Still relevant.
H-70.994	Coding of Physician and Non-Physician Services	Retain. Still relevant.
H-70.995	Collapsing the Codes	Retain. Still relevant.
H-120.947	Preserving Patients' Ability to Have Legally Valid Prescriptions Filled	Retain. Still relevant.
H-130.975	The Emergency Department and the Medical Staff	Retain. Still relevant.
H-155.963	Health System Expenditures	Retain. Still relevant.
H-160.930	Home Health Care	Retain. Still relevant.
H-160.951	Access to Primary Care Services	Retain. Still relevant.
H-165.847	Comprehensive Health System Reform	Rescind. Superseded by Policies H-165.904, H-165.920 and H-165.838.
H-165.861	Use of Federal Surpluses for Uninsured Americans	Retain. Still relevant.
H-165.877	Increasing Coverage for Children	Retain. Still relevant.
H-185.948	Health Insurance for Children	Retain.
H-185.966	Physician-Performed Microscopy	Retain. Still relevant.
H-185.991	Uniform Definition of Experimental Procedures and Therapies	Rescind. Health Insurance Association of America no longer exists. Additionally, Policies H-450.935 and H-410.948 supersede in their provision for updating guidelines to reflect evolving evidence.
H-185.993	Third Party Encumbrances	Retain. Still relevant.
H-185.999	Multiple Coverage in Voluntary Health Insurance	Retain. Still relevant.
H-200.969	Definition of Primary Care	Retain. Still relevant.
H-205.998	Regionalization of Medical Services	Retain. Still relevant.
H-210.981	On-Site Physician Home Health Care	Retain. Still relevant.
H-210.994	Home Health Care	Retain. Still relevant
H-215.973	Emergent Care Adjacent to Hospitals	Retain. Still relevant.
H-215.991	Medicare Hospital Inspection and Certification Process	Retain. Still relevant.
H-220.933	Critical Relevancy of Medical Staff in JCAHO Standards	Rescind, superseded by the adoption of Leadership Standard LD.02.04.01.
H-220.934	Conflicting Accreditation Standards Among Various Accreditors	Retain, amend as follows: Our AMA will work: (1) with <u>The Joint Commission</u> on Accreditation of Healthcare Organizations, the Centers for Medicare & Medicaid Services, state legislatures and regulating agencies, and other appropriate accrediting organizations, to ensure that there are no conflicts among the standards and their interpretation; (2) to ensure that accreditation remain in the private sector, and not become a function of government.
H-220.966	Future Directions of <u>The</u> JCAHO	Retain, amend as follows: The AMA urges <u>The JCAHO Joint Commission</u> , in any standards revision process, to make efforts to reduce burdensome and expensive administrative requirements imposed on health care providers that do not directly affect the quality of patient care.
H-225.956	Behaviors That Undermine Safety	Retain in part. Section 1 is still relevant, but the directive set forth in section 2 should be rescinded as accomplished. In December 2008, the AMA asked The Joint Commission to delay implementation of Joint

Policy #	Policy Title	Recommended Action and Rationale
		<p>Commission Standard LD.03.01.01, in part, because of its broad definition of disruptive behavior. The AMA also adopted its own Model Medical Staff Code of Conduct and continues to encourage organized medical staffs to adopt the AMA model code as part of their medical staff bylaws.</p> <p>1. Our AMA adopted the following policies: A. The Medical Staff... B. The Hospital...</p> <p><u>2. Our AMA Commissioners to the Joint Commission will urgently convey to The Joint Commission that a one year moratorium on The Joint Commission Standard LD.03.01.01 is necessary to provide a feasible time frame for the medical staff to bring the medical staff bylaws into compliance with the Standard.</u></p>
H-225.980	Hospital Medical Staff Section Representation on State Governing Boards	Retain. Still relevant.
H-225.982	Hospitals' Contractual Relationships with Health Plans	Retain. Still relevant.
H-230.968	Practice Limitations	Retain. Still relevant.
H-230.994	Encouragement of Open Hospital Medical Staffs	Retain. Still relevant.
H-235.999	Physicians Employed by Hospitals Required to be on Staff	Retain. Still relevant.
H-240.975	Realistic DRG Reimbursement	Retain. Still relevant.
H-280.956	Medicare Prospective Payment System for Skilled Nursing Facilities	Retain. Still relevant.
H-285.913	Medicare Advantage Policies	Retain. Still relevant.
H-285.934	Physician Recredentialing by Managed Care Plans	Retain. Still relevant.
H-285.935	Patient Rights During Health Plan Sales	Retain. Still relevant.
H-285.938	AMA Establishment of a Nationwide Federation of Physician Networks	Retain. Still relevant.
H-285.946	Fair Physician Contracts	Retain. Still relevant.
H-285.953	Managed Care Organizations - Credentialing	Retain. Still relevant.
H-320.960	Secondary Utilization Review	Retain. Still relevant.
H-330.917	Medicare Reimbursements for Medications	Retain. Still relevant.
H-330.923	Medicare Toll-Free Number	Rescind. No longer relevant now that toll-free numbers are available and widely publicized by carriers.
H-330.926	Reform of CMS Technology Assessment Process	Rescind. The Medicare coverage policy envisioned by the policy has been accomplished.
H-330.936	Physician Ordering of Durable Medical Equipment and Home Health Services	Retain. Still relevant.
H-335.994	CMS - Standards of Care, Hospital Admissions	Retain. Still relevant.
H-340.904	Quality Improvement Organization Program Status	Rescind. Superseded by Policy H-340.910.
H-340.910	Quality Improvement Organization Program Status	Retain. Still relevant.
H-340.968	Medicare Review	Retain. Still relevant.
H-345.986	Fifty Percent Copayment Requirement for Codes 290-310 Mental Disorders	Retain. Still relevant.
H-375.998	Review Committees for Medical Practices	Rescind. Superseded by Policies H-375.997 and H-375.962.

Policy #	Policy Title	Recommended Action and Rationale
H-380.984	The Role of Cash Payments in All Physician Practices	Retain. Still relevant.
H-380.991	Accurate Reporting of Physician Charges	Retain. Still relevant.
H-385.938	Most Favored Nation Clause within Insurance Contracts	Retain. Still relevant.
H-385.939	Hospital Billing on Behalf of Physicians	Retain. Still relevant.
H-385.942	CMS Use of Regulatory Authority to Implement Reimbursement Policy	Retain. Still relevant.
H-385.979	Reimbursement for Physicians in a Rehabilitation Setting	Retain. Still relevant.
H-390.865	Universal Explanation of Benefits Forms	Retain. Still relevant
H-390.870	Payment Denial Explanation on Medicare Benefit Statements	Retain. Still relevant.
H-390.879	Medicare Reimbursement for Multiple Physician's Visits on the Same Day Regardless of the Place of Service	Retain. Still relevant.
H-390.904	Timely Part B Medicare Payments to Physicians	Retain. Still relevant.
H-390.917	Consultation Follow-Up and Concurrent Care of Referral for Principal Care	Retain in part. In 2010 Medicare ceased paying for CPT consultation codes. Instead, providers may code for a patient evaluation and management (E&M) visit when appropriate. Modify policy to read as follows: (1) It is the policy of the AMA that: (a) the completion of a consultation may require multiple encounters after the initial consultative evaluation (in the inpatient setting these encounters may be reported using the follow-up consultation codes in CPT and in the outpatient setting these encounters may be reported using the appropriate office or other outpatient setting codes); and (b) after completion of the consultation, the consultant may be excused from responsibility of the care of the patient or may share with the primary care physician in concurrent care; he/she may also have the patient referred for care and thus become the principal care physician. (2) The AMA communicate the appropriate use of consultation, <u>evaluation and management</u> , and office medical services codes to third party payers and advocate the appropriate reimbursement for these services in order to encourage high quality, comprehensive and appropriate consultations for patients.
H-390.947	Medicare Payment Policies/Requirement That Carriers Delay Processing Claims	Retain. Still relevant.
H-390.951	Medicare Deductibles and Co-Payments	Retain. Still relevant.
H-390.953	Medicare Payments for Physicians' Services in Puerto Rico	Retain. Still relevant.
H-400.945	Insurance Compensation When Medicare Rates Are Decreased	Retain. Still relevant.
H-400.946	Uncoupling Commercial Fee Schedules from Medicare Conversion Factors	Retain. Still relevant.
H-400.962	The AMA/Specialty Society RVS Update Process	Retain. Still relevant
H-410.969	Payer Use of Practice Parameters	Retain. Still relevant.
H-465.999	Certification of Rural Hospitals for Medicare	Retain. Still relevant.

Policy #	Policy Title	Recommended Action and Rationale
H-480.954	National Agency for Technology Evaluations	Retain. Still relevant.

2. IMPROVING AFFORDABILITY IN THE HEALTH INSURANCE EXCHANGES

Reference committee hearing: see report of Reference Committee A.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**
See Policies H-165.824 and H-165.842

At the 2017 Annual Meeting, the House of Delegates adopted Policy D-165.934, “Studying Mechanisms Including a Public Option to Improve Health Insurance Marketplace Affordability, Competition and Stabilization.” The policy states that “our American Medical Association (AMA) will study: (1) mechanisms to improve affordability, competition and stability in the individual health insurance marketplace; and (2) the feasibility of a public option insurance plan as a model as a part of a pluralistic health care system to improve access to care.”

The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2018 Annual Meeting. In response to Policy D-165.934, the Council is presenting two reports at the 2018 Annual Meeting: this one, which is focused on improving affordability in the individual health insurance marketplace, and Council on Medical Service Report 3, “Ensuring Marketplace Competition and Health Plan Choice.”

This report provides background on recent premium increases in the Affordable Care Act (ACA) individual health insurance marketplaces and their associated impact on health plan affordability, outlines potential approaches to improve affordability in the ACA marketplaces, summarizes relevant AMA policy, and presents policy recommendations.

BACKGROUND

Premiums in ACA marketplaces rose significantly in many counties across the country from 2017 to 2018, due to factors including health insurer uncertainty about payment of cost-sharing reductions (CSRs) and enforcement of the individual mandate, lower insurer participation in the marketplaces, as well as more characteristic factors contributing to annual increases, including health care costs and trends. Depending on the county of residence and eligibility for premium tax credits, however, not all individuals have faced increases in their premiums from 2017 to 2018. For example, for a 40 year-old, unsubsidized premiums for the lowest-cost bronze, silver and gold plans increased nationally by an average of 17 percent, 32 percent and 18 percent respectively between 2017 and 2018. Premiums for silver plans experienced larger increases than bronze and gold plans as a result of insurer and state strategies employed in response to the termination of CSR payments.¹ For those consumers who enrolled in coverage via the healthcare.gov platform during the 2017 and 2018 open enrollment periods, the average premium before the application of any tax credit increased from \$476 in 2017 to \$621 in 2018.²

Even though the federal government has stopped reimbursing insurers for CSRs, insurers are still required under the ACA to offer CSRs to individuals with incomes up to 250 percent of the federal poverty level (FPL) who enroll in silver plans. Insurers, depending on the state in which they offer plans, responded to the termination of CSR payments in one of four main ways in setting premiums for the 2018 plan year:

- Increasing premiums only for silver plans offered inside the marketplace, because CSRs are only available for these plans;
- Increasing premiums for all silver plans, including those offered inside and outside the marketplace;
- Increasing premiums for all ACA-compliant individual market plans, including those offered inside and outside the marketplace; and
- Not adjusting premiums at all in response to the termination of CSR payments, though this strategy was very uncommon.³

Partially as a result of insurer responses to termination of CSR payments, for individuals who are eligible for premium tax credits, subsidized premiums are often lower in 2018 than 2017. Of note, of those consumers who selected or were automatically reenrolled in an ACA marketplace plan during open enrollment this year, 83 percent received a tax credit to lower their premiums.⁴ The amount of premium tax credits an individual receives is based on the cost of the second lowest cost silver (benchmark) plan available to them. In 2018, for states using the healthcare.gov platform, the average monthly premium for the benchmark plan for a 27 year-old increased by 37 percent (\$411) compared to 2017 (\$300). Such increases in benchmark plan premiums have yielded much higher tax credit amounts for many individuals. For states using the healthcare.gov platform, the average premium tax credit for individuals with 2017 coverage was estimated to increase by 45 percent from 2017 to 2018, from \$382 to \$555.⁵ For consumers who enrolled in plans during the 2018 open enrollment period in states using the healthcare.gov platform and received a tax credit to lower their premiums, the average premium tax credit was \$550. Among these consumers with a premium tax credit, the tax credit covered approximately 86 percent of the total premium on average. After the application of the tax credit, the average premium was \$89 per month.⁶ With higher premium tax credit amounts, gold plans became much more affordable, with bronze plans oftentimes having very low or no premiums. In some counties, the premium of the lowest-cost gold plan was even cheaper than the lowest-cost silver plan.

Looking ahead to 2019, resulting from the elimination of the individual mandate penalty due to enactment of tax reform legislation, individuals will become uninsured, and premiums will increase. In fact, the Congressional Budget Office has projected that repealing the individual mandate, starting in 2019, would cause the number of individuals with health insurance coverage to decrease by four million in 2019 and 13 million in 2027. At the same time, average premiums in the nongroup market would increase by approximately 10 percent in most years of the coming decade.⁷

APPROACHES TO IMPROVE AFFORDABILITY IN THE INDIVIDUAL MARKETPLACE

State-Level Individual Mandates and Auto-Enrollment

In light of the elimination of the federal individual mandate penalty, states have begun contemplating approaches to prevent the projected coverage losses and the level of premium increases anticipated in 2019. While the individual mandate of Massachusetts remains in place, some states are moving forward with individual mandate requirements, with the status and substance of such discussions varying by locality. For example, the New Jersey legislature approved the New Jersey Health Insurance Market Preservation Act, which would institute an individual mandate penalty in the state that largely resembles that of the ACA.⁸ The Council notes that state approaches to instituting state-level individual mandates, as well as auto-enrollment, depend on whether a state has an income tax and the extent to which a state operates its own health insurance marketplace.

The auto-enrollment option is also being considered in some states, to be either implemented separately from or in concert with a state-level individual mandate. For example, in Maryland, the Protect Maryland Health Care Act of 2018 has been introduced, which, if enacted into law, would give uninsured residents who would otherwise be charged an individual mandate penalty a choice: pay the penalty, or instead use the penalty amount as a down payment to assist them in purchasing health insurance coverage. If there are plans available that cost no more than any applicable federal premium tax credit amount and the down payment, consumers would be enrolled in such plans. If there are no “zero premium” plans available, the down payment would be placed into an escrow account that accumulates interest, which could then be used to purchase health insurance coverage during the following open enrollment period. If consumers do not select a plan by the end of open enrollment, and a “zero premium” plan has become available to them, they will be auto-enrolled in such coverage. Otherwise, their down payment would be deposited into the newly established Maryland Insurance Stabilization Fund, and be applied toward such initiatives as reinsurance.^{9,10}

State and Federal Reinsurance Programs

The recommendations of Council on Medical Service Report 4-I-17 established Policy H-165.842[3], which prefers reinsurance as a cost-effective and equitable mechanism to subsidize the costs of high-cost and high-risk patients. State and federal reinsurance programs have been shown to be effective in yielding premium reductions, in comparison to what they otherwise would have been. On the federal level, the ACA’s temporary reinsurance program helped stabilize premiums in the individual marketplace during the early years of ACA implementation. The program provided payments to plans that enrolled higher-cost individuals whose costs exceeded a certain threshold, also known as an attachment point, up to the reinsurance cap.¹¹ To fund the ACA’s transitional reinsurance program, insurers and third party administrators paid \$63 per enrollee per year in 2014, \$44 in 2015 and \$27 in 2016. These investments in

reinsurance yielded premium reductions. For example, in 2014, the \$10 billion reinsurance fund, the result of the \$63 per enrollee per year contributions, was estimated to reduce premiums by 10 to 14 percent. The American Academy of Actuaries has stated that a permanent program to reimburse plans for the costs of their high-risk enrollees would reduce premiums.¹²

States are also using ACA Section 1332 waivers to fund state reinsurance programs. Through an approved 1332 waiver, Alaska was able to implement the Alaska Reinsurance Program (ARP) for 2018 and subsequent years. The ARP covers claims in the individual market for individuals with one or more of 33 identified high-cost conditions to help stabilize premiums. As a result, insurers relinquish both premiums received for such individuals as well as claims they would have paid absent the waiver. Accordingly, premiums are 20 percent lower this year in the average plan on the individual market than they would have been absent the waiver.¹³ Other states have moved forward with implementing more traditional state reinsurance programs through Section 1332 waivers. For example, due to an approved 1332 waiver, premiums in Oregon were lower this year in comparison to what they would have otherwise been.¹⁴

In the 115th Congress, federal legislation has been introduced to provide funding for reinsurance programs. In the Senate, Senators Susan Collins (R-ME) and Bill Nelson (D-FL) introduced S 1835, the Lower Premiums Through Reinsurance Act of 2017, which would allow states to leverage Section 1332 waivers to apply and receive funding for reinsurance or invisible high-risk pool programs. The legislation would provide \$5 billion in total for funding, split evenly between fiscal years 2018 and 2019.¹⁵

In the House of Representatives, Congressmen Ryan Costello (R-PA) and Collin Peterson (D-MN) introduced HR 4666, the Premium Relief Act of 2017, which would establish the Patient and State Stability Fund, which would provide up to \$30 billion from 2019 to 2021 for the Secretary of Health and Human Services (HHS) to allocate at his discretion to be used for defined, outlined purposes, including reinsurance. If states do not apply for funding and administer their own programs under the bill, a federal reinsurance program would be established in said states by default. The legislation would also provide for reimbursements to insurers for CSR payments retroactively for the last quarter of 2017, as well as for 2019 and 2020.¹⁶

HR 3311/S 1354, the Individual Health Insurance Marketplace Improvement Act, has been introduced by Senator Thomas Carper (D-DE) and Congressman James Langevin (D-RI). If enacted into law, the legislation would create a permanent federal reinsurance program. The reinsurance program would provide payments to health plans to cover 80 percent of insurance claims incurred by plan enrollees between \$50,000 and \$500,000 from 2018-2020, and between \$100,000 and \$500,000 in 2021 and beyond.^{17,18}

There was also debate to include funding for reinsurance as part of HR 1625, the Consolidated Appropriations Act of 2018. However, ultimately such funding for reinsurance was not included in the final package.

Expansion of Eligibility for Premium Tax Credits

Under the ACA, 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 tax 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 benchmark plan, which is the second-lowest-cost silver plan offered on the exchange. The premium credit thereby caps the percentage of income that individuals pay for their premiums.

Individuals and families with incomes over 400 percent FPL are left without any premium assistance. The Council notes that the policy of our AMA in support of an individual responsibility requirement (Policy H-165.848) states that once a system of refundable, advanceable tax credits inversely related to income is implemented, that individuals and families earning less than 500 percent FPL should be required to obtain coverage. Extending advanceable premium tax credits to those with incomes above 400 percent FPL would not only cause some individuals with incomes between 400 and 500 percent FPL to be able to afford and obtain health insurance coverage, but would also be highly consistent with Policy H-165.848.

Enhanced Premium Tax Credits for Young Adults

In order to improve insurance take-up rates among young adults and help balance the individual health insurance market risk pool, young adults ages 19 to 30 who are eligible for advance premium tax credits could be provided with “enhanced” premium tax credits—eg, an additional \$50 per month—while maintaining the current premium tax credit structure which is inversely related to income, as well as the current 3:1 age rating ratio. Smaller amounts could be provided to individuals between ages 30–35. Under this policy option, the total credit, including the “enhanced” tax credit, could not exceed the cost of the second-lowest-cost silver plan available to them. Modeling of “enhanced” premium tax credits projects that individual market enrollment would increase by one million with the proposal in place.¹⁹ Of note, this approach to expanding coverage among young adults would cost less to the federal government than changing the age rating ratio from 3:1 to 5:1, as the latter would cause premiums for older adults to increase, as well as the associated premium tax credit amounts. Significantly, changing the age rating would cause some older adults to become uninsured; whereas with “enhanced” premium tax credits, individual market enrollment among older adults would remain largely unchanged.^{20,21}

Improved Outreach About Premium Subsidies

In August 2017, the Centers for Medicare & Medicaid Services announced that it would be spending \$10 million on educational activities targeted at new and returning marketplace enrollees for the open enrollment period for the 2018 plan year,²² which represented a 90 percent cut from the \$100 million spent on ACA-related advertising in 2017.²³ In addition, federal spending on the ACA’s navigator program, which provides outreach, education and enrollment assistance to consumers eligible for marketplace coverage as well as Medicaid, was cut 40 percent.²⁴ However, states operating their own health insurance marketplaces and navigator programs continued to dedicate financial resources to outreach and educational activities, as did some non-profit entities. It has been suggested that the difference in resources dedicated to outreach and education between states operating their own marketplaces and states that relied on healthcare.gov impacted enrollment successes in the marketplaces for 2018. For example, in the 16 states and DC with state-based marketplaces, 2018 plan signups during the open enrollment period stayed consistent with that of 2017, with a very slight increase. On the other hand, in the 34 states that fully relied on the federal healthcare.gov platform, total plan signups decreased by more than five percent in comparison to 2017.²⁵

At the same time, of the 27.5 million nonelderly people who were uninsured in 2016, 7.9 million were eligible for premium tax credits to purchase coverage through the marketplace. Data suggest that there remains a lack of awareness about premium tax credits and other financial assistance that may be available, as well as confusion about eligibility rules.²⁶ The Council notes that for individuals who are eligible for premium tax credits but remain uninsured, improved outreach and education about premium subsidies and their coverage options in the marketplace will be critical to increase the number of people who are insured, and may help to balance the individual market risk pool by increasing marketplace enrollment.

RELEVANT AMA POLICY

Over the course of the past couple of years, the Council has developed and presented reports specifically addressing improving health insurance affordability. CMS Report 4-I-17 focused on essential health benefits and the relative merits of high-risk pools versus reinsurance. The resulting policies, H-165.846[3] and H-165.842[3], oppose the removal of categories from the essential health benefits (EHB) package and their associated protections against annual and lifetime limits, and out-of-pocket expenses; oppose waivers of EHB requirements that lead to the elimination of EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses; and prefer reinsurance as a cost-effective and equitable mechanism to subsidize the costs of high-cost and high-risk patients. CMS Report 8-I-15 established Policy H-165.828, which supports legislation or regulation to fix the “family glitch;” supports allowing workers and their families to be eligible for subsidized exchange coverage if their employer coverage has premiums high enough to make them exempt from the individual mandate; encourages 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 partially funded by an amount determined to be equivalent to the cost-sharing subsidy; and supports 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.

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-165.920 supports individual tax credits as the preferred method for people to obtain health insurance coverage. Policy H-165.865 states that tax credits should be refundable; inversely related to income; large enough to ensure that health insurance is affordable for most people; fixed-dollar amounts for a given income and family structure; and advanceable for low-income persons who could not afford the monthly out-of-pocket premium costs. 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-165.848 supports a requirement that individuals and families who can afford health insurance be required to obtain it, using the tax structure to achieve compliance. The policy advocates a requirement that those earning greater than 500 percent FPL obtain a minimum level of catastrophic and preventive coverage. Only upon implementation of tax credits or other coverage subsidies would those earning less than 500 percent FPL be subject to the coverage requirement. Policy H-165.856 supports health insurance coverage of pre-existing conditions with guaranteed issue within the context of an individual mandate, in addition to guaranteed renewability. In CMS Report 9-A-11, "Covering the Uninsured and Individual Responsibility," the Council gave thoughtful consideration to alternatives to requiring individual responsibility, including the imposition of penalties for late enrollment, similar to Medicare Part D. The Council found that analyses fail to prove that such alternatives would be as effective in covering the uninsured and promoting a balanced risk pool of individuals between those who are sick and those who are healthy as an individual responsibility requirement.

Addressing state innovation, Policy D-165.942 advocates that state governments be given the freedom to develop and test different models for covering the uninsured, provided that their proposed alternatives: a) meet or exceed the projected percentage of individuals covered under an individual responsibility requirement while maintaining or improving upon established levels of quality of care; b) ensure and maximize patient choice of physician and private health plan; and c) include reforms that eliminate denials for pre-existing conditions.

DISCUSSION

With almost 12 million Americans enrolled in coverage offered through health insurance exchanges this year, the Council affirms that progress has been made on a long-standing policy priority of the AMA—supporting the purchase of individually selected and owned health insurance coverage with use of refundable and advanceable tax credits inversely related to income. However, the Council remains concerned with the premium increases experienced in the health insurance marketplaces from their launch in the 2014 plan year, and at the same time recognizes that such increases primarily impact those who are not eligible for premium tax credits. The Council believes that there is an opportunity to extend eligibility for advance premium tax credits which are inversely related to income consistent with Policy H-165.865 to 500 percent of FPL, which would assist individuals with incomes between 400 and 500 percent FPL to obtain coverage, consistent with Policy H-165.848 on individual responsibility.

The Council recognizes that the effectiveness of premium tax credits as a mechanism to improve health insurance affordability relies on individuals who are eligible for such assistance being aware of it. It is noteworthy that of the 27.5 million nonelderly people who were uninsured in 2016, 7.9 million were eligible for premium tax credits to purchase coverage through the marketplace. There is a clear opportunity to improve awareness about premium tax credits and other financial assistance that may be available to enrollees, as well as clear up confusion about eligibility rules. Accordingly, the Council recommends adequate funding for and expansion of outreach efforts to increase public awareness of premium tax credits to not only increase the number of people who are insured, but also help to balance the individual market risk pool by increasing overall marketplace enrollment.

Another key mechanism to help balance the individual market risk pool and increase coverage rates is the provision of "enhanced" tax credits to young adults. This proposal, which provides those aged 19 to 35 who are eligible for advance premium tax credits with "enhanced" premium tax credits—eg, an additional \$50 per month for those ages 19-30, the amount declining to age 35—has been projected to spur increases in young adult enrollment in the marketplace. Importantly, this policy recommendation maintains the current premium tax credit structure which is inversely related to income and as such is highly consistent with AMA policy. The Council notes that, as outlined in long-standing Policy H-165.920 and Policy H-165.828, eliminating or capping the employee tax exclusion for

employment-based insurance could be used as a funding stream for the mechanisms proposed to improve health insurance affordability in this report.

The elimination of the federal individual mandate penalty has the potential to cause not only premium increases and coverage losses, but increased market instability starting in 2019. An opportunity exists for state innovation to maximize the number of individuals covered and stabilize health insurance premiums. In particular, the Council is encouraged by activities and discussions on the state level pursuing state-level individual mandates, auto-enrollment and/or reinsurance, and believes those mechanisms hold great promise moving forward.

Finally, the Council is encouraged by the success of the ACA's reinsurance program as well as state reinsurance programs under Section 1332 waiver authority in reducing premiums in comparison to what they otherwise would have been. By partially reimbursing plans for the costs of their high-risk enrollees, reinsurance would help stabilize premiums for all individuals with ACA marketplace coverage, while protecting patients with pre-existing conditions. Therefore, the Council is recommending the establishment of a permanent federal reinsurance program. Upon the program's launch, it will be essential to monitor and evaluate the program's impact on premiums.

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) support adequate funding for and expansion of outreach efforts to increase public awareness of advance premium tax credits.
2. That our AMA support expanding eligibility for premium tax credits up to 500 percent of the federal poverty level.
3. That our AMA support providing young adults with enhanced premium tax credits while maintaining the current premium tax credit structure which is inversely related to income.
4. That our AMA encourage state innovation, including considering state-level individual mandates, auto-enrollment and/or reinsurance, to maximize the number of individuals covered and stabilize health insurance premiums without undercutting any existing patient protections.
5. That our AMA support the establishment of a permanent federal reinsurance program.

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3. ENSURING MARKETPLACE COMPETITION AND HEALTH PLAN CHOICE

Reference committee hearing: see report of Reference Committee A.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policy H-165.825, H-165.838 and D-180.986

At the 2017 Annual Meeting, the House of Delegates adopted Policy D-165.934, "Studying Mechanisms Including a Public Option to Improve Health Insurance Marketplace Affordability, Competition and Stabilization." The policy states that "our American Medical Association (AMA) will study: (1) mechanisms to improve affordability, competition and stability in the individual health insurance marketplace; and (2) the feasibility of a public option insurance plan as a model as a part of a pluralistic health care system to improve access to care."

The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2018 Annual Meeting. In response to Policy D-165.934, the Council is presenting two reports at the 2018 Annual Meeting: this one, which is focused on ensuring marketplace competition and health plan choice and specifically

reviews approaches to a public option, and Council on Medical Service Report 2, “Improving Affordability in the Health Insurance Exchanges.”

This report provides background on health plan choice and competition in the Affordable Care Act (ACA) marketplaces, highlights regulatory and legislative activity that could have marketplace impacts, outlines various approaches to ensuring marketplace coverage options, summarizes relevant AMA policy, and presents policy recommendations.

BACKGROUND

This year, there is an average of 3.5 insurers participating in each state’s ACA health insurance marketplace, ranging from one insurer in Alaska, Delaware, Iowa, Mississippi, Nebraska, Oklahoma, South Carolina, and Wyoming, to 12 insurers in New York. Approximately 26 percent of marketplace enrollees, living in 52 percent of counties, have only one insurer on the marketplace from which to select plans. Conversely, roughly half of enrollees, living in 18 percent of counties, have a choice of three or more insurers. Within states, there are differences between rural and urban areas as to insurer participation in the marketplace. For 2018, counties in metropolitan areas have on average two insurers participating in the marketplace, whereas non-metro counties have 1.6 insurers participating on average. In 2017, 87 percent of marketplace enrollees lived in counties in metropolitan areas.¹

Plans that are sold in the ACA marketplaces are required to be certified as qualified health plans (QHPs). As a condition of QHP certification, QHP insurers must provide at least one silver (covers 70 percent of benefit costs) and one gold level plan (covers 80 percent of benefit costs).² Therefore, at a minimum, consumers in counties with one insurer are expected to have at least two plans from which to choose. Data show, however, that there is wide variation in the number of unique plans offered, even in counties with one or two insurers participating in the marketplace. In 2017, in states using the healthcare.gov platform, counties with a single insurer participating had between two and 28 unique plan offerings with the average nearing 11. In counties with two insurers participating, there were between four and 61 unique plans to choose from, with 16 plans being the approximate average.^{3,4}

REGULATORY ACTIVITY IMPACTING MARKETPLACES

Association Health Plan Proposed Rule

Proposed federal regulations have been released this year, which, if finalized, could impact the competition in and stability of ACA marketplaces. In January, the Department of Labor (DOL) released a proposed rule regarding Association Health Plans (AHPs) in response to Presidential Executive Order 13813 (Promoting Healthcare Choice and Competition Across the United States).⁵ The proposed rule interprets the term “employer” to include self-employed and sole-proprietors for purposes of becoming an employer member of an AHP, which is important to the risk pool of the ACA marketplaces.

Under the proposed rule, AHPs with 51 or more “employees” can offer health insurance that qualifies as large group coverage to all of its employer members. Large group coverage does not have to comply with many of the ACA’s consumer protections. These protections include providing 10 essential health benefit (EHB) categories – including maternity care, prescription drugs, and mental health and substance use disorder services – that the ACA requires of insurance sold to individuals and small businesses; prohibiting varying rates based on gender, age, occupation, and group size; having a single risk pool for all enrollees to set premium rates; and risk adjustments of claims. Importantly, key cost protections guaranteed in the ACA, such as the annual cap on out-of-pocket costs and the ban on annual and lifetime limits, are only applicable to services considered EHBs.

Concerns have been raised that by enabling self-employed individuals and sole-proprietors to have access to AHP group coverage, the proposed rule has the potential to lead to healthy self-employed individuals enrolling in AHP coverage rather than ACA marketplace coverage. As a result of such adverse selection, individuals in plans following ACA requirements are expected to face higher premiums, resulting from sicker risk pools.^{6,7,8} At the same time, the Council notes, self-employed individuals enrolling in AHP coverage could be without guaranteed coverage of EHBs and their associated protections against annual and lifetime limits, and out-of-pocket expenses. Such coverage could be potentially problematic for individuals with pre-existing conditions, or enrollees who become sick over the course of the plan year.

Short-Term Limited Duration Plan Proposed Rule

In February, also in response to Presidential Executive Order 13813, the Departments of Health and Human Services (HHS), Labor, and Treasury issued a proposed rule addressing the regulation of short-term, limited duration insurance (STLDI) coverage. Unlike ACA marketplace plans, STLDI plans do not have to comply with the market reforms and consumer protections of the ACA. As such, STLDI plans can deny coverage or charge higher premiums based on health status; exclude coverage for pre-existing conditions; impose annual or lifetime limits; have higher out-of-pocket limits than the ACA maximums; not cover EHB categories; rescind coverage; and not comply with medical loss ratio requirements. Currently, STLDI coverage can only be offered for three months at a time, and if individuals enroll in STLDI plans for more than three months, they may have to pay the individual mandate penalty. By limiting STLDI coverage to three months, the purpose of STLDI plans was to serve as a bridge between coverage in plans offering meaningful coverage.⁹ Under the proposed rule, however, STLDI coverage could again be offered for periods up to 364 days, with the potential for consumers to reapply for coverage at the end of the 364-day period.

In the proposed rule, the agencies outlined the following potential benefits and costs:

- “Increased access to affordable health insurance for consumers unable or unwilling to purchase Patient Protection and Affordable Care Act (PPACA)-compliant plans, potentially resulting in improved health outcomes for them;
- “Increased choice at lower cost and increased protection (for consumers who are currently uninsured) from catastrophic health care expenses for consumers purchasing short-term, limited-duration insurance;
- “Potentially broader access to health care providers compared to PPACA-compliant plans for some consumers;
- “Reduced access to some services and providers for some consumers who switch from PPACA-compliant plans;
- “Increased out-of-pocket costs for some consumers, possibly leading to financial hardship; and,
- “Worsening of States’ individual market single risk pools and potential reduced choice for some other individuals remaining in those risk pools.”¹⁰

State-Level Activities: Idaho and Iowa

In January, Idaho Governor Butch Otter issued Executive Order No. 2018-02, “Restoring Choice in Health Insurance for Idahoans,” which directed “the Idaho Department of Insurance to approve options that follow all State-based requirements, even if not all PPACA requirements are met, so long as the carrier offering the option also offers an exchange-certified alternative in Idaho.”¹¹ As a result, the Idaho Insurance Department director issued an insurance bulletin recognizing and outlining the requirements of such plans. As outlined in the bulletin, state-based plans could have pre-existing condition exclusions for individuals without continuous qualifying coverage within 63 days of the plan’s effective date. In addition, such plans would not be required to cover all EHB categories required under the ACA, have the ability to impose annual limits of \$1 million, and not be required to abide by the out-of-pocket maximums outlined in the ACA. While enrollees in state-based and ACA-compliant plans would be considered to be in the same risk pool, premiums for state-based plans could vary based on age (5:1 instead of 3:1 ratio), tobacco use and health status.¹² In response, the Centers for Medicare & Medicaid Services (CMS) issued a letter to Idaho regarding its bulletin, stating that that the agency has reason to believe that Idaho would be failing to substantially enforce the provisions of the ACA. If Idaho fails to enforce the ACA, CMS stated that it has the authority to enforce the provisions of the law on behalf of the state. At the same time, CMS also stated that Idaho could potentially modify its proposal to offer state-based plans under the exception for STLDI coverage.¹³

In Iowa, legislation has been signed into law that will allow the Iowa Farm Bureau Federation to offer health insurance plans that would not, under law, be considered to be insurance. As such, the plans would not have to comply with ACA benefit standards and consumer protections, including prohibitions on pre-existing condition exclusions and denials, essential health benefits and age rating. In addition, they would not be subject to customary state regulations pertaining to health insurance, including those pertaining to rate review and solvency.^{14,15} The Council notes that the state of Tennessee has a similar law in place.

VARIOUS APPROACHES TO ENSURE MARKETPLACE COVERAGE OPTIONS

Concerns about insufficient competition on the marketplaces and affordability have led thought leaders, as well as federal and state legislators and gubernatorial candidates, to put forward proposals to ensure marketplace coverage options, including the creation of a public option. Approaches to a public option vary in many respects. For example, while some proposals would require provider participation in a public option, others would allow providers to choose

whether or not they want to participate in the plan offerings put forth in the event of bare counties. There are also different approaches to provider payment: through negotiation, or being tied to Medicare or Medicaid payment levels. In addition, while some public option proposals would build upon the Medicaid or Medicare programs, other proposals would use private health plans to ensure marketplace competition.

Federal and State Legislative Approaches

In the 115th Congress, federal legislation has been introduced addressing a public option. Congressman Peter DeFazio (D-OR) has introduced HR 1307, the Public Option Deficit Reduction Act, which would require the Secretary of HHS to offer a public option on the marketplaces. The public option envisioned in HR 1307 would comply with requirements for plans offered through marketplaces, including requirements related to benefits, benefit levels, provider networks, notices, consumer protections, and cost sharing. In addition, it would offer bronze, silver and gold plans, with the option to also offer platinum plans. Premiums would be geographically adjusted, and set at a level sufficient to fully finance the costs of the health benefits provided, administrative costs, and a contingency margin. Provider payment rates would be at Medicare rates, with the Secretary of HHS modifying payment rates in order to accommodate payment for services not otherwise covered in Medicare, including well-child visits. For the first three years, payment rates would be five percent higher than Medicare in order to incentivize provider participation. Medicare participating providers would also be considered to be providers in the public option unless they opt out. The bill appropriates funding for the establishment of the public health insurance option, which HHS must repay over 10 years.¹⁶

Senator Brian Schatz (D-HI) and Congressman Ben Ray Luján (D-NM) introduced S 2001/HR 4129, the State Public Option Act. If enacted into law, the legislation would give states the option to establish a Medicaid buy-in plan for residents regardless of income. Interestingly, for individuals ineligible for premium tax credits, their premiums cannot exceed 9.5 percent of household income. If these individuals were to enroll in other plans on state ACA marketplaces, their premiums would not be capped as a percentage of their income. In terms of physician payment rates, the State Public Option Act would make permanent a payment increase to Medicare levels for a range of primary care providers.^{17,18} These bills are similar to Assembly Bill 374 that passed the Nevada legislature, but was vetoed by the governor in June 2017. Other states have also considered a Medicaid buy-in approach, including Massachusetts and Minnesota.¹⁹

Senator Debbie Stabenow (D-MI) has introduced S 1742, the Medicare at 55 Act, which would provide an option for individuals age 55 to 64 to buy into Medicare or Medicare Advantage.²⁰ Similarly, Congressman Brian Higgins (D-NY) introduced HR 3748, the Medicare Buy-In and Health Care Stabilization Act of 2017, which would allow individuals age 50 and 64 to buy into Medicare.²¹ Under both bills, premiums would be based on estimating the average, annual per capita amount for benefits and administrative expenses that would be payable under Parts A, B, and D (including, as applicable, under Part C) for the buy-in populations. Notably, individuals would be able to apply premium tax credits and cost-sharing reductions toward the purchase of such coverage. These proposals are alternatives to more comprehensive proposals that would allow all individuals to buy into Medicare, or provide Medicare for all (eg, S. 1804, the Medicare for All Act of 2017, introduced by Senator Bernie Sanders [I-VT]).

Congresswoman Dita Titus (D-NV) introduced HR 4394, the Bare County Buy-in Act of 2017, which would require the Secretary of HHS to make available a public option for health insurance coverage for individuals residing in an area without any marketplace plan options. The public option would consist of a silver-level plan that provides coverage for essential health benefits. Providers who participate in Medicare or Medicaid would be considered to be participating providers in the public option unless they opt out. While the legislation states that the Secretary of HHS should establish provider payment rates through negotiated agreements, the bill also stipulates that if the Secretary and health care providers are unable to reach a negotiated agreement, that Medicare fee-for-service (FFS) payment rates should be used.²²

Leveraging FEHBP to Ensure Marketplace Plan Choice

The Federal Employees Health Benefits Program (FEHBP) provided health insurance coverage to approximately 8.2 million federal employees, retirees, and their dependents in 2016. By entering into contracts with qualified health insurance carriers, the US Office of Personnel Management (OPM) offers through FEHBP two primary types of plans – FFS plans (most of which have a preferred provider organization component) and health management organization (HMO) plans. While FFS plans are offered nationwide to all enrollees, HMO plans offer coverage in certain

geographic areas. In reviewing health plans to be offered under FEHBP, OPM considers the ability of plans to provide reasonable access to and choice of primary and specialty medical care throughout the service area.

In 2015, the median number of FEHBP plan offerings in a county was 24, most of which were nationwide FFS plans available in all counties. However, despite this level of choice of health plan, FEHBP enrollment is highly concentrated. The median county market share held by the largest FEHBP carrier was 72 percent in 2015, with the market share of the largest three carriers being 90 percent. Blue Cross Blue Shield Association (BCBSA), which offers two nationwide FFS plans, was the largest FEHBP carrier in 98 percent of counties in 2015. BCBSA's two nationwide FFS plans vary based on factors including premiums and provider network breadth. The Government Employees Health Association, Inc., which also offers nationwide FFS plans, held the second or third largest market share in 77 percent of counties in 2015. Kaiser Permanente, which offers HMO plans, was the third largest FEHBP carrier in 2015.²³

Leveraging health plan FEHBP participation has been included in a leading proposed solution to prevent bare counties in the marketplaces. Tim Jost, a health law expert who is Emeritus Professor at the Washington and Lee University School of Law and contributor to the Health Affairs Blog, proposed that, in the short term, "the largest two FEHBP insurers in any county should be required as a condition of continued participation in the program to offer at least one silver-level plan though the federal exchange in all counties that would otherwise be without coverage. These plans should be eligible for premium tax credits and could otherwise charge actuarially appropriate premiums."²⁴ Jost's proposal was cited in a bipartisan agreement to fix the ACA released in 2017, notably supported by Joseph Antos (American Enterprise Institute); Stuart Butler (The Brookings Institution); Lanhee Chen (Hoover Institution, Stanford University, Romney-Ryan 2012); John McDonough (Harvard University, Senator Ted Kennedy); Ron Pollack (Families USA); Sara Rosenbaum (George Washington University, former MACPAC chair); Grace-Marie Turner (Galen Institute); Vikki Wachino (Former Director, Center for Medicaid and CHIP Services); and Gail Wilensky (former HCFA Administrator and Deputy Assistant to President G HW Bush).²⁵

RELEVANT AMA POLICY

Policy H-165.838 supports health system reform initiatives that are consistent with long-standing AMA policies on pluralism, freedom of choice, freedom of practice, and universal access for patients. The policy also states that insurance coverage options offered in a health insurance exchange should be self-supporting, have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians. Policy H-165.839 states that health insurance exchanges should maximize health plan choice for individuals and families purchasing coverage.

Regarding meaningful coverage, Policy H-165.846 states that existing federal guidelines regarding types of health insurance coverage (eg, Title 26 of the US Tax Code and FEHBP regulations) should be used as a reference when considering if a given plan would provide meaningful coverage. The policy also advocates that the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program be used as the model for any EHB package for children; opposes the removal of categories from the EHB package and their associated protections against annual and lifetime limits, and out-of-pocket expenses; and opposes waivers of EHB requirements that lead to the elimination of EHB categories and their associated protections against annual and lifetime limits, and out-of-pocket expenses. Policy H-165.865 states that in order to qualify for a tax credit for the purchase of individual health insurance, the health insurance purchased must provide coverage for hospital care, surgical and medical care, and catastrophic coverage of medical expenses as defined by Title 26 Section 9832 of the US Code.

Addressing AHPs, Policy D-165.971 supports any AHPs that safeguard state and federal patient protection laws, including those state regulations regarding fiscal soundness and prompt payment. Similarly, Policy H-180.946 supports the selling of insurance across state lines that ensure that patient and provider protection laws are consistent with and enforceable under the laws of the state in which the patient resides. Relevant to both AHPs and STLDI plans, while Policy H-165.856 supports the removal of barriers to the formation and operation of group purchasing alliances, the policy also calls for greater national uniformity of market regulation regardless of type of sub-market, geographic location, or type of health plan, and raises concerns with adverse selection.

Policy D-180.986 states that our AMA will encourage local, state, and federal regulatory authorities to aggressively pursue action against "sham" health insurers. By contrast, Policy H-165.882 supports federal legislation to encourage the formation of small employer and other voluntary choice cooperatives by exempting insurance plans offered by

such cooperatives from selected state regulations regarding mandated benefits, premium taxes, and small group rating laws, while safeguarding state and federal patient protection laws.

Regarding a Medicare buy-in, Policy H-330.896 supports restructuring age-eligibility requirements and incentives to match the Social Security schedule of benefits. Concerning Medicaid, Policy D-290.979 states that the AMA, at the invitation of state medical societies, will work with state and specialty medical societies in advocating at the state level to expand Medicaid eligibility to 133 percent of the federal poverty level (FPL), or 138 percent FPL including the income disregard, as authorized by the ACA and will advocate for an increase in Medicaid payments to physicians and improvements and innovations in Medicaid that will reduce administrative burdens and deliver health care services more effectively, even as coverage is expanded.

DISCUSSION

In light of long-standing AMA policy (Policy H-165.856) advocating for greater national uniformity of market regulation across health insurance markets, and recognizing that departures from such uniform regulation should not create adverse selection, the Council believes it is essential that health plans competing to enroll individuals operate on a level playing field with the same rules applying to all plans. The Council is concerned with the potential for certain state and federal activities to lead to market segmentation, with healthier individuals enrolling in skimpier plans, and with individuals who for health and other reasons enrolling in plans following ACA requirements. As a result of such adverse selection the risk pools will likely be less healthy and there will likely be increased costs for individuals in plans following ACA requirements.

The AMA has long supported efforts to maximize health plan choices for individuals seeking coverage. However, it is imperative that state and federal consumer protection laws be maintained, AMA's key principles on health system reform be upheld, and patients have meaningful health insurance coverage options. AMA policy opposes denials and exclusions due to pre-existing conditions, and recognizes the protection that EHB coverage provides against out-of-pocket expenses, and annual and lifetime limits.

To strengthen and ensure the sustainability of the individual health insurance marketplace, upon which AMA's proposal for reform relies, the Council supports health plans offering coverage options for individuals and small groups competing on a level playing field, including providing coverage for pre-existing conditions and EHBs. In the same light, the Council believes that the AMA should not support coverage options that are exempted from such mandated benefits, due to their negative impact on marketplace stability, risk pools and plan affordability, resulting from adverse selection. As such, the Council recommends the reaffirmation of Policy D-180.986, which states that our AMA will encourage local, state, and federal regulatory authorities to aggressively pursue action against "sham" health insurers, and the rescission of Policy H-165.882, as it has been superseded by Policy D-180.986 and other AMA policies, and predates the ACA. The Council also recommends rescinding Policy D-165.934, which calls for the study that has been accomplished by the development of this report.

The Council agrees with the sentiment of many physicians that insufficient competition in the ACA marketplaces remains an issue to be addressed. However, the Council is concerned that public option proposals that rely on Medicaid and/or Medicare payment rates and/or tie physician participation in Medicare and/or Medicaid to a public option could negatively impact physician practices and physician practice sustainability, as well as patient access to care and choice of health plan. As such, the Council recommends the reaffirmation of Policy H-165.838, which states that health insurance coverage options offered in a health insurance exchange should be self-supporting; have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians.

To ensure patients are not left without coverage options in the marketplaces, consistent with the recommendation of a wide array of policy experts across the political spectrum, the Council recommends that our AMA support requiring the largest two FEHBP insurers in counties that lack a marketplace plan to offer at least one silver-level marketplace plan as a condition of FEHBP participation. The Council notes that this proposal would not allow individuals to buy-in to FEHBP plans. Rather, individuals in otherwise bare counties would have the choice of at least two silver plans that abide by ACA requirements, offered by the two largest FEHBP insurers in their county. Importantly, this proposal, unlike some others advocating for a public option, enables patient choice of private health plans, ensures physician

freedom of practice, does not require physician participation, and recognizes the value of payment rates being established through meaningful negotiations and contracts.

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) support health plans offering coverage options for individuals and small groups competing on a level playing field, including providing coverage for pre-existing conditions and essential health benefits.
2. That our AMA oppose the sale of health insurance plans in the individual and small group markets that do not guarantee a) pre-existing condition protections and b) coverage of essential health benefits and their associated protections against annual and lifetime limits and out of pocket expenses, except in the limited circumstance of short-term limited duration insurance offered for no more than three months.
3. That our AMA reaffirm Policy H-165.838, which states that health insurance coverage options offered in a health insurance exchange should be self-supporting; have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians.
4. That our AMA support requiring the largest two Federal Employees Health Benefits Program (FEHBP) insurers in counties that lack a marketplace plan to offer at least one silver-level marketplace plan as a condition of FEHBP participation.
5. That our AMA reaffirm Policy D-180.986, which states that our AMA will encourage local, state, and federal regulatory authorities to aggressively pursue action against "sham" health insurers.
6. That AMA Policy H-165.882 be rescinded.
7. That AMA Policy D-165.934 be rescinded.

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4. HEALTH PLANS’ MEDICAL ADVICE (RESOLUTION 705-A-17)

Reference committee hearing: see report of Reference Committee G.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

**IN LIEU OF RESOLUTION 705-A-17
REMAINDER OF REPORT FILED**

See Policies H-35.971, H-140.919, H-160.935, H-180.945, H-285.944, H-285.995 and H-285.998

At the 2017 Annual Meeting, the House of Delegates referred Resolution 705, “Regulating Health Plans Medical Advice,” which was introduced by the Washington Delegation. The Board of Trustees assigned this resolution to the Council on Medical Service for a report back to the House of Delegates. Resolution 705-A-17 asked:

That our American Medical Association (AMA) define when medical advice is the practice of medicine, and study options for regulating medical advice given by health plans.

This report provides background on medical advice services provided by health plans, discusses California’s regulation of telephone medical advice services, summarizes relevant AMA policy, and makes policy recommendations.

BACKGROUND

Health plans have been offering medical advice services (eg, “nurse lines,” “ask a nurse,” or “telephone triage”) since at least the 1980s, when managed care organizations began using health professionals (predominantly nurses) to manage demand and also prevent unnecessary physician office and emergency department visits. Although Resolution

705-A-17 pertains to medical advice services provided by health plans, some hospitals and large physician practices also operate telephone and/or online medical advice services. The “advice” is usually provided by nurses using detailed screening protocols to answer questions, provide basic health information, or determine when enrollees should be urged to go to a hospital emergency department or make an appointment with a physician. Although these services may be provided directly by a health plan or care provider, most large health plans contract with vendors to operate their medical advice services.

Many health plans advertise medical advice services as a no-cost benefit for enrollees who can call nurse lines, or fill out online “e-visit” questionnaires, to ask basic health questions at any hour of the day or night. Assessments of users’ health care needs are obviously limited, however, because enrollees are not physically observed. Many health plans also offer condition-specific programs—such as those for pregnant women or chronic disease patients—that provide text messages to enrollees in addition to online or telephone access. Patient navigator and nurse advocate programs are also offered by health plans to enrollees with complex medical conditions.

Health plans include an assortment of legal disclaimers when advertising medical information and advice services. Most clarify that call center or online staff (typically nurses) cannot diagnose conditions or prescribe or recommend treatment, and further state that the information provided is not a substitute for care by physicians. Some services specify that staff cannot give medical advice, while others advertise themselves as medical advice lines. Although these services are likely to produce some cost savings by reducing unnecessary physician and emergency department visits, there have been questions and concerns over the years regarding how they are managed, whether staff are qualified to evaluate enrollees’ medical needs and make appropriate referrals, and how care is coordinated with enrollees’ medical homes or treating physicians. Additionally, there have been allegations that medical call centers, in particular, have engaged in the unauthorized practice of medicine.¹ Call centers operated by health plans and hospitals can voluntarily seek accreditation by meeting a set of “health call center” standards developed by the Utilization Review Accreditation Committee, a nonprofit accrediting organization.²

Resolution 705-A-17 posits that medical advice given by health plans may be considered the practice of medicine when it is specific to a person’s illness or injury. It is the policy of the AMA that the diagnosis of disease and diagnostic interpretation of studies for specific patients constitutes the practice of medicine. Because states are responsible for providing medical licenses, each state regulates the practice of medicine and defines conduct that constitutes the practice of medicine within its jurisdiction. States may define the practice of medicine slightly differently. Each state could similarly define “medical advice” in statute or regulation. However, a Lexis search for state regulations defining “medical advice” or “telephone medical advice” turned up just a single result—California’s regulation of telephone medical advice services, which was cited in Resolution 705-A-17.

California regulation of telephone medical advice services

California enacted legislation in 2003 to protect consumers receiving telephone medical advice services. California Health and Safety Code §1348 requires that telephone medical advice must be provided by appropriately licensed health professionals, and prohibits other staff from misrepresenting themselves as licensed, certified or registered professionals.³ “Telephone medical advice” is defined in the Code as a “telephonic communication between a patient and health care professional in which the health care professional’s primary function is to provide the patient a telephonic response to the patient’s questions regarding his or her or a family member’s medical care or treatment.”⁴ It includes assessment, evaluation, or advice provided to patients and their families. Health care service plans providing telephone medical advice are required to make physicians and surgeons available on an on-call basis, and must maintain records—including transcripts of conversations and complaints—for five years.⁵ Until 2017, when the Telephone Medical Advice Services Bureau was repealed, businesses engaged in telephone medical advice were required to register with the state.⁶

Neither “medical advice” nor “telephone medical advice” is defined in AMA policy, in part because these terms do not have universally accepted legal definitions and could vary by state. However, it is important to ensure that medical advice services—which do not allow users to be physically examined—are not engaged in the practice of medicine, which generally involves the diagnosis and treatment of disease or injury. Health plans’ medical advice services are not usually used for these purposes. If they were, the services could be considered telemedicine in those states that do not exclude telephone calls from their definition of telemedicine.

Apart from medical advice services, many health plans offer their own telemedicine services whereby enrollees can access physicians virtually via computer or mobile device, usually for a fee. Some health plans also contract with vendors offering home visits and other care management services that constitute the practice of medicine and are provided outside of established patient-physician relationships. While the Council has concerns regarding the expansion of care management services—including telemedicine—that are increasingly provided by health plans, and the coordination of these services with patients' treating physicians, the scope of this report is limited to health plan medical advice services.

AMA POLICY

Policy H-140.919 affirms that the physician-patient relationship should be reinforced and not disrupted by direct communications from health plans to patients regarding clinical matters. This policy further states that health plan communications to patients promoting improved outcomes through evidence-based approaches (eg, promotion of preventive measures or disease management programs) should reinforce the primacy of the patient-physician relationship, and also be sensitive to confidentiality as well as patients' concerns about their health status. If a health plan directly communicates with a patient, Policy H-140.919 asserts that a copy of that communication should be sent to the patient's primary physician.

Disease management and demand management, through the use of telephone triage by health plans, is addressed by Policy H-285.944. Principles outlined in this policy specify that referral algorithms or protocols used in telephone triage should be developed by knowledgeable physicians, and should be updated regularly; telephone triage centers should routinely inform primary or principal care physicians of the disposition of all calls received from their patients; telephone counseling and triage should be performed by health professionals with a level of knowledge and training no less than that of a registered nurse; and qualified physicians should be readily accessible for consultation and second-level triage to the nurses or other health professionals providing telephone counseling or triage. Additional policy on "phone counseling" (Policy H-160.935) maintains that medical phone counseling services must appoint a physician director, and that the director is ultimately responsible for telephone triaging patients, updating the protocols and algorithms used by non-physicians, and maintaining accountability for patients until referrals have been effected by accepting physicians.

Guidelines for patient navigator and patient advocacy programs, including those offered by health plans, are outlined in Policy H-373.994. This policy states that these programs should establish procedures to ensure direct communication between patient navigators and the patient's medical team, and that navigators should refrain from activity that could be construed as clinical in nature.

Policy H-35.971 affirms that the diagnosis of disease and diagnostic interpretation of studies for specific patients constitutes the practice of medicine. Policy H-285.998^[5] states that physicians who make judgments or recommendations regarding the necessity or appropriateness of services or site of services should be licensed to practice medicine and actively practicing in the same jurisdiction as the practitioner who is proposing or providing the reviewed service and should be professionally and individually accountable for his or her decisions. Policy H-285.995^[7] reaffirms that the portion of AMA model state legislation that calls for certain elements of utilization review to be defined as the practice of medicine.

The practice of medicine by non-physicians is the focus of Policy H-160.949. This policy actively opposes legislation allowing non-physicians to engage in the practice of medicine without physician training or physician supervision. The AMA also opposes regulations and legislation that would interfere with and/or redefine the practice of medicine (Policy H-390.994). 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 (eg, health plan, physician practice, hospital or integrated delivery system).

The AMA has substantial policy on telemedicine, including Policy H-480.946, which outlines principles guiding appropriate coverage of and payment for telemedicine services, and also how to establish a valid patient-physician relationship via telemedicine. This policy also maintains that physicians and other health practitioners delivering telemedicine services must abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services, and be licensed in the state where the patient receives services, or be providing services as authorized by that state's medical board. Additional principles affirm that telemedicine services must be consistent with state scope of practice laws, and that the provision of telemedicine services must include care

coordination with the patient's medical home and treating physicians, who should be provided with a copy of the medical record. Principles for the supervision of non-physician providers when telemedicine is used are outlined in Policy H-160.937, which asserts that in all settings and circumstances, physician supervision is required when non-physician providers deliver services via telemedicine. A compilation of AMA policy on telemedicine can be found at <https://www.ama-assn.org/sites/default/files/media-browser/public/arc-public/telemed-policy.pdf>.

DISCUSSION

The Council's deliberations distinguished between health plans' medical advice services, which are the subject of referred Resolution 705-A-17, and medical management and telemedicine services offered by plans that explicitly constitute the practice of medicine. Policies H-35.971, H-285.998 and H-285.995, which delineate the practice of medicine, are recommended for reaffirmation.

Medical advice services are typically provided by health plans via telephone or online questionnaire, and are offered to enrollees free of charge. Nurses usually provide the service, with industry disclaimers clarifying that medical advice service staff cannot diagnose conditions or recommend specific treatments, and that the information provided is not a substitute for physician care. AMA policy on health plan disease management programs and demand management through telephone triage (Policy H-285.944), as well as phone counseling (H-160.935), remain relevant to the Council's discussion and are recommended for reaffirmation. The Council further recommends reaffirmation of Policy H-140.919, which maintains that the physician-patient relationship should be reinforced and not disrupted by direct communications from health plans to patients regarding clinical matters, and that in cases where a health plan directly communicates with a patient, a copy of that communication should be sent to the patient's primary physician.

The Council recognizes that health plans' medical advice services offer enrollees convenient, 24/7 access to nurses or other health professionals for general information and advice. The Council further recognizes that these services may be used to manage overall costs to the plan and that safeguards may be needed to ensure that patients receive timely and appropriate care. Because state medical practice laws vary, it would be difficult for the Council to precisely define all of the circumstances in which medical advice crosses over into the practice of medicine. Instead, the Council recommends a more general policy statement: That real-time interactions between health plans and enrollees that are utilized for patient assessments and result in the creation of treatment plans constitute the practice of medicine.

The Council also utilized existing AMA policy and the California regulation to develop guidelines that health plans' medical advice services should adhere to. Accordingly, the Council recommends that AMA policy affirm that medical advice services provided by health plans should adhere to a series of guidelines related to their primary goals, relevant requirements under state law, staff knowledge and training, physician availability, policies and procedures regarding efficiency and responsiveness to treating physicians, assurance that non-clinical staff are not providing medical advice, and disclosure of training and credentials. Finally, the Council recommends that the AMA work with interested state medical associations to advocate for appropriate policy on health plans' medical advice services.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 705-A-17, and the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-35.971, which states that the diagnosis of disease and diagnostic interpretation of studies for specific patients constitutes the practice of medicine; Policy H-285.998, which states that physicians who make judgements or recommendations regarding the necessity or appropriateness of services or site of service should be licensed to practice medicine; and Policy H-285.995, which reaffirms that certain elements of utilization review be defined as the practice of medicine.
2. That our AMA reaffirm Policy H-285.944, which outlines principles that should guide health plans' disease management programs and demand management through telephone triage, and Policy H-160.935 on phone counseling.
3. That our AMA reaffirm Policy H-140.919, which maintains that the physician-patient relationship should be reinforced and not disrupted by direct communications from health plans to patients regarding clinical matters,

and that in cases where a health plan directly communicates with a patient, a copy of that communication should be sent to the patient's primary physician.

4. That it be the policy of our AMA that real-time interactions between health plans and enrollees that are utilized for patient assessments and result in the creation of treatment plans constitute the practice of medicine.
5. That our AMA policy affirm that medical advice services provided by health plans should adhere to the following guidelines:
 - a) The primary goals of health plans' medical advice services should be to inform, educate and empower patients to make good health care choices and receive timely and appropriate care. These services should not be used to assess patients in order to inform diagnosis or treatment.
 - b) Health plans' medical advice services should comply with state licensure laws, state medical, nursing, or other relevant practice acts, state scope of practice laws, and other relevant requirements within the state in which enrollees receive services.
 - c) Staff providing health plans' medical advice services should have a level of knowledge and training no less than a registered nurse and be appropriately licensed in the state in which enrollees receive services.
 - d) Qualified physicians should be available for consultation to persons offering medical advice services at all times that the medical advice service is advertised as available.
 - e) Health plans should have policies and procedures in place that allow medical advice services to quickly and effectively respond to enrollees' health concerns.
 - f) Health plans should have policies and procedures in place to ensure that medical advice service providers routinely provide feedback to enrollees' treating physicians regarding the nature of the enrollees' contacts.
 - g) Health plans should ensure that non-clinical staff who may be screening enrollee calls or emails for the medical advice service are neither providing medical advice nor making medical decisions.
 - h) Health plans' medical advice services staff should fully disclose relevant training and credentials, and not misrepresent themselves to users.
6. That our AMA work with interested state medical associations to advocate for appropriate policy on health plans' medical advice services.

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5. FINANCING OF LONG-TERM SERVICES AND SUPPORTS

Reference committee hearing: see report of Reference Committee G.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED

See Policies H-165.852, H-280.945 and H-280.991

This report, initiated by the Council, addresses the growing need for long-term care services and supports (LTSS) in the US. The report provides an overview of LTSS; details the cost and need for LTSS; discusses the lack of public education on LTSS; provides a summary of the current financing structure for LTSS; outlines possible LTSS financing mechanisms; summarizes relevant policy; and presents policy recommendations to modify the current financing structure of LTSS with options that weave together financing reforms through publicly funded programs and private insurance.

BACKGROUND

Long-term services and supports (LTSS) refers to the range of clinical health and social services that assist individuals in their activities of daily living (ADL) when these individuals are limited or unable to care for themselves.¹ ADLs include eating, bathing, dressing, and instrumental tasks like medication management, house cleaning, and meal preparation. Unlike medical care, LTSS are function-based and holistic in nature.² In 2013, national spending for LTSS was \$310 billion and by 2015, that figure grew to \$331 billion.³ Medicaid spending accounts for over half of national spending for LTSS and is the primary payer for LTSS across the nation.

NEED FOR REFORM

The need for LTSS is expected to increase sharply in the coming decades; however, a possible funding source, long-term care insurance (LTCI), is too expensive and complex for most consumers, and its traditional policy design has not been sustainable. With few affordable options in the private insurance market and limited coverage under Medicare, individuals with insufficient resources rely on Medicaid to fund their LTSS needs, which puts a strain on Medicaid financing that will worsen as baby boomers age. More effective methods of financing LTSS and expanding the availability and affordability of LTCI through a mix of public and private reforms would help not only alleviate the financial strain on public payers but also avert the need for individuals to deplete their retirement funds and savings to pay for LTSS or to be eligible for Medicaid.

COST AND NEED FOR LTSS

The number of Americans needing LTSS in 2010 was 12 million, and it is expected that by 2050, 27 million Americans will need LTSS.⁴ This increased demand for LTSS is driven by a life expectancy that remains relatively high, the aging of the large baby boomer generation, and advances in technology that allow people with chronic illness and disabling conditions to live longer.

The number of elderly people is expected to more than double in the next 40 years. Baby boomers began turning 65 in 2011, and, within the next 20 years, the 65+ population will double and the 80+ population will more than double. Additionally, it is estimated that at least 70 percent of baby boomers will need some form of LTSS at some point in their lives, and 40 percent are expected to require nursing home care.⁵

Not only is the size of the baby boomer generation a strain on the LTSS system, but baby boomers are also more likely than previous generations to be divorced, have fewer children, and have more children in the workforce, making informal family caregiving less likely. Further, many baby boomers have not saved enough for retirement and appear to be unprepared for unplanned expenses such as LTSS. The average retirement savings for baby boomers is about \$75,000 while the cost of providing LTSS is significant.⁶ For example, in 2017 the average annual cost for a community-based adult day-care center was \$16,900; a home health aide was approximately \$49,000; and the average annual cost to live in a nursing facility was \$97,455. The need for LTSS is one of the primary risks to retirement security, and some aging individuals will have to deplete their retirement savings and overwhelm funding sources such as Medicaid to meet their LTSS needs.

There is great variation in LTSS spending among individuals. Although some individuals will not have any LTSS needs, others will have significantly high spending. About 27 percent of individuals turning 65 will have LTSS costs of at least \$100,000 over their lifetimes, and 15 percent will have costs that exceed \$250,000.⁷

PAYING FOR LTSS

The responsibility of paying for LTSS is shared among the elderly, people with disabilities, family, friends, volunteer caregivers, communities, states, and the federal government. However, this shared-responsibility system is severely stressed and increasingly will become unable to withstand the swelling demand for LTSS.⁸

LTSS are expensive, with institutional care costs far exceeding costs for home and community-based services (HCBS). Aside from unpaid care provided by friends or relatives, LTSS costs often exceed what individuals and families can afford out-of-pocket. Therefore, many with LTSS needs rely on publicly funded programs to help pay for or supplement the cost of their care needs.

Many people expect Medicare to be their primary source of health coverage in retirement, but long-term care (LTC) is only covered in limited circumstances and for a short period of time.⁹ Medicare only pays for LTC for individuals requiring skilled services or rehabilitation care, generally following a hospitalization. Importantly, there is an expectation that the beneficiary will recover from the condition. In a nursing home, Medicare pays for a maximum of 100 days; however, the average covered stay is about 22 days. If a beneficiary is receiving skilled home health or other skilled in-home services, commonly these are provided only for a short period of time. Notably, Medicare does not pay for non-skilled ADL, which make up the majority of needed LTC services.

Already, about 40 percent of state Medicaid budgets go toward LTSS.¹⁰ Medicaid pays for most of LTSS while Medicare post-acute care pays for 23 percent of LTSS. The remaining sources of funding include out-of-pocket spending, LTCI, other private sources, and other public sources.¹¹

Because many middle-class people fail to anticipate and plan for their LTC needs, Medicaid has effectively become the default payer instead of a safety net for the poorest individuals. This creates an enormous strain in funding and threatens services for the poorest and most vulnerable.

Individuals are only eligible for public LTC coverage through Medicaid after they spend down most, if not all, of their personal liquid financial resources.¹² In order to qualify for Medicaid services, one's income must be below a certain level and must meet minimum state eligibility requirements based on the amount of assistance needed with ADL. Generally, in order to qualify for Medicaid, one cannot have assets exceeding \$2,000, which excludes a car or home if the applicant intends to move back into the home or a spouse or dependent lives in the home.¹³ Medicaid is the default payer for about 65 percent of nursing home residents.¹⁴

Individuals and families must pay for LTSS that are not covered or partially covered by a public or private insurance program. Individuals pay for about 53 percent of their total LTSS expenditures out-of-pocket, typically through savings, retirement funds, or borrowed funds such as a reverse mortgage. For those who lack sufficient personal resources to pay for LTSS out-of-pocket, Medicaid is the primary payer. As baby boomers begin to need these services and supports, states will face a great challenge balancing their budgets with an increasing amount used in financing LTSS under Medicaid.

LACK OF PUBLIC EDUCATION

Exacerbating the lack of funding for LTSS is the public's misunderstanding of how much such care costs and how it is currently financed. Many Americans mistakenly believe that Medicare will pay for their LTSS needs. A recent survey conducted by the SCAN Foundation found that 57 percent of respondents said that they expect to rely on Medicare for LTSS. Only 25 percent of respondents think that they will get help from Medicaid, and many respondents are counting on Social Security to finance LTSS needs, even though average Social Security benefits would pay for less than 15 percent of the cost of a typical nursing home and perhaps one-third of the cost of assisted living.¹⁵

Some others know parents or friends who have received LTSS through Medicaid and fail to understand the limits of Medicaid coverage and strict eligibility criteria. In order to qualify for Medicaid, individuals have to have spent practically all of their assets or have appropriately given away or transferred them at least five years before the date

that they are applying for Medicaid benefits. Some generally have a belief that the government will ultimately pay for any future LTSS needs, further encouraging them to avoid the expense and discomfort of purchasing LTCI.

HURDLES TO LONG-TERM CARE INSURANCE ENROLLMENT

LTCI provides an opportunity to shift some of the cost of providing LTSS from Medicaid but has remained a relatively niche product. Not only is LTCI often cost-prohibitive, but also, often potential purchasers do not believe that they will need the benefit later in life, are in denial about the probability of future care needs, or erroneously believe that Medicare will pay for their LTSS needs. Less than 10 percent of individuals in their early 60s have LTCI, which puts pressure on the Medicaid program to bear most of this burden.¹⁶

Because of the declining LTCI market, many insurance carriers are reluctant to offer LTCI due to the difficulty of predicting costs far in the future and the risk that many beneficiaries will live for a long time. This reluctance to participate in the LTCI market and inability to predict future costs drives up premiums, especially for those in their 60s when they are likely to have preexisting conditions that may disqualify them from coverage and fewer working years to pay premiums that usually increase with age.^{17,18}

In addition, LTCI marketing materials are often confusing, and, at this stage in life, consumers are also balancing other competing financial demands such as saving for their own retirement and paying for children's college tuition.

PUBLIC CATASTROPHIC INSURANCE

Seventy percent of older Americans will need LTSS at some point in their lives.¹⁹ Fifteen percent of the population will have significant LTSS expenses representing lifetime costs of over \$250,000. For this high-cost population in particular, personal assets and informal family caregiving will not meet their care needs. The vast majority of those facing catastrophic costs must deplete their personal savings and sell assets to qualify for Medicaid.

In 2015, Milliman, Inc. and the Urban Institute conducted a microsimulation analysis of financing options for LTSS.²⁰ The analysis found that a universal approach would not only be less expensive for individuals than a voluntary approach but also save the Medicaid program and states significant funds and avert out-of-pocket spending. For example, they projected that a mandatory public catastrophic insurance plan would reduce Medicaid LTSS spending by 35 percent in 2070, while a voluntary subsidized public catastrophic plan would reduce Medicaid LTSS by 7 percent.

Additionally, the analysis found that public catastrophic plans that cover LTSS later by providing back-end benefits would offset more Medicaid spending than alternatives that cover only front-end costs.²¹ Without the ability to accurately predict future costs, many insurers have instituted significant rate increases further driving potential buyers out of the private insurance market. However, a public catastrophic insurance option could ease the reluctance of insurance carriers to offer LTCI and the reluctance of consumers to purchase LTCI thereby reducing the cost of private LTCI. Importantly, a back-end catastrophic program would have the effect of stabilizing the private insurance market. For example, a back-end catastrophic program with a five year waiting period and a \$100 per day lifetime benefit would cost a median-income worker about \$300 per year.²²

Insurers will only participate in the private market on any meaningful scale if they have enough information to accurately price their products, and a public back-end catastrophic program allows for accurate prediction. The path to affordable private LTCI depends on a competitive and growing private insurance market, which relies on predictability.²³ Offering public back-end insurance could encourage new private insurers to enter the market in the context of well-defined public and private responsibilities.²⁴

LTCI BENEFIT UNDER MEDIGAP AND MEDICARE ADVANTAGE

Most seniors are enrolled in either Medicare with a supplemental insurance policy (Medigap) or a Medicare Advantage (MA) plan, but they do not have LTCI.²⁵ Medigap insurance is offered on a guaranteed basis without medical underwriting at the time a beneficiary enrolls in Medicare. Many MA plans also provide supplemental benefits for services that are not covered under Medicare Part A or Part B. MA plans can provide either mandatory supplemental benefits that generally must be provided to all beneficiaries or optional supplemental benefits in which the MA plan

provides the beneficiary with the option of enrolling in coverage of additional services not covered by Medicare in exchange for additional premiums that are paid by the beneficiary.²⁶

In February 2018, Congress passed the Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care (CHRONIC) Act that will, for the first time, allow MA plans to pay for some LTSS.²⁷ While the law does not change the rules for traditional FFS Medicare, it allows MA plans to include in their benefit packages nonmedical services such as home-delivered meals or transportation to and from medical appointments.

Milliman, Inc. and the Bipartisan Policy Center analyzed a potential limited LTSS benefit for Medigap and MA plans wherein the Centers for Medicare & Medicaid Services (CMS) would amend Medigap and MA requirements to permit plans to offer existing benefits as well as a new limited and voluntary LTSS benefit.²⁸ In the model analysis, beneficiaries could choose to enroll in and pay corresponding premiums to cover the cost of the new benefit. When estimating the added cost of the benefit to Medigap or MA premiums, one analysis assumed a \$75 daily benefit with a 180-day elimination period that would need to be satisfied prior to commencement of the benefit.²⁹ Consistent with existing Medigap policies, beneficiaries would have a one-time option to purchase this coverage when enrolling in Medicare. The analysis suggests that this policy could result in premiums of \$35-\$40 per member per month.³⁰

RESPITE CARE

A significant amount of LTSS is provided by unpaid caregivers who are typically family members or friends. Though potentially rewarding, caregiving can be strenuous physically, mentally, and financially. Many caregivers often miss work time or leave the labor market altogether thereby eroding their ability to accumulate resources for retirement and their own LTC needs. Though valuing unpaid care is difficult, it is estimated that, in 2013, 40 million family caregivers in the US provided 37 billion hours of care to adults with ADL limitations representing a total economic value of unpaid caregiving of \$470 billion.³¹

Family caregivers on average spend 13 days per month on tasks such as shopping and housekeeping and six days per month on personal tasks such as feeding, dressing, and grooming. Taken together, the average individual with LTSS needs who relies exclusively on family for help receives about 173 hours of care over the course of a month, which is equivalent to a full-time job.³² Without this family-provided support, the economic cost of providing LTSS would rise sharply and worsen the current financing crisis.

Respite care helps individuals needing assistance to stay in their homes while giving their caregivers a reprieve from caregiving, which can prevent the caregiver from declining physically or emotionally.³³ Currently, respite care benefits are only available for Medicare beneficiaries who are enrolled in Medicare's hospice benefit, a benefit that is only available for beneficiaries expected to die within six months.³⁴

The Urban Institute and the Bipartisan Policy Center analyzed the cost of a potential respite care benefit in Medicare and MA that would be triggered when certain Medicare providers determined that respite care was needed. Among several analyses, one found that the 10-year federal budgetary cost of a 96-hour respite benefit would cost \$29 billion if beneficiaries with spousal caregivers were eligible for the benefit.³⁵

HOME AND COMMUNITY-BASED SETTINGS (HCBS)

Historically, states and the federal government have limited the use of Medicaid-funded LTSS by restricting eligibility for services and providing care primarily in institutional settings such as nursing homes and residential facilities. However, there has been significant agreement that the current bias toward LTSS being delivered in an institution should be eliminated.³⁶ Not only are HCBS significantly cheaper than institutional care, but also, there has been a growth in beneficiary and societal preferences for them.³⁷ Over the years, states have used waivers and state plan options to enable Medicaid-funded LTSS to be delivered in other less expensive settings. Progress has been made at the community level in finding ways to keep seniors and people with disabilities out of institutions and in the community. HCBS keep people happier, less isolated, and can be provided more effectively and cheaper than nursing home facilities. Expanding HCBS could provide individuals with more flexibility in how they receive LTSS and a higher quality of life.

There has also been a call to better integrate medical care and social care, predominantly for the dually eligible population. The Program of All-Inclusive Care for the Elderly (PACE) both supports HCBS and improves the delivery

of LTSS through better care integration for this particular population. PACE is a program under Medicare wherein states can elect to provide services to Medicaid beneficiaries as an optional Medicaid benefit.³⁸ The PACE program becomes the sole source of Medicaid and Medicare benefits for participants. It provides comprehensive medical and social services to certain frail, elderly individuals enabling them to remain in the community rather than receive care in a nursing home. The PACE program is an interdisciplinary team of health professionals providing participants with coordinated care. Notably, financing for the program is bundled, allowing the providers to deliver all services participants need rather than only those reimbursable under Medicare and Medicaid fee-for-service plans.³⁹

RELEVANT AMA POLICY

Policy H-280.991 addresses financing of LTC and outlines relevant principles and policy proposals for LTC. It states that programs to finance LTC should cover needed services in a timely, coordinated manner in the least restrictive setting appropriate to the health care needs of the individual and coordinate benefits across different LTC financing programs. Policy H-210.994 echoes providing LTC services in the least restrictive setting by affirming support of home health care as an alternative to nursing home or institutional care. Further, Policy H-280.991 suggests providing coverage for the medical components of LTC through Medicaid for all individuals with income below 100 percent of the poverty level and providing sliding scale subsidies for the purchase of LTCI coverage for individuals with income between 100-200 percent of the poverty level.

Policy H-280.991 also considers tax incentives and employer-based LTC coverage to help fund LTC including creating tax incentives to allow individuals to prospectively finance the cost of LTC coverage and encouraging employers to offer such policies as a part of employee benefit packages and otherwise treat employer-provided coverage in the same fashion as health insurance coverage and allow tax-free withdrawals from IRAs and Employee Trusts for payment of LTCI premiums and expenses. Additionally, the policy supports use of a tax deduction or credit to encourage family caregiving.

Furthermore, Policy H-280.991 states that consumer information programs should be expanded to emphasize the need for prefunding anticipated costs for LTC and to describe the coverage limitations of Medicare, Medicaid, and traditional Medigap policies. State medical associations should be encouraged to seek appropriate legislation or regulation in their jurisdictions to provide an environment within their states that permits innovative LTC financing and delivery arrangements, and assures that private LTC financing and delivery systems, once developed, provide the appropriate safeguards for the delivery of high quality care. Additionally, consistent with other AMA policy on state-based innovation, Policy H-280.991 supports health system reform legislative initiatives that could increase state flexibility to design and implement long-term care delivery and financing programs.

Policy H-165.852 supports legislation promoting the establishment and use of Health Savings Accounts (HSAs) and allowing the tax-free use of such accounts for health care expenses, including health and long-term care insurance premiums and other costs of long-term care.

Policy H-290.982 supports allowing states to use LTC eligibility criteria that distinguish between persons who can be served in a home or community-based setting and those who can only be served safely and cost-effectively in a nursing facility. Such criteria should include measures of functional impairment which take into account impairments caused by cognitive and mental disorders and measures of medically related LTC needs; and supports buy-ins for home and community-based care for persons with incomes and assets above Medicaid eligibility limits; and providing grants to states to develop new LTC infrastructures and to encourage expansion of LTC financing to middle-income families who need assistance.

DISCUSSION

The Council's recommendations are intended to provide feasible steps forward to alleviating the financial strain of providing LTSS on Medicaid and families. The Council's recommendations are not intended to solve the LTSS financing crisis in its entirety. The Council recognizes that a growing consensus has emerged around a set of incremental steps that have the ability to improve the availability and affordability of LTSS. To that end, the Council proposes a multi-pronged approach to alter the financing and viability of LTSS through a mix of public and private reforms. Though the following recommendations are consistent with Policy H-280.991, the Council considers these recommendations to be distinct and with a broader view of LTSS financing.

The Council believes it is important to help consumers prepare thoughtfully for their LTSS needs and to provide individuals with a reasonable assessment of the likelihood of future need. Accordingly, the Council recommends reaffirming Policy H-280.991, which states that consumer information programs should be expanded to emphasize the need for prefunding anticipated costs for LTC and to describe the coverage limitations of Medicare, Medicaid, and traditional Medigap policies.

Regarding private reform, the Council firmly believes in the importance of strengthening and improving the private insurance market. There are a number of steps that may be taken to revitalize the market for private LTCI. First, the Council recommends a policy statement to standardize and simplify private LTCI to achieve increased coverage and improved affordability. Additionally, Policy H-280.991 encourages employers to offer LTCI policies as a part of employee benefit packages, and the Council recommends expanding this principle to support adding LTCI coverage as part of workplace automatic enrollment with an opt-out provision. In this case, enrollment in the LTCI coverage would be paid through annual premiums that are almost half the cost of typical current-market LTCI policies. Additionally, the Council stipulates that these employer-offered plans should be available to both current employees and retirees.

To further improve the market for private insurance, the Council recommends allowing retirement savings to be used for LTCI premiums. Such a strategy includes supporting penalty-free withdrawals from employer-based retirement savings accounts for purchase of private LTCI. The Council notes that Policy H-280.991 already supports the creation of tax incentives to allow individuals to prospectively finance the cost of LTC coverage, encourage employers to offer such policies as a part of employee benefit packages and otherwise treat employer-provided coverage in the same fashion as health insurance coverage, and allow tax-free withdrawals from IRAs for payment of LTC insurance premiums and expenses. Similarly, the Council recommends reaffirming Policy H-165.852 promoting the establishment and use of HSAs and allowing the tax-free use of such accounts for health care expenses, including health and long-term care insurance premiums and other costs of long-term care. The Council is confident that such private reforms would reduce premium costs while reaching segments of the population that are not yet served by private LTCI.

As another step toward developing the private insurance market, the Council recommends exploring innovations in LTCI product design. Such innovations may include LTCI covering home and community-based LTC needs as well as marketing products with health insurance, life insurance, or annuities. Not only is home and community-based care less expensive than traditional facility-based care, but also, most people are able to stay at home and avoid nursing home care altogether.⁴⁰

The Council believes increasing the availability of LTCI is vital to a sustainable financing structure moving forward. As such, the Council recommends supporting the ability of Medigap plans to offer a limited LTSS benefit as an optional supplemental benefit, or as a separate insurance policy, financed through additional premiums paid by the beneficiaries who choose to enroll. Similarly, the Council recommends supporting the implementation of the CHRONIC Act allowing MA plans to offer social supports in benefit packages. Correspondingly, the Council recommends permitting a respite care benefit as part of Medigap and MA policies.

There is widespread agreement among advocacy organizations and think tanks of the need for a public catastrophic program for individuals with extraordinary LTSS costs to protect against poverty and bankruptcy.⁴¹ There is also public support for such a program. A recent survey found that about two-thirds of people favor a public catastrophic insurance program.⁴² Many agree that a public catastrophic option should help cover the back-end risk of LTSS costs that discourages private insurers from offering comprehensive protection. Back-end catastrophic coverage could be compared to the concept of reinsurance in that it may protect against premium increases in the private LTCI market by serving as a safety-net to those high-cost individuals who may require LTSS for a long period of time. It would be used in the event of catastrophic LTSS expenses after a period of using private LTCI or self-funding. Therefore, such a program could stabilize the private insurance market and allow insurers to focus on shorter-term, defined, and predictable coverage. The Council believes that a back-end public catastrophic insurance program could help shift away from the current welfare-based model and toward a system of insurance.

Consistent with Policy H-280.991 advocating for states to be permitted to pilot innovative LTSS financing and delivery arrangements, the Council suggests incentivizing states to expand the availability of and access to HCBS. Such services could help individuals remain in home and community settings for a longer period of time and relieve some of the burden of more costly LTSS care such as that provided in nursing homes. Increasing the availability of

HCBS not only helps in eliminating the current bias in financing toward more expensive institutional care but also relieves family caregivers and allows them some time off. Furthermore, and consistent with Policy H-280.991 supporting the coverage of services in a coordinated manner in the least restrictive setting, the Council supports better integration of health and social services and supports, including the PACE.

Demand for LTSS will more than double over the next 30 years, and the challenges to affordable and politically viable LTSS financing mechanisms are varied and complex. While it is unlikely that there is one straightforward solution to the growing demand for LTSS, the Council offers these recommendations as a pragmatic step forward to address the needs of an aging population and help shift away from an LTSS system dependent on insolvency and last-resort public financing to a sustainable system of meaningful insurance.

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-280.991 supporting consumer education regarding the likelihood of future need for long-term services and supports (LTSS) and the limits of public funding sources and supporting tax-free withdrawals from retirement savings accounts for payment of long-term care insurance (LTCI) premiums and expenses.
2. That our AMA reaffirm Policy H-165.852 supporting legislation promoting the establishment and use of Health Savings Accounts and allowing the tax-free use of such accounts for health care expenses, including health and long-term care insurance premiums and other costs of long-term care.
3. That our AMA support policies that standardize and simplify private LTCI to achieve increased coverage and improved affordability.
4. That our AMA support adding transferable and portable LTCI coverage as part of workplace automatic enrollment with an opt-out provision potentially available to both current employees and retirees.
5. That our AMA support allowing employer-based retirement savings to be used for LTCI premiums and LTSS expenses, including supporting penalty-free withdrawals from retirement savings accounts for purchase of private LTCI.
6. That our AMA support innovations in LTCI product design, including the insurance of home and community-based services, and the marketing of long-term care products with health insurance, life insurance, and annuities.
7. That our AMA support permitting Medigap plans to offer a limited LTSS benefit as an optional supplemental benefit or as separate insurance policy.
8. That our AMA support Medicare Advantage plans offering LTSS in their benefit packages.
9. That our AMA support permitting Medigap and Medicare Advantage plans to offer a respite care benefit as an optional benefit.
10. That our AMA support a back-end public catastrophic long-term care insurance program.
11. That our AMA support incentivizing states to expand the availability of and access to home and community-based services.
12. That our AMA support better integration of health and social services and supports, including the Program of All-Inclusive Care for the Elderly.

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6. INTEGRATING PRECISION MEDICINE INTO ALTERNATIVE PAYMENT MODELS

Reference committee hearing: see report of Reference Committee G.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

REMAINDER OF REPORT FILED

See Policies H-185.923, H-410948, H-450.933 and D-185.980

This report, initiated by the Council, explores how alternative payment models (APMs) can support and integrate genetic/genomic precision medicine services with the end goal of providing high-quality, high-value health care. Previous Council reports have discussed physician-focused APMs (Report 9-A-16) and barriers that interfere with the shift to these value-based payment models (Report 10-A-17). Policy developed via the I-17 Joint Report of the Councils on Science and Public Health and Medical Service is intended to facilitate more consistent payment and coverage for evidence-based genetic/genomic precision medicine services.

This report discusses APMs and precision medicine; describes clinical pathways and decision support tools; provides examples of APMs that incorporate precision medicine approaches; discusses AMA activity; summarizes relevant AMA policy; and presents policy recommendations.

BACKGROUND

Precision medicine, which is a tailored approach to health care that accounts for individual variability in the genes, environment and lifestyle of each person, has the potential to revolutionize diagnosis and treatment of disease and, in doing so, improve health outcomes downstream. It has the potential to more accurately diagnose disease, predict individual susceptibility to disease, detect the onset of disease at earlier stages, and reduce invasive procedures and no longer necessary screenings and treatments. Physicians already practice precision medicine by diagnosing and treating each patient according to his or her unique symptoms, history, and preferences. However, significant advances in technology—including the development of large-scale biological databases, powerful methods for characterizing patients (eg, proteomics, metabolomics, genomics, cellular assays, and mobile health technologies), and computational tools for analyzing large sets of data—have vastly expanded the ability to apply precision medicine principles to patient care.

Accelerated rates of genetic/genomic discoveries and clinical innovations are occurring simultaneously with payment and delivery reforms including the proliferation of APMs driven by the push for cost-containment strategies and value-based purchasing. Driven by the Affordable Care Act (ACA) and Medicare Access and Chip Reauthorization Act (MACRA), the Centers for Medicare & Medicaid Services (CMS) has developed and implemented a number of initiatives to test APMs.

New health care payment and delivery models focus on value and require that health care services demonstrate their value to patients and the health care system as a prerequisite for payment and coverage. The sustained push to contain health care costs has led to increased interest in APMs that incentivize high-quality, cost-effective care. Examples of well-known APMs include accountable care organizations (ACOs), bundled payments, and patient-centered medical

homes (PCMHs). APMs have the capacity to create incentives for the use of care protocols, clinical pathways, and shared decision-making. However, such tools should reflect advances in precision medicine and support continued scientific innovation so that “one-size-fits-all protocols” are not universally imposed when evidence-based targeted treatments may be more cost-effective in the long term.

Precision medicine holds the potential to improve patient care and may ultimately help address rising health care costs overall by streamlining clinical decision-making, reducing unnecessary treatments and hospitalizations, tailoring treatments, reducing late-stage diagnoses, and improving outcomes over time. For example, genotype testing of patients initiating warfarin treatment has been found to reduce hospitalizations for bleeding or thromboembolism.¹ Another study estimated that there would be substantial cost savings (\$604 million) if patients with metastatic colorectal cancer were screened for the KRAS gene prior to beginning treatment.² A retrospective analysis of precision medicine outcomes in patients with advanced cancer found improved progression-free survival and lower charges per week for patients who received genomic testing and targeted therapy.³ Over time, it is anticipated that genetic/genomic services will become more affordable and thus potentially produce greater cost savings. Payment and coverage for genetic/genomic services, which was addressed in the I-17 Joint Report, continues to be a barrier to patient access to precision medicine. While some genetic/genomic tests and therapeutics are covered by insurers, many others are not, and there is substantial variability among public and private insurers with regard to payment and coverage and prior authorization requirements. Coverage may also vary based on the intended use of genetic/genomic testing.

The market shift from a fee-for-service (FFS) to a value-based model should support and encourage the adoption of evidence-based genetic/genomic precision medicine services. However, it is a challenge to design new payment models that aim to improve care for whole populations while implementing precision medicine that is aimed at identifying the correct diagnosis and treatment plan for an individual patient. Stakeholders must engage in ongoing discussions to identify areas where APMs and precision medicine may work together and support one another. If properly designed and incentivized, together APMs and precision medicine have the capacity to yield better care, better health, and lower costs over the long term.

POTENTIAL IMPACT OF APMS ON PRECISION MEDICINE

Precision medicine represents life-altering opportunities and potential. However, policymakers must be diligent to appropriately weigh the balance between quality and cost-savings and, in particular, short term cost-savings. The drive to make genetic/genomic medicine available may be stifled when providers are assessed or penalized for spending, as they are in APMs. Such assessment of providers based on spending may be particularly problematic when that spending yields improvements that cannot be considered in a specific or small window of time.⁴

A recent MedPAC report denotes a potential issue with the structure of many APMs being that the paradigm of cost savings in a specific period of time may be appropriate for some services and procedures that have remained unchanged over the course of many years; however, such a structure may not be appropriate for new tests and technologies, especially those that might improve patient quality of life over the course of many years.⁵ For example, it may be challenging to align a payment system, such as a bundled payment APM, with the appropriate quality measures. While the use of precision medicine could improve a patient’s quality of life or prevent downstream disease recurrence, it is difficult to identify and promote quality measures that capture the value of such interventions within a specified window. Policymakers must acknowledge such challenges of implementing precision medicine within the context of APMs so as to realize the potential of innovative technologies to improve care quality, value, and patient satisfaction.

As medical knowledge of the genome continues to evolve and grow, the number of options and tools to assist providers in diagnosis and treatment is rapidly expanding. While tens of thousands of genetic tests are currently available,⁶ there is widespread variability in the costs and insurer coverage of these tests and clinicians may have a difficult time determining the right test for a given patient. For example, oncology clinical practice guidelines currently recommend more than 30 tumor biomarkers across all cancers to support appropriate treatment and decision-making with the list of potential biomarkers growing and changing in response to the rapid pace of clinical research.⁷ Genetic tests range from testing for a specific alteration and a specific gene to testing large genetic panels on many hundreds of genes at the same time.⁸ Though guidelines from the National Comprehensive Cancer Network and other professional groups help direct physicians to the best genetic tests for a given patient, physicians need the decision support to help determine which mutations to consider for a specific tumor type and what genetic tests are most appropriate for a given patient. Studies have suggested that many physicians report being inadequately prepared to use genetic/genomic

information for patient care,⁹ while others remain unsure that genomic information is clinically useful.^{10,11} Education and awareness are needed for successful implementation of genetic/genomic precision medicine, and tools used by APMs may be able to help address some of the knowledge gaps.

CLINICAL PATHWAYS AND DECISION SUPPORT TOOLS

Many APMs already create incentives to use care protocols, clinical pathways, and other decision support tools in treatment decision-making. Pathways act as a decision support tool for physicians to know the right genetic test to use for each patient based on the nature of the patient's disease.¹² The pathways then recommend treatments based on the test results. At times these pathways receive prior authorization from payers, having the effect of expediting the process of getting the test and treatment to the patient. Yet many providers can have difficulty using the decision support resources necessary to assess the value of precision medicine when confronted with high upfront costs of new technologies.

Often clinical pathways produce a single instance of savings after use. However, because pathways are generally developed based on the broader population, requirements to adhere to clinical pathways may have the effect of constraining the ability of providers and patient to identify and choose the patient's best available treatment options. Therefore, one-size-fits-all pathways and adherence requirements may result in missed opportunities to tailor treatment based on individual patient genetics, environment, and lifestyle choices.

Stakeholders are attempting to combat the issue of one-size-fits-all pathways by using data registries that expand the evidence base of available therapies. The use of data registries and rapid learning systems can extract clinically relevant data and apply the data to practice guidelines in real-time. One example of an adjustable pathway model is the Department of Veterans Affairs (VA) Point-of-Care Precision Oncology Program (POCOP). The POCOP uses electronic health records (EHRs) and real-time data sharing to integrate knowledge from external sources about molecular medicine in cancer with experience and information of other veterans in the program including genomic information from a patient's tumor and history with prior therapies.¹³ Ultimately, the POCOP could guard against simply using short-term lower cost pathways and serve as a model of rapid data-sharing, creating an evidence base that is continuously updated and can inform treatment decisions at the point of care.¹⁴

Similarly, the American Society of Clinical Oncology (ASCO) is developing a rapid learning system by building a cloud-based, big data, health IT platform called CancerLinQ.¹⁵ CancerLinQ extracts data from EHRs and other data sources and employs data analytics to generate knowledge that is available at the point of care to oncologists and patients. The primary objective of the learning system is to provide real-time feedback to physicians to enable them to deliver personalized insights at the point of care and accelerate new clinical hypotheses and pathways by uncovering patterns in patient and tumor characteristics, therapies, and outcomes. As precision medicine evolves and we gain insight on the role of genetic and other variation in patient response to treatment, clinical pathways and other decision support tools will need to keep pace.

INCORPORATING PRECISION MEDICINE INTO APMs TO IMPROVE DIAGNOSIS

A current barrier in the health care delivery and payment system is a lack of payment for some key aspects of the work associated with obtaining an accurate diagnosis. Current payment structures often do not pay for consultation with other physicians, and patients often face delays in access to care, particularly specialists, which can lead to exacerbations in symptoms and disease progression before a diagnosis is established and a treatment plan is developed. Furthermore, often significant amounts of time are dedicated to ruling out diagnoses rather than establishing an accurate diagnosis. This issue of the diagnostic odyssey is driven in part by the structure of FFS in which payments are made for conducting tests rather than paying for the process of determining what tests to order.

To overcome this barrier, APMs should be encouraged to leverage technology to support the goals of the APM and help physicians improve patient engagement, collaboration, diagnosis, treatment planning, and quality. APMs have the capacity to support more accurate diagnoses and tailored treatment plans, and precision medicine can play an important role in realizing this potential. Not only can APMs support collaborative efforts between various health professionals such as pathologists, radiologists, and others, but also, APMs, with the help of clinical pathways and guidelines, can pay for targeted genetic and genomic tests that support faster and more accurate diagnoses and the development of an individualized treatment plan. It is important to note that genetic/genomic testing provides clinical

information beyond diagnostics, including prognosis and therapeutic tailoring. APMs should support new approaches to care delivery, and precision medicine is an important component of achieving more accurate diagnoses.

EXAMPLES OF APMS IMPLEMENTING PRECISION MEDICINE

The Radiation Oncology Alternative Payment Model (RO-APM)

Though the role of precision medicine across health care settings and payment models is still evolving, oncology care illustrates how an APM can help support precision medicine. Specifically, the American Society for Radiation Oncology is developing the RO-APM, which would incentivize the appropriate use of cancer treatments that result in the highest quality of care and best patient outcomes. The RO-APM holds physicians accountable for the spending related to the condition and applies to major disease sites treated with radiation therapy, creating an episode-based payment that begins with clinical treatment planning and concludes 90 days after the last radiation treatment. Throughout the episode, clinicians must adhere to nationally accepted clinical treatment guidelines and other quality improvement requirements.

With the use of genetic/genomic precision medicine, providers can optimize radiation therapy based on a patient's tumor profile. Its use can shape dosage to minimize side effects and spare healthy tissue. A recent study conducted at the University of North Carolina found that approximately 20 percent of radiation therapy patients experienced an unplanned hospital admission within 90 days of their treatment.¹⁶ Precision medicine can yield better, more targeted treatment planning to lower the risk of post-radiation therapy toxicities and avoid the need for toxicity-related inpatient visits. An APM can support enhanced patient monitoring and better management of patient care and result in fewer inpatient visits, ultimately decreasing the average cost of care per radiation therapy patient.

Patient-Centered Oncology Payment

The ASCO developed the Patient-Centered Oncology Payment (PCOP) model to improve the quality and affordability of cancer care. The model pays practices for services that are not currently billable, including non-face-to-face visits and consultation with other specialists, and imparts practices with the flexibility to tailor services to unique patient needs, which results in the delivery of high-quality, individualized services. The PCOP system is designed to provide supplemental, non-visit-based payments to practices to support accurate diagnosis, treatment planning, and care management. Using PCOP, practices would bill for new patient treatment planning, care management, active monitoring, and participation in clinical trials. In return for PCOP paying adequately for patient services at the outset, practices agree to adhere to appropriate use criteria and other accepted standards of care. Furthermore, practices and payers agree to a robust performance measurement system, so payers are assured that oncology practices are accepting accountability for spending and agreeing to standards of care while focusing on care approaches that have the demonstrated ability to lower costs without harming quality.¹⁷

Private Insurer Incorporating Precision Medicine into Value-Based Care

Harvard Pilgrim Health Care is an example of a private insurer that has taken steps to incorporate precision medicine into a value-based care model. In February 2018, Harvard Pilgrim entered into a contract with the test developer Illumina to broaden eligibility of noninvasive, prenatal genetic testing to pregnant women under age 35 (average risk pregnancies). While the insurer anticipates that savings on other prenatal screenings will offset the costs of the next generation sequencing tests, Illumina has agreed to pay for cost overages. A two-year study will help determine whether expanded availability of noninvasive prenatal genetic testing will affect spending and demonstrate clinical value to patients.¹⁸

AMA ACTIVITY

The AMA continues to work to aid physicians in the implementation of APMs and other components of MACRA. The AMA has conducted educational activities including webinars and regional conferences for physicians and staff and continues these activities. Recent AMA advocacy activity has called for improvements in the methodologies behind APMs to reduce barriers and enable more physicians to participate. The AMA has made extensive comments on all MACRA proposed and final rules and has successfully advocated for a number of changes, including the modification of the definition of financial risk.

AMA advocacy efforts are also focused on the Physician-Focused Payment Model Technical Advisory Committee (PTAC) and Physician-Focused Payment Models (PFPMs). The AMA attends and makes public comments at meetings of the PTAC, submits comments on its draft documents and stakeholder proposals, and works with specialty societies developing PFPM proposals to help address challenges they face in APM design. To that end, the AMA has convened APM workshops to bring together many of the leading physicians who are working on PFPM proposals to discuss potential solutions to these issues.

The AMA is also engaged in ongoing advocacy related to genetic/genomic precision medicine, including oversight of laboratory-developed tests, and implementation of the Protecting Access to Medicare Act which significantly revised the Medicare payment system for laboratory tests, including genetic tests.

Health IT and Digital Health

Significant improvements in EHRs and other health IT capabilities are critically needed for precision medicine to reach its potential under the new payment models. Robust and interoperable health IT systems must be able to access and display longitudinal health data from each patient regardless of where the data are stored. EHRs hold biological, behavioral and environmental data; however, impediments to accessing and securely exchanging data across health care systems must be overcome. The AMA actively promotes EHRs that can provide clinical decision support and use genetic/genomic data to provide clinically meaningful information to physicians. The AMA's Integrated Health Model Initiative supports a continuous learning environment to enable interoperable technology solutions and care models that evolve based on real-world use and feedback.

Beyond EHRs, the AMA is committed to influencing the evolution of health IT and digital health, both of which are integral to the implementation of precision medicine. The AMA provides leadership on digital solutions involving telemedicine and telehealth, mobile health, wearables, and remote monitoring. Using the expertise of physicians and input from partners on the leading edge of health technology, the AMA has developed resources, toolkits and training to help physicians evaluate and optimally use newly available technology for improved care.

Additionally, the AMA continues to educate physicians about the clinical uses of genetic/genomic services. To assist physicians encountering new precision medicine technologies, the AMA has partnered with Scripps Translational Science Institute and The Jackson Laboratory to develop "Precision Medicine for Your Practice," a series of online continuing medical education modules covering topics such as expanded carrier screening in prenatal care, prenatal cell-free DNA screening, somatic cancer panel testing, large scale sequencing as a diagnostic tool, and pharmacogenomics.¹⁹ The AMA has partnered with the NIH *All of Us* Research Program, a soon-to-be launched precision medicine initiative to study one million or more Americans.^{20, 21} Furthermore, the AMA has conducted surveys to better understand physician awareness and confidence with precision medicine practices. The AMA is also maintaining dialogue with other key stakeholders through activities such as the National Academies of Science, Engineering and Medicine Genomics Roundtable.²²

RELEVANT AMA POLICY

Policy H-385.913 created foundational policy to support the appropriate shift to physician-focused APMs. Policy H-385.913 promulgated goals for physician-focused APMs, developed guidelines for medical societies and physicians to begin identifying and developing APMs, and encouraged CMS and private payers to support provision of assistance to physician practices implementing APMs. The policy has been influential in related AMA advocacy thus far, which has included submission of extensive comments on the MACRA proposed and final rules and responses to draft documents from the PTAC and proposed models from Center for Medicare & Medicaid Innovation. The AMA has a key role in helping physicians develop and participate in APMs.

Building on Policy H-385.913, Policy H-385.908 offers a set of guidelines to address the barriers that interfere with the shift to value-based payment. Such barriers to the development and implementation of APMs include limitations of existing health IT capabilities, resource use measures, and resource use challenges including risk adjustment, attribution, and performance target-setting.

The AMA has extensive policy related to physician-led payment reform models. AMA policy is committed to promoting physician-led payment reform programs that serve as models for others working to improve patient care and lower costs (Policy D-385.963). Policy H-390.844 emphasizes the importance of physician leadership and

accountability to deliver high quality and high value to patients. In transitioning from the sustainable growth rate (SGR), the AMA advocates for providing opportunities for physicians to determine payment models that work best for their patients, their practices, and their regions (Policy H-390.844). Policy D-390.953 directs the AMA to advocate with CMS and Congress for APMs developed in concert with specialty and state medical organizations. Policy H-450.931 recognizes that physicians will need assistance transitioning to APMs.

Policy H-390.849 directs the AMA to advocate for the adoption of physician payment reforms that promote improved patient access to high-quality and cost-effective care and that such reforms be designed with input from the physician community. It calls for reformed payment rates that are sufficient to maintain a sustainable medical practice and that payment reform implementation should be undertaken within a reasonable timeframe and with adequate assistance.

Policy D-185.980 established foundational policy on payment and coverage for genetic/genomic precision medicine. The policy encourages payers to adopt processes and methodologies for determining coverage and payment for genetic/genomic precision medicine that: promote transparency and clarity; involve multidisciplinary stakeholders; describe the evidence being considered; provide opportunities for comment and review as well as meaningful reconsiderations; and incorporate value assessments that consider the value of genetic/genomic tests and therapeutics to patients, families and society as a whole, including the impact on quality of life and survival. Policy D-185.980 also encourages the development of a comprehensive payment strategy that facilitates more consistent coverage of genetic/genomic tests and therapeutics that have clinical impact, and also encourages national medical specialty societies to develop clinical practice guidelines incorporating precision medicine approaches.

Policy H-410.948 provides guidance on the development of clinical pathways and supports the development of transparent, collaboratively constructed clinical pathways that are implemented in ways that promote administrative efficiencies for both providers and payers; promote access to evidence-based care for patients; recognize medical variability among patients and individual patient autonomy; promote access to clinical trials; and are continuously updated to reflect the rapid development of new scientific knowledge. Additionally, the AMA has significant and comprehensive policy on health IT. Policy H-450.933 encourages efforts to develop and fund clinical data registries; supports flexibility in the development and implementation of clinical data registries; encourages physicians to participate in clinical data registries; and advocate for and support initiatives that minimize the costs of physician participation in clinical data registries.

DISCUSSION

With MACRA taking effect and precision medicine gaining traction in clinical practice, the Council believes that physicians need to lead the development and integration of these two promising innovations. It is important that the payment and delivery reform movement recognizes the incremental value of precision medicine, especially as more evidence of its effectiveness becomes available. With the emergence of APMs and the drive to value, the AMA is poised to be a leader in addressing unnecessary care costs and realizing the benefits of APMs, and one of the most valuable ways to maximize value may be through precision medicine, particularly for certain specialties.

The Council believes that clinical pathways provide an opportunity to confront the tension between achieving cost-savings targets and providing better patient care and improving outcomes and recognizes the utility of data registries. To that end, AMA policy on clinical pathways (Policy H-410.948) and data registries (Policy H-450.933) is recommended for reaffirmation. To further ensure that clinical pathways are successful, the Council recommends affirming that they should be developed by clinical experts, including national medical specialty societies, and be leveraged by or integrated into EHRs for decision support, unified documentation, and automation of communication with payers for authorization.

Because expert-driven, evidence-based clinical pathways can help physicians identify genetic/genomic tests and services for patients, the Council recommends encouraging APMs to incorporate them as appropriate and as recommended by national medical specialty societies. The Council further believes that appeal mechanisms should be available to patients and physicians when national medical specialty society-recommended pathways are rejected. The Council also recognizes the potential impact of rapid learning systems on precision medicine and APMs, and recommends supporting transparent and accessible rapid learning systems with the ability to extract clinically meaningful information and use it to modify clinical practice guidelines and pathways in real-time.

For many providers, especially those participating in APMs, it is challenging to use the resources necessary to assess the full clinical and economic value of precision medicine when confronted with high up front cost of new technologies, particularly when the use of new tests or therapeutics may negatively affect a provider's cost-savings targets. Accordingly, the Council recommends that the AMA support assessment within new payment and delivery models of the value of evidence-based precision medicine tests and therapeutics to patients, families and the health care system, including the impact on patient experience, disease progression, quality of life and survival.

The Council firmly believes that the APM focus on lowering costs must not have the unintended effect of discouraging adoption and use of innovative tests and therapeutics that, though more expensive in the short-term, have the potential to deliver better long-term outcomes for patients. Accordingly, the Council recommends that the AMA encourage APMs to integrate precision medicine approaches, where appropriate, to improve the diagnostic process and personalize patient care.

Finally, the Council recognizes that a key challenge to integrating precision medicine into new payment models is that APMs are generally structured around cost savings within a specified window of time and may not account for improved outcomes downstream. Therefore, the Council recommends that the AMA encourage APMs to consider measuring patient outcomes and quality improvements over time to allow for the use of precision medicine tests and therapeutics that have clinical value.

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-410.948 supporting the development of transparent, collaboratively constructed clinical pathways that promote administrative efficiencies and access to evidence-based care, recognize variability among patients and individual patient autonomy, promote access to clinical trials, and are continuously updated to reflect new scientific knowledge.
2. That our AMA reaffirm Policy H-450.933 encouraging efforts to develop and fund clinical data registries, and supporting flexibility in the development and implementation of clinical data registries.
3. That our AMA affirm that clinical pathways should be developed by clinical experts, including national medical specialty societies, and should be leveraged by or integrated into electronic health records for decision support, seamless documentation, and automation of communication with payers for authorization.
4. That our AMA encourage alternative payment models (APMs) to incorporate evidence-based clinical pathways as appropriate and as recommended by national medical specialty societies.
5. That our AMA support transparent and accessible rapid learning systems with the ability to extract clinically meaningful information and use it to modify clinical practice guidelines and pathways in real-time.
6. That our AMA support assessment within new payment and delivery models of the value of evidence-based precision medicine tests and therapeutics to patients, families and the health care system, including the impact on patient experience, disease progression, quality of life and survival.
7. That our AMA encourage APMs to integrate precision medicine approaches, where appropriate, to improve the diagnostic process and personalize patient care.
8. That our AMA encourage APMs to measure patient outcomes and quality improvements over time to allow for the use of precision medicine tests and therapeutics that have clinical value.
9. That our AMA reaffirm Policy D-185.980, which encourages public and private payers to adopt a series of processes and methodologies for determining coverage and payment for genetic/genomic precision medicine.

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7. INSULIN AFFORDABILITY (RESOLUTION 826-I-17)

Reference committee hearing: see report of Reference Committee A.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

IN LIEU OF RESOLUTION 826-I-17 REMAINDER OF REPORT FILED

See Policies H-100.980, H-110.984, H-110.986, H-110.987, H-110.990, H-110.991, H-110.992, H-125.979, H-155.960 and H-185.939

At the 2017 Interim Meeting, the House of Delegates referred Resolution 826, "Improving Affordability of Insulin," which was sponsored by the American Association of Clinical Endocrinologists (AACE) and the Endocrine Society (ES), and which directed the American Medical Association (AMA) to:

(1) work with relevant medical specialty societies to convene a summit with participation by patients, clinicians, manufacturers, pharmacy benefit managers (PBMs), insurers and the appropriate federal representatives to

highlight the dramatic increase in insulin costs and identify potential solutions; (2) pursue solutions to reduce patient cost sharing for insulin and ensure patients benefit from rebates at the point of sale; (3) work with health insurance companies and federal agencies to stabilize drug formularies and reduce non-medical switching by encouraging plans to cover insulin products at the same cost listed on a drug formulary throughout the entire plan year; (4) encourage insulin price and cost transparency among pharmaceutical companies, PBMs and health insurance companies; and (5) work with electronic medical record vendors and insurance companies to integrate current formularies and price information into all systems so physicians and patients can make informed decisions on insulin products to reduce cost burdens on patients.

The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2018 Annual Meeting. This report highlights insulin as one among the many prescription drugs to recently experience exceptional price increases, government and legal actions to address insulin affordability, opportunities to identify more affordable options for patients in need, and the strong ongoing efforts of the AMA to address affordability of pharmaceuticals. Finally, this report presents policy recommendations.

BACKGROUND

Approximately 30 million Americans have diabetes,¹ and approximately six million Americans use insulin.² As explained by the AACE and the ES, patients with type 1 diabetes need insulin for survival and frequently insulin is the only drug that can control the diabetes of patients with type 2 diabetes.³ Insulin can be very expensive, and the price has increased dramatically over the course of the past decade. For example, the annual retail price of Humulin R (U-500) 500 units/mL—an insulin marketed by Eli Lilly and Company (Lilly)—increased from \$2,487 at the end of 2005 to \$15,860 by the end of 2015.⁴ Humulin is one of six brand-name drugs that increased in price by 500 percent or more from 2006 to 2015.⁵ In general, the mean price per milliliter of insulin increased almost 200 percent, from \$4.34 per milliliter in 2002 to \$12.92 per milliliter in 2013.⁶

High insulin prices impact stakeholders throughout the health care system. Of course, uninsured patients paying cash for their prescriptions are exposed directly to high insulin prices. Insured patients are also directly impacted by high insulin prices when they are still in the deductible period, when the drug prescribed is not covered by their insurance, when a nonpreferred formulary status for a particular insulin product leads to a higher patient cost-share, and when a Medicare Part D beneficiary is in the “donut hole.”⁷ As the number of patients enrolled in high-deductible health plans and Medicare Part D continues to rise, more patients will be vulnerable to significant drug prices. Insulin prices also impact health plans/payers and PBMs. The impact of insulin expenditures on Medicare and Medicaid has been noteworthy. For example, expenditures for just one long-acting insulin analogue, glargine, were the second largest of all Medicare expenditures in 2015.⁸ In that year, Medicare Part D spent more than \$4.3 billion and Medicaid spent more than \$1.4 billion on glargine alone.⁹

Pharmaceutical manufacturers, PBMs and others in the pharmacy supply chain continue to blame each other for high drug prices,¹⁰ but some have taken steps that may ameliorate the impact on patients. For example, Novo Nordisk has indicated that it would limit future annual price increase percentages to not exceed single digits, ensure that a lower-priced option for human insulin remains available, and continue support of copay assistance and patient assistance programs, which are described later in this report.¹¹

At the same time, it is important to emphasize that insulin is one of the many essential drugs across all categories of pharmaceuticals—brand name, specialty, and generic—to experience remarkable price increases. For example, the brand name drug Wellbutrin XL, used to treat depression, experienced a price increase of 1,185 percent over a ten-year study period ending in 2015.¹² Over the same ten-year study period, the specialty drug Enbrel, used to treat inflammatory and immunological disorders, experienced a 172 percent price increase.¹³ Finally, between 2010 and 2015, the generic drug divalproex sodium, an anticonvulsant, experienced a price increase of 450.6 percent.¹⁴ The Council acknowledges that, as with insulin, if patients are not able to take these medications correctly due to affordability, complications can result.

GOVERNMENT AND LEGAL ACTIONS TO ADDRESS INSULIN AFFORDABILITY

The significant and complicated factors contributing to increases in insulin prices have led both state and federal governments, as well as private citizens, to take formal action. To date, at least five states and a federal prosecutor are demanding information from insulin manufacturers and PBMs.¹⁵ In addition, prominent class-action attorneys are

bringing lawsuits on behalf of patients.¹⁶ For example, a class action complaint filed in Massachusetts in January 2017 points to evidence that, “In 13 instances since 2009, Sanofi and Novo Nordisk raised the benchmark prices of their long-acting analog insulins, Lantus and Levemir, in tandem, ‘taking the same price increase down to the decimal point within a few days of each other’ . . . Eli Lilly and Novo Nordisk have engaged in the same lock-step behavior with respect to their rapid-acting analog insulins, Humalog and Novolog.”¹⁷ The complaint further alleges that these pharmaceutical companies artificially inflated their list prices to secure positions on PBMs’ formularies, with PBMs demanding higher rebates in exchange for including drugs on their preferred-drug lists.¹⁸ Similarly, three of the main insulin manufacturers—Sanofi-Aventis, Novo Nordisk and Lilly—along with three of the largest PBMs—CVS Health, Express Scripts and OptumRx—are subject to a class action lawsuit, alleging that they together caused “rapid and lockstep price increases of more than 150 percent in insulin treatments.”¹⁹

In addition, there has recently been legislative and regulatory action to improve insulin affordability. In November 2016, two US Senators requested that the Department of Justice (DOJ) and the Federal Trade Commission (FTC) investigate possible collusion among insulin makers.²⁰ Concerns regarding PBMs became a theme in a February 2018 hearing by the House Energy and Commerce Subcommittee on Oversight and Investigations that was focused on concentration in the health care system.²¹ Specifically relevant to this report, Ranking Member of the Subcommittee, Rep. Diana DeGette (D-Colo.), explored whether PBM consolidation contributed to higher prices for insulin.²² Additionally, the Food and Drug Administration (FDA) is working to “improve transparency and encourage the development and submission of abbreviated new drug applications (ANDAs) in markets with limited competition.”²³ To that end, it has developed a list identifying approved new drug application (NDA) drug products that are off-patent and off-exclusivity, and for which the FDA has not yet approved an ANDA. This list of applications was updated in December 2017, and it includes several insulin products (insulin human, insulin lispro protamine recombinant, and insulin lispro recombinant).²⁴ On the state level, in 2017, Nevada passed an act that requires the state’s Department of Health and Human Services to compile a list of prescription drugs that it determines to be essential for treating diabetes.²⁵ The manufacturers and PBMs associated with essential diabetes drugs will have to submit annual reports to the state containing drug cost information,²⁶ which will be analyzed by the state and reported on its website.²⁷ However, pharmaceutical companies have begun challenging the Nevada law in court.²⁸

OPPORTUNITIES TO IDENTIFY MORE AFFORDABLE ALTERNATIVES

Value-Based Insurance Design

Value-based insurance design (VBID) uses cost-sharing as a tool to encourage the use of specific “high-value services,” which have been defined as those services that are clinically meaningful in the practice of medicine, improve quality of care or clinical outcomes for patients, and are usually standards of care as part of evidence-based guidelines or clinical care pathways.²⁹ Unlike traditional benefit designs that apply a standard set of cost-sharing requirements to all services and all patients, VBID determines coverage and cost-sharing rules based on an assessment of the clinical value of individual health care treatments or services.

Diabetes management is an especially strong example of VBID’s potential. Aligning incentives to encourage blood glucose control prevents long-term complications from diabetes that can be physically and financially devastating to patients and the health care system. As AACE and ES have explained, without adequate control of diabetes, patients have a higher risk of developing microvascular complications such as blindness, kidney disease and nerve damage, and macrovascular complications including heart attacks and strokes.³⁰ A recent study used actuarial modeling to predict the financial impact of VBID for Medicare beneficiaries, and it used a design that incorporated targeted reductions in cost-sharing for select chronic conditions.³¹ The study specifically focused on diabetes patients and included insulin and other glycemic-lowering agents among the high-value services targeted for reduced cost-sharing. The actuarial assumptions of this model indicated that removing cost-sharing for targeted high-value services would increase their use by five to 15 percent, and the fiscal impact of that additional spending would be partially offset by fewer inpatient stays and emergency department visits. The study found that for diabetes patients under this model, member cost-sharing would decrease, societal impact would be close to cost neutral, and the increase in cost to health plans would be “very modest.”³²

Recognizing its potential, VBID is gaining traction as an insurance design to improve affordability. The recently enacted Bipartisan Budget Act of 2018 incorporates the [Creating High-Quality Results and Outcomes Necessary to Improve Chronic \(CHRONIC\) Care Act of 2017](#), which includes expansion of the [Medicare Advantage Value-Based Insurance Design Model](#) to all 50 states by no later than January 1, 2020.³³ The model allows Medicare Advantage

plans the flexibility to reduce cost-sharing or offer supplemental benefits to enrollees with specified chronic conditions, focusing on the services that are of highest clinical value to them. This Act demonstrates growing bipartisan support for the expanded role of VBID principles in public and private payers.

The Role of Biosimilars

Biosimilars may play a unique role in the insulin market. Currently, no insulin glargine products are licensed under the Public Health Service Act, so there is no “reference product” for a proposed biosimilar product. Instead, when Basaglar launched in December 2016, the FDA referred to it as “follow-on” insulin to the originator drug, Lantus. (This definitional confusion should resolve following a change to FDA law in 2020).³⁴ As with other drugs, the price patients will pay for Basaglar varies depending on their health insurance plan.³⁵ Additionally, Basaglar experienced uptake that varied based on patients’ insurance type.³⁶ As of March 2017, Basaglar had achieved only approximately five percent market share. However, in the small portion of the market where insurance formularies preferred Basaglar to Lantus, it achieved approximately 50 percent market share.³⁷ Notably, this year, Basaglar is preferred in Medicare Part D plans, as well as other commercial plans.³⁸ Another key item to watch is a second follow-on insulin glargine, Lusduna, which gained tentative FDA approval in July 2017, but will not be issued final approval until a patent infringement suit, brought by Lantus’ maker, Sanofi, concludes.³⁹ Due to stringent regulations and the cost of bringing “follow-on” or biosimilar insulins to market, some analysts expect that the mean price of insulin will not decrease as a result of “generic” competition.⁴⁰ In contrast, other analysts have speculated that once several follow-on insulin glargine products are actively competing with Lantus and its next-generation insulin glargine brand, discounts and rebates could mean savings of approximately 30 percent, as the market niche becomes saturated.⁴¹

The Role of Older Insulins

To avoid the high price of many insulin regimens, some physicians and analysts have advocated for use of older, less expensive insulins, when clinically appropriate to do so,⁴² and this may vary among patients with type 1 and type 2 diabetes. As a general principle, the more severe the insulin deficiency (for type 1 and for some type 2 diabetes), “the more important it is to have considerable mimicry of normal physiology to successfully lower glucose and do so with safety. Although not superior in overall glycemic lowering efficacy compared to human insulin, the analogs . . . have gained progressive popularity despite their increased cost. Today, analogs used as basal bolus therapy are considered the standard of care for patients who have type 1 diabetes mellitus and are increasingly used in type 2 diabetes.”⁴³

In fact, the proportion of patients using more expensive, newer insulin analogs has substantially increased, even though data suggests that there is “little clinical benefit” to using insulin analog versus regular human insulin and neutral protamine Hagedorn (NPH) for type 2 diabetes.⁴⁴ In 2000, 19 percent of privately insured adults with type 2 diabetes were using analog insulin, but by 2010, 96 percent of that population was using insulin analogs.⁴⁵ The older insulins, however, are still considered to be as effective as the analogs in controlling blood glucose for most patients with type 2 diabetes.⁴⁶ Moreover, a vial of NPH (N), human regular (R), or premixed 70/30 N/R insulin (Novolin N, R, or 70/30) can be obtained for as little as \$25.⁴⁷ At the same time, given the substantial increase in use of insulin analogs since 2000, younger clinicians may not be as well versed in the use of older insulins, with many training programs no longer emphasizing the use of human insulins.⁴⁸ Accordingly, guidance and educational materials can help younger physicians become more comfortable with prescribing more affordable insulin alternatives.⁴⁹ Consistent with these recommendations, a recent study compared prescription drug spending in the US to nine other high-income countries and found that US citizens consume a mix of drugs that include a high proportion of newer, more expensive medications without evidence of better health outcomes than the other nine countries examined.⁵⁰ The study observed that, unlike the US, the other nine countries have processes to assess not just whether a new drug is effective, but whether it is more effective than existing therapies, and sometimes, whether it is cost-effective.⁵¹ A process for including cost-effectiveness in comparative effectiveness research for pharmaceuticals is consistent with AMA Policy H-110.986, which is detailed in the policy section below.

Improving Price Transparency

With timely, accurate information about what a specific prescription will cost a specific patient, physicians and patients will be in a stronger position to jointly develop optimal treatment plans. As detailed below, the AMA is engaged in significant activity, supported by longstanding policy, to advocate for improved prescription drug price transparency. Improved transparency at the point of sale may also help patients address affordability concerns.

Many health care industry stakeholders can potentially help improve insulin affordability. In November 2017, Surescripts announced a Real-Time Prescription Benefit to advance this goal. Surescripts is collaborating with six electronic health records (EHR) companies (representing 53 percent of the US physician base) and leveraging information from PBMs CVS Health and Express Scripts (representing nearly two-thirds of US patients), “to deliver patient-specific benefit and price information to providers in real time at the point of care. Once integrated with the EHR, the solution will also display therapeutic alternatives so that the prescriber and patient can collaborate in selecting a medication that is both clinically appropriate and affordable.”⁵² UnitedHealthcare and OptumRx are collaborating to provide a similar tool, specifically for their enrollees.⁵³ With PreCheck MyScript, before prescribing a medication, physicians can run a pharmacy trial claim to see how much a patient would be charged for a specific medication. The system will also provide lower-cost alternatives, when available.

In addition, pharmacists play an important role. Pharmacists may be aware of less expensive prescription drug options, but pharmacists can be prevented from informing patients of these options due to certain provisions in their contracts with PBMs.⁵⁴ For example, a drug formulary can require patients to spend more on a prescription copay than they would be charged if they purchased the drug without insurance.⁵⁵ So called “gag clauses” in pharmacy-PBM contracts can bar pharmacists from telling consumers about less expensive options, such as not using their insurance. Moreover, “clawback” provisions can allow PBMs to take back the difference between a higher copay amount and a lower negotiated rate. Bipartisan bills have recently been introduced in both the Senate⁵⁶ and the House⁵⁷ to prohibit these restrictions on pharmacies and pharmacists.

Additionally, financial assistance programs can help eligible patients, but as the ES has explained, these programs are often inaccessible or overly complicated for the patients who need them the most.⁵⁸ For example, the Novo Nordisk Savings Card can help patients save hundreds of dollars on their diabetes medication.⁵⁹ However, to be eligible for this program, patients must be enrolled in a commercial insurance plan (patients paying cash and those insured through any federal or state plan are ineligible).⁶⁰ Additionally, the discount only applies for up to 24 months, and is subject to maximum benefit limitations.⁶¹ Sanofi-Aventis similarly offers a Sanofi Rx Savings Card, but it too carries eligibility restrictions that are not easily found on its website.⁶² Finally, Lilly offers limited time offers for discounts on insulin products, but each offer is subject to eligibility requirements and differing expiration dates.⁶³

Some patients may benefit from other forms of financial assistance, but this too is complicated. Patients without health insurance or without prescription drug coverage can apply for patient assistance programs, and the nonprofit NeedyMeds can help patients find programs that offer free or low-cost insulin for those who meet eligibility requirements.⁶⁴ Some patients who have prescription drug coverage, especially those with high deductible health plans, may find that cash and coupon prices can be lower than their insurance copay or coinsurance.⁶⁵ Websites like GoodRx can help patients find the lowest prices for their insulin.⁶⁶ However, companies that provide health insurance and prescription drug coverage have started instituting “copay accumulators,” which can significantly impact patients’ out-of-pocket costs when using drug coupons.⁶⁷ Previously, when patients used copay coupons to reduce the price they pay for their prescriptions, the value of those coupons counted toward their deductible or out-of-pocket maximum. However, the new copay accumulators will not count the coupons’ value toward helping patients spend down their deductibles and out-of-pocket maximum. Accordingly, once patients use the full value of their drug coupons, they will be subject to more of the cost than they had been before.⁶⁸ Moreover, some insurance companies limit insured patients’ abilities to use prescription coupons at all.⁶⁹

AMA POLICY AND ADVOCACY

Extensive AMA policy and highly visible AMA advocacy directly respond to the resolves of referred Resolution 826-I-17 and continue to strive for greater prescription drug cost transparency and affordability.

AMA Policy

The Council agrees with the AACE and ES that a key issue in addressing insulin affordability is working toward reduced patient cost-sharing. AMA policy has historically strongly supported VBID, which can achieve reduced patient cost-sharing. For example, Policy H-155.960 encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. The policy stipulates that consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance. Policy H-185.939 outlines principles to guide the design and implementation of VBID programs, stating that VBID explicitly consider the clinical benefit of a given service or

treatment when determining cost-sharing or other benefit design elements, and that coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Supporting the role of physicians in engaging patients in joint decision-making to select an insulin regimen that appropriately balances clinical needs and cost-effectiveness, Policy H-450.938 stipulates that the cost of alternate interventions, in addition to patient insurance coverage and cost-sharing requirements, should be evaluated. Moreover, the policy states, physicians should encourage their patients to participate in making value-based health care decisions.

AMA policy also supports value-based pricing for pharmaceuticals (Policy H-110.986). The policy specifically calls for value-based pricing processes that incorporate affordability criteria and that include cost-effectiveness analyses in comparative effectiveness research. Similarly, Policy H-110.990 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. Finally, Policy H-125.977 advocates for economic assistance, including coupons and other discounts for patients, whether they are enrolled in government health insurance programs, enrolled in commercial insurance plans, or are uninsured.

Another key to improving insulin affordability is improving price transparency. Consistent with Resolution 826-I-17 and ES recommendations,⁷⁰ Policy H-125.979 supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term. Additionally, the AMA developed model state legislation entitled, "An Act to Increase Drug Cost Transparency and Protect Patients from Surprise Drug Cost Increases during the Plan Year" (AMA Model Act), and it directly addresses the issue of stabilized formularies and cost transparency. The AMA Model Act specifically responds to Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs and health insurance companies. The policy also supports drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase, and legislation that authorizes the Attorney General and/or the FTC to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients. In addition, the policy encourages FTC actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives. Also, Policy H-110.991 advocates for greater prescription drug price transparency at the pharmacy point of sale by: (1) advocating that both the retail price and the patient's copay be listed on prescription receipts, (2) pursuing legislation that would require pharmacies to inform patients of the cash price as well as the formulary price of any medication prior to purchase, and (3) opposing provisions in contracts between pharmacies and PBMs that would prohibit pharmacies from disclosing when a patient's copay is higher than the drug's cash price.

Physicians will be in a stronger position to help their patients with insulin affordability concerns if information systems can integrate price information, thus empowering physicians and patients to make informed decisions at the point of prescribing. The AMA Model Act also addresses the issue of timely decision support, consistent with Policy H-450.938, which states that physicians should have easy access to and review the best available data associated with costs at the point of decision-making, which necessitates cost data to be delivered in a reasonable and useable manner by third-party payers and purchasers. In addition, the policy calls for physicians to seek opportunities to improve their information technology infrastructures to include new and innovative technologies to facilitate increased access to needed and useable evidence and information at the point of decision-making. Related, Policy H-125.979 encourages PBMs, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing, and promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide. Similarly, Policy H-110.990 supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can jointly decide on treatment.

Several AMA policies support the FDA's efforts to highlight drugs that are off-patent and off-exclusivity. Specifically, Policy H-100.980 supports a strong and adequately funded FDA to ensure that safe and effective medical products become available as efficiently as possible. The policy 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. Related, Policy H-125.984 states that Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process. Finally, Policy H-125.980 supports FDA implementation of the Biologics

Price Competition and Innovation Act of 2009 in a manner that places appropriate emphasis on promoting patient access, protecting patient safety, and preserving market competition and innovation.

Also noteworthy are the many policies establishing a framework for the AMA's approach to improving drug pricing. For example, 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 PBMs 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.

AMA Activity

AMA Model Legislation: The AMA Model Act referenced previously provides a template that state legislatures can modify to increase prescription drug cost transparency in a variety of ways, and it specifically advances many of the goals of Resolution 826-I-17 with regard to price and cost transparency, as well as integration into EHRs. Specifically, under the AMA Model Act, manufacturers of prescription medication available in any state that implements this act would be required to disclose a variety of their costs, as well as the amount of financial assistance they provide to patients; health insurers and PBMs operating in the state would be required to disclose any discounts or other financial consideration they received that affects the price and cost-sharing of covered medicines placed on a formulary. Consistent with ES recommendations,⁷¹ the AMA Model Act would also authorize a pilot study to integrate transparency data at the point of care, with information such as medicines' formulary status, cost-sharing tier, patient out-of-pocket cost, and coverage restrictions (eg, prior authorization, step therapy, quantity limits) being integrated into the clinical and prescribing workflows of physicians and other health care providers in EHR or electronic prescribing systems. Finally, consistent with Policy H-110.991, the AMA prepared a new model bill that prohibits clawbacks and standard gag clauses in pharmacy-PBM contracts. Several states have enacted and/or are considering similar legislation, and with its new model bill, the AMA will advocate for greater nation-wide adoption of such policies.

AMA State and National Engagement: The AMA has been engaged in legislative and regulatory advocacy concerning prescription drug pricing and costs. For example, in December 2017, the AMA testified at a hearing of the Health Subcommittee of the House Committee on Energy and Commerce on examining the pharmaceutical supply chain. The AMA has been engaged at the National Association of Insurance Commissioners as it develops its Prescription Drug Benefit Management Model Act, including with regard to mid-year formulary changes. On the state level, in 2017, the AMA supported Assembly Bill 762 in New Jersey, which would help provide patients and the legislature with relevant information about the manufacturing, production, research and development, advertising and other associated costs for prescription medications. Additionally, the AMA continues to urge state medical associations to have the AMA Model Act introduced.

AMA Grassroots Campaign: Pursuant to Policy H-110.987, and consistent with Resolution 826-I-17, in 2016, the AMA convened a Task Force on Pharmaceutical Costs, which met four times to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs. The Task Force agreed that increasing transparency among pharmaceutical companies, health plans and PBMs should be the first focus of the grassroots campaign, which led to the launch of the *TruthinRx* campaign in 2016. The goal of *TruthinRx* is to expose the opaque process that pharmaceutical companies, PBMs, and health plans engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to demand transparency. To date, over 150,000 individuals have signed a petition to members of Congress in support of greater drug pricing transparency. Additionally, the *TruthinRx.org* website provides a template letter that website visitors can customize and directly send to their US Senators and US

Representatives, calling on them to support increased transparency in prescription drug prices.⁷² Finally, the Council notes that the *TruthinRx.org* website has content specifically addressing insulin pricing.⁷³ Coordinated with AMA model legislation, and state and national engagement, *TruthinRx* is continuously updated to reflect advances in AMA policy and pharmaceutical industry activities.

DISCUSSION

The Council lauds the sponsors of Resolution 826-I-17 for highlighting the price increases of insulin and shares the concerns that have led to class action lawsuits, state and federal actions, and congressional requests that the DOJ and FTC investigate possible collusion among insulin makers. The market factors contributing to the insulin price increases are complex and span the pharmaceutical supply chain. Pursuant to Policy H-110.992, the AMA is committed to monitoring the relationships between PBMs and the pharmaceutical industry and strongly discouraging arrangements that could cause a negative impact on the cost or availability of essential drugs. In addition, Policy H-110.987 supports legislation that authorizes the Attorney General and/or the FTC to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients. Building upon these policies, the Council recommends that the AMA encourage the FTC and DOJ to monitor insulin pricing and market competition and take enforcement actions, as appropriate.

As demonstrated by the extensive policy and activity summarized in this report, the AMA is deeply committed to efforts to improve prescription drug affordability in general, and insulin affordability, in particular. In addition to supporting the FTC and DOJ, the AMA has established policy that supports the FDA as it strives to increase access to high quality generic and biosimilar drugs. Specifically, under Policy H-100.980, the AMA affirms its commitment to continuing to work with the FDA on controversial issues concerning drugs, biologics and pharmaceuticals to try to resolve concerns of physicians.

VBID presents a powerful opportunity to reduce patient cost-sharing for high-value services, such as diabetes treatment, and AMA policy strongly supports this model. Policy H-185.939 outlines principles to guide the design and implementation of VBID programs, including that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements. Policy H-110.986 specifically supports value-based pricing for pharmaceuticals, and Policy H-155.960 encourages third-party payers to use targeted benefit design, with cost-sharing requirements determined based on the clinical value of a health care service, with consideration given to patient income and other factors known to impact compliance. Similarly, Policy H-110.990 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. In addition, the policy supports joint physician-patient decision-making, encouraging the development and use of technology to enable physicians and patients to determine the actual price and out-of-pocket costs of prescription drugs prior to making prescribing decisions.

In recent years, the AMA has demonstrated an ongoing commitment to improving prescription drug price transparency. As detailed above, the *TruthinRx* campaign continues a powerful grassroots campaign for greater transparency in prescription drug pricing, and the AMA Model Act specifically responds to Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs, and health insurance companies. Moreover, pursuant to Policy H-110.987, the AMA supports drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase. Similarly supporting transparency and collaboration across the pharmacy supply chain, Policy H-125.979 supports AMA efforts to encourage PBMs, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing. In this way, health care technology and shared information can promote optimal physician-patient joint decision making. Together, these efforts are accomplishing the goals of Resolution 826-I-17. As a logical next step, the Council recommends that the AMA disseminate the model state legislation it has developed to promote increased drug price and cost transparency and to prohibit “clawbacks” and standard gag clauses in contracts between pharmacies and PBMs that bar pharmacists from telling consumers about less expensive options, such as choosing to pay cash rather than using insurance, to purchase their medication. Moreover, the Council recommends that the AMA provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.

The Council also thanks the AACE and the ES for their expertise and for calling attention to the need for training on the appropriate use of regular human insulin and neutral protamine Hagedorn for post-graduate physicians, fellows, residents, and students. The Council recommends that the AMA support initiatives, such as those by AACE, ES, and other national medical specialty societies, that strive to fill this gap in continuing medical education. Similarly, to help physicians better understand the complex challenges their patients may face in paying for their medication, the Council recommends that the AMA support physician education regarding drug price and cost transparency and challenges that arise at the pharmacy.

As described above, it is important to continue to view insulin affordability within the context of the much broader issue of prescription drug affordability in the US. The AMA has a deep and longstanding commitment to improving patient access to affordable prescriptions. Recognizing that access to critical drugs across many critical disease states is jeopardized by high prices and continued price increases, the AMA has made a strategic decision to work toward broad-based reforms, rather than to examine one disease state or drug at a time. Otherwise, the AMA would be in a position to require individual summits and advocacy campaigns that are unique to each of the critical pharmaceutical challenges facing AMA members and their patients, which would not be a sustainable advocacy model. Accordingly, the Council's recommendations encourage continued AMA leadership on a broad strategy to address pharmaceutical pricing, while supporting initiatives to improve the affordability of insulin for our patients.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 826-I-17, and that the remainder of the report be filed:

1. That our American Medical Association (AMA) encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate.
2. That our AMA disseminate model state legislation to promote increased drug price and cost transparency and to prohibit "clawbacks" and standard gag clauses in contracts between pharmacies and pharmacy benefit managers (PBMs) that bar pharmacists from telling consumers about less-expensive options for purchasing their medication.
3. That our AMA provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
4. That our AMA support physician education regarding drug price and cost transparency and challenges patients may encounter at the pharmacy point-of-sale.
5. That our AMA support initiatives, including those by national medical specialty societies, that provide physician education regarding the cost-effectiveness of insulin therapies.
6. That our AMA reaffirm Policy H-110.992, which 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.
7. That our AMA reaffirm Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies; supports drug price transparency legislation that requires public notice by pharmaceutical manufacturers when certain price increase triggers are reached; and supports legislation that authorizes the Attorney General and/or the FTC to take legal action to address price gouging by pharmaceutical manufacturers and increase patient access to affordable drugs.
8. That our AMA reaffirm Policy H-100.980, which states that the AMA will continue to work with the Food and Drug Administration on controversial issues, including those concerning drugs, biologics, and pharmaceuticals, to try to resolve concerns of physicians.
9. That our AMA reaffirm Policy H-125.979, which supports legislation or regulation to ensure that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding

year, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term.

10. That our AMA reaffirm Policies H-185.939, H-155.960 and H-110.986 which support value based insurance design and value based pricing for pharmaceuticals.
11. That our AMA reaffirm Policy H-110.990 which supports cost-sharing requirements for prescription drugs that consider factors known to affect patient compliance and the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of prescription drugs prior to making prescribing decisions.

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APPENDIX - Policies Recommended for Reaffirmation

H-100.980 Food and Drug Administration

(1) AMA policy states that a strong and adequately funded FDA is essential to ensuring that safe and effective medical products are made available to the American public as efficiently as possible. (2) Our AMA: (a) continue to monitor and respond appropriately to legislation that affects the FDA and to regulations proposed by the FDA; (b) continue to work with the FDA on controversial issues concerning food, drugs, biologics, radioactive tracers and pharmaceuticals, and devices to try to resolve

concerns of physicians and to support FDA initiatives of potential benefit to patients and physicians; and (c) continue to affirm its support of an adequate budget for the FDA so as to favor the agency's ability to function efficiently and effectively. (3) Our AMA will continue to monitor and evaluate proposed changes in the FDA and will respond as appropriate.

Policy Timeline Sub. Res. 548, A-92 BOT Rep. 32, A-95 BOT Rep. 18, A-96 Reaffirmed: BOT Rep. 7, I-01 Reaffirmation I-07

H-110.986 Incorporating Value into Pharmaceutical Pricing

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

2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. 3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size.

Policy Timeline CMS Rep. 05, I-16 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: CMS-CSAPH Rep. 01, A-17

H-110.987 Pharmaceutical Costs

1. Our AMA encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.

2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.

3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.

4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.

5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.

6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.

7. Our AMA supports legislation to shorten the exclusivity period for biologics.

8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.

9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.

10. Our AMA supports: (a) drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10% or more each year or per course of treatment and provide justification for the price increase; (b) legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and (c) the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10% or more each year or per course of treatment. 11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.

Policy Timeline CMS Rep. 2, I-15 Reaffirmed in lieu of: Res. 817, I-16 Appended: Res. 201, A-17 Reaffirmed in lieu of: Res. 207, A-17 Modified: Speakers Rep. 01, A-17 Appended: Alt. Res. 806, I-17

H-110.990 Cost Sharing Arrangements for Prescription Drugs

Our AMA:

1. believes that cost-sharing arrangements for prescription drugs should be designed to encourage the judicious use of health care resources, rather than simply shifting costs to patients;

2. believes that cost-sharing requirements should be based on considerations such as: unit cost of medication; availability of therapeutic alternatives; medical condition being treated; personal income; and other factors known to affect patient compliance and health outcomes; and

3. supports the development and use of tools and technology that enable physicians and patients to determine the actual price and out-of-pocket costs of individual prescription drugs prior to making prescribing decisions, so that physicians and patients can work together to determine the most efficient and effective treatment for the patient's medical condition.

Policy Timeline CMS Rep. 1, I-07 Reaffirmation A-08 Reaffirmed: CMS Rep. 1, I-12 Reaffirmed in lieu of Res. 105, A-13 Reaffirmed in lieu of: Res. 205, A-17 Reaffirmed in lieu of: Res. 207, A-17

H-110.992 Study of Actions to Control Pharmaceutical Costs

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

H-125.979 Private Health Insurance Formulary Transparency

1. Our AMA will work with pharmacy benefit managers, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing.
2. Our AMA supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, that formulary information be specific as to generic versus trade name and include copay responsibilities, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term.
3. Our AMA will develop model legislation (a) requiring insurance companies to declare which drugs on their formulary will be covered under trade names versus generic, (b) requiring insurance carriers to make this information available to consumers by October 1 of each year and, (c) forbidding insurance carriers from making formulary deletions within the policy term.
4. Our AMA will promote the following insurer-pharmacy benefits manager - pharmacy (IPBMP) to physician procedural policy: In the event that a specific drug is not or is no longer on the formulary when the prescription is presented, the IPBMP shall provide notice of covered formulary alternatives to the prescriber promptly so that appropriate medication can be provided to the patient within 72 hours.
5. Drugs requiring prior authorization, shall be adjudicated by the IPBMP within 72 hours of receipt of the prescription.
6. Our AMA (a) promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide, and (b) supports state medical societies in advocating for state legislation to ensure online access to up-to-date and accurate prescription drug formularies for all insurance plans.
7. Our AMA will continue its efforts with the National Association of Insurance Commissioners addressing the development and management of pharmacy benefits.
8. Our AMA will develop model state legislation on the development and management of pharmacy benefits.

Policy Timeline Sub. Res. 724, A-14 Appended: Res. 701, A-16 Appended: Alt. Res. 806, I-17

H-155.960 Strategies to Address Rising Health Care Costs

Our AMA:

- (1) recognizes that successful cost-containment and quality-improvement initiatives must involve physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government;
- (2) supports the following broad strategies for addressing rising health care costs: (a) reduce the burden of preventable disease; (b) make health care delivery more efficient; (c) reduce non-clinical health system costs that do not contribute value to patient care; and
- (d) promote “value-based decision-making” at all levels;
- (3) will continue to advocate that physicians be supported in routinely providing lifestyle counseling to patients through: adequate third-party reimbursement; inclusion of lifestyle counseling in quality measurement and pay-for-performance incentives; and medical education and training;
- (4) will continue to advocate that sources of medical research funding give priority to studies that collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well as clinical outcomes; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers;
- (5) will continue to advocate that health information systems be designed to provide physicians and other health care decision-makers with relevant, timely, actionable information, automatically at the point of care and without imposing undue administrative burden, including: clinical guidelines and protocols; relative cost-effectiveness of alternative diagnostic services and treatments; quality measurement and pay-for-performance criteria; patient-specific clinical and insurance information; prompts and other functionality to support lifestyle counseling, disease management, and case management; and alerts to flag and avert potential medical errors;
- (6) encourages the development and adoption of clinical performance and quality measures aimed at reducing overuse of clinically unwarranted services and increasing the use of recommended services known to yield cost savings;
- (7) encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. Consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance; and
- (8) supports ongoing investigation and cost-effectiveness analysis of non-clinical health system spending, to reduce costs that do not add value to patient care.
- (9) Our AMA will, in all reform efforts, continue to identify appropriate cost savings strategies for our patients and the health care system.

Policy Timeline CMS Rep. 8, A-07 Reaffirmed: CMS Rep. 7, A-08 Reaffirmed in lieu of Res. 828, I-08 Reaffirmation A-09 Reaffirmation I-09 Reaffirmation A-11 Reaffirmation I-11 Appended: Res. 239, A-12 Reaffirmed in lieu of Res. 706, A-12 Reaffirmed: CMS Rep. 1, I-12 Modified: CMS Rep. 2, A-13 Reaffirmed in lieu of Res. 122, A-15 Reaffirmed in lieu of: Res. 121, A-16 Reaffirmed: CMS Rep. 05, I-16 Reaffirmation I-16 Reaffirmed in lieu of: Res. 712, A-17

H-185.939 Value-Based Insurance Design

Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles: (a) Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements. (b) Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists. (c) High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan. (d) The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients. (e) Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design. (f) VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices. (g) Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties. (h) Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence. (i) VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972). Policy Timeline CMS Rep. 2, A-13 Reaffirmed in lieu of Res. 122, A-15 Reaffirmed in lieu of: Res. 121, A-16 Reaffirmed: CMS Rep. 05, I-16 Reaffirmation I-16

8. ADDRESSING THE SITE-OF-SERVICE DIFFERENTIAL (RESOLUTION 817-I-17)

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

At the 2017 Interim Meeting, the House of Delegates referred Resolution 817, "Addressing the Site of Service Differential," which was introduced by the New Mexico Delegation and assigned to the Council on Medical Service for a report back to the House of Delegates at the 2018 Annual Meeting. Resolution 817-I-17 asked:

That our American Medical Association (AMA) study the site-of-service differential with a report back no later than the 2018 Interim Meeting, including: a) the rising gap between independent practice expenses and Medicare reimbursement, taking into account the costs of the regulatory requirements; b) the increased cost of medical personnel and equipment, including electronic health record (EHR/EMR) purchase, software requirements, and ongoing support and maintenance; c) the expense of maintaining hospital based facilities not common to independent practices, such as burn units and emergency departments, and determine what payment should be provided to cover those explicit costs; and d) the methodology by which hospitals report their uncompensated care, and the extent to which this is based on actual costs, not charges; and

That our AMA advocate for a combined Health Care Payment System for patients who receive care that is paid for by the Centers for Medicare & Medicaid Services, that: a) follows the recommendation of MedPAC to pay "site-neutral" reimbursement that sufficiently covers practice expenses without regard to whether services are performed under the Hospital Outpatient Prospective Payment System (HOPPS) or the Physician Fee Schedule (PFS); b) pays appropriate facility fees for both hospital owned facilities and independently owned non-hospital facilities, computed using the real costs of a facility based on its fair market value; and c) provides independent practices with the same opportunity to receive reimbursement for uncompensated care as is provided to hospital owned practices.

Resolution 817-I-17 raised a number of complex cost and payment issues spanning several subject matter areas in need of extensive study. These issues are further complicated by the Medicare program's use of separate payment methodologies for each outpatient setting (ie, physician offices, hospital outpatient facilities, and ambulatory surgical centers). A current AMA [Issue Brief](#) provides an overview of these payment variations. The Council supports payment policies that are site-neutral to the extent possible without lowering payments overall and that fairly reflect the actual costs of providing services. AMA policy supporting equitable payments across outpatient sites of service, including policy established via Council reports, is appended. The Council recognizes the need for further study, and its deliberations of options for achieving payment parity under the Medicare program are ongoing. Accordingly, the

Council intends to submit its final report with recommendations addressing the site-of-service differential at the 2018 Interim Meeting.

APPENDIX

H-240.979 Intrusion by Hospitals into the Private Practice of Medicine

The AMA urges private third party payers to implement coverage policies that do not unfairly discriminate between hospital-owned and independently-owned outpatient facilities with respect to payment of "facility" costs. (CMS Rep. H, I-87; Modified: Sunset Report, I-97; Reaffirmed: CMS Rep. 9, A-07; Reaffirmed: Res. 116, A-14; Reaffirmation A-14; Reaffirmation A-15)

H-240.993 Discontinuance of Federal Funding for Ambulatory Care Centers

The AMA strongly urges more aggressive implementation by HHS of existing provisions in federal legislation calling for equity of reimbursement between services provided by hospitals on an outpatient basis and similar services in physicians' offices. (CMS Rep. B, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmation I-98; Reaffirmation I-03; Reaffirmation I-07; Reaffirmed: CMS Rep. 3, A-13; Reaffirmation A-15)

D-240.994 Payment Variations Across Outpatient Sites of Service

Our AMA will work with states to advocate that third party payers be required to: a. Assess equal or lower facility coinsurance for lower-cost sites of service (hospital outpatient department, ambulatory surgical center, or office-based facility); b. Publish and routinely update pertinent information related to patient cost-sharing; and c. Allow their plan's participating physicians to perform outpatient procedures at an appropriate site of service as chosen by the physician and the patient. (CMS Rep. 3, A-13; Reaffirmation I-17)

H-330.925 Appropriate Payment Level Differences by Place and Type of Service

Our AMA (1) encourages CMS to adopt policy and establish mechanisms to fairly reimburse physicians for office-based procedures; (2) encourages CMS to adopt a site neutral payment policy for hospital outpatient departments and ambulatory surgical centers; (3) advocates for the use of valid and reliable data in the development of any payment methodology for the provision of ambulatory services; (4) advocates that in place of the Consumer Price Index for all Urban Consumers (CPI-U), CMS use the hospital market basket index to annually update ambulatory surgical center payment rates; (5) encourages the use of CPT codes across all sites-of-service as the only acceptable approach to payment methodology; and (6) will join other interested organizations and lobby for any needed changes in existing and proposed regulations affecting payment for ambulatory surgical centers to assure a fair rate of reimbursement for ambulatory surgery. (Sub. Res. 104, A-98; Reaffirmation I-98; Appended: CMS Rep. 7, A-99; Reaffirmation A-00; Reaffirmation I-03; Reaffirmation A-11; Reaffirmed: CMS Rep. 3, A-13; Reaffirmed: Sub. Res. 104, A-14; Reaffirmed: Res. 116, A-14; Modified: CMS Rep. 3, A-14; Reaffirmation A-14; Reaffirmation A-15; Reaffirmation I-17)

D-330.997 Appropriate Payment Level Differences by Place and Type of Service

1. Our AMA encourages CMS to: (A) define Medicare services consistently across settings and, in particular, to avoid the use of diagnosis codes in determining Medicare payments to hospital outpatient departments and other ambulatory settings; and (B) adopt payment methodology for hospital outpatient departments and ambulatory surgical centers that will assist in leveling the playing field across all sites-of-service. If necessary, the AMA should consider seeking a legislative remedy to the payment disparities between hospital outpatient departments and ambulatory surgical centers. 2. Our AMA will continue to encourage the CMS to collect data on the frequency, type and cost of services furnished in off-campus, provider-based departments. (CMS Rep. 7, A-99; Reaffirmation I-03; Reaffirmed: CMS Rep. 3, A-13; Reaffirmed: CMS Rep. 4, A-13; Appended: CMS Rep. 3, A-14; Reaffirmed: Sub. Res. 104, A-14; Reaffirmation A-14; Reaffirmation A-15; Reaffirmation I-17)

D-390.997 CMS Practice Expense Formula

Our AMA will seek from Congress legislation directing CMS that it include in the RBRVS practice expense allocation all costs incurred by physicians, including those costs incurred in hospitals and ambulatory surgical centers. (Sub. Res. 819, I-99 Reaffirmed: CMS Rep. 5, A-09)

H-400.957 Medicare Reimbursement of Office-Based Procedures

Our AMA will: (1) encourage CMS to expand the extent and amount of reimbursement for procedures performed in the physician's office, to shift more procedures from the hospital to the office setting, which is more cost effective; (2) seek to have the RBRVS practice expense RVUs reflect the true cost of performing office procedures; and (3) work with CMS to develop consistent regulations to be followed by carriers that include reimbursement for the costs of disposable supplies and surgical tray fees incurred with office-based procedures and surgery. (Sub. Res. 103, I-93 Reaffirmed by Rules & Credentials Cmt., A-96 Reaffirmation A-04 Reaffirmation I-04 Reaffirmed: CMS Rep. 1, A-14 Reaffirmed: CMS Rep. 3, A-14)

H-400.966 Medicare Payment Schedule Conversion Factor

(1) The AMA will aggressively promote the compilation of accurate data on all components of physician practice costs and the changes in such costs over time, as the basis for informed and effective advocacy with Congress and the Administration concerning physician payment under Medicare. (2) The AMA will work aggressively with CMS, the Bureau of Labor Statistics, and other appropriate federal agencies to improve the accuracy of such indices of market activity as the Medicare Economic Index and the medical component of the Consumer Price Index. (CMS Rep. B, I-92 Reaffirmed: CMS Rep. 10, A-03 Reaffirmed: CMS Rep. 6, I-08 Reaffirmed: CMS Rep. 1, I11

Reaffirmation: I-12 Reaffirmed in lieu of Res. 113, A-13 Reaffirmation I-13 Reaffirmed: CMS Rep. 3, A-14)

H-400.956 RBRVS Development

(1) That the AMA strongly advocate CMS adoption and implementation of all the RUC's recommendations for the five-year review; (2) That the AMA closely monitor all phases in the development of resource-based practice expense relative values to ensure that studies are methodologically sound and produce valid data, that practicing physicians and organized medicine have meaningful opportunities to participate, and that any implementation plans are consistent with AMA policies; (3) That the AMA work to ensure that the integrity of the physician work relative values is not compromised by annual budget neutrality or other adjustments that are unrelated to physician work; (4) That the AMA encourage payers using the relative work values of the Medicare RBRVS to also incorporate the key assumptions underlying these values, such as the Medicare global periods; and (5) That the AMA continue to pursue a favorable advisory opinion from the Federal Trade Commission regarding AMA provision of a valid RBRVS as developed by the RUC process to private payers and physicians. (BOT Rep. 16, A-95 BOT Rep. 11, A-96 Reaffirmed: CMS Rep. 4, I-02 Reaffirmed: BOT Rep. 14, A-08 Reaffirmed: Sub. Res. 104, A-14 Reaffirmation A-15)

H-400.969 RVS Updating

Status Report and Future Plans: The AMA/Specialty Society RVS Update Committee (RUC) represents an important opportunity for the medical profession to maintain professional control of the clinical practice of medicine. The AMA urges each and every organization represented in its House of Delegates to become an advocate for the RUC process in its interactions with the federal government and with its physician members. The AMA (1) will continue to urge CMS to adopt the recommendations of the AMA/Specialty Society RVS Update Committee for physician work relative values for new and revised CPT codes; (2) supports strongly use of this AMA/Specialty Society process as the principal method of refining and maintaining the Medicare RVS; (3) encourages CMS to rely upon this process as it considers new methodologies for addressing the practice expense components of the Medicare RVS and other RBRVS issues; and (4) opposes changes in Relative Value Units that are in excess of those recommended by the AMA/Specialty Society Relative Value Scale Update Committee (RUC). (BOT Rep. O, I-92 Reaffirmed by BOT Rep. 8 - I-94 Reaffirmed by BOT Rep. 7, A-98 Reaffirmed: CMS Rep. 12, A-99 Reaffirmed: CMS Rep. 4, I-02 Reaffirmed: BOT Rep. 14, A-08 Reaffirmation I-10 Appended: Res. 822, I-12 Reaffirmation I-13 Reaffirmed: Sub. Res. 104, A-14 Reaffirmed in lieu of Res. 216, I-14 Reaffirmation A-15)

D-478.996 Information Technology Standards and Costs

1. Our AMA will: (a) encourage the setting of standards for health care information technology whereby the different products will be interoperable and able to retrieve and share data for the identified important functions while allowing the software companies to develop competitive systems; (b) work with Congress and insurance companies to appropriately align incentives as part of the development of a National Health Information Infrastructure (NHII), so that the financial burden on physicians is not disproportionate when they implement these technologies in their offices; (c) review the following issues when participating in or commenting on initiatives to create a NHII: (i) cost to physicians at the office-based level; (ii) security of electronic records; and (iii) the standardization of electronic systems; (d) continue to advocate for and support initiatives that minimize the financial burden to physician practices of adopting and maintaining electronic medical records; and (e) continue its active involvement in efforts to define and promote standards that will facilitate the interoperability of health information technology systems. 2. Our AMA advocates that physicians: (a) are offered flexibility related to the adoption and use of new certified Electronic Health Records (EHRs) versions or editions when there is not a sufficient choice of EHR products that meet the specified certification standards; and (b) not be financially penalized for certified EHR technology not meeting current standards. (Res. 717, A-04; Reaffirmation, A-05; Appended: Sub. Res. 707, A-06; Reaffirmation A-07; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation I-08; Reaffirmation I-09; Reaffirmation A-10; Reaffirmation I-10; Reaffirmed: Res. 205, A-11; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed in lieu of Res. 724, A-13; Reaffirmation I-13; Reaffirmation A-14; Reaffirmed: BOT Rep. 03, I-16; Reaffirmed: BOT Rep. 05, I-16; Appended: Res. 204, I-17; Reaffirmation I-17)