

## REPORTS OF THE COUNCIL ON MEDICAL SERVICE

The following reports, 1–11, were presented by James G. Hinsdale, MD, Chair.

### 1. COUNCIL ON MEDICAL SERVICE SUNSET REVIEW OF 2009 AMA HOUSE POLICIES

*Reference committee hearing: see report of Reference Committee G.*

#### HOUSE ACTION: RECOMMENDATIONS ADOPTED 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 reestablish 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 2009 Socioeconomic Policies

Policy #	Policy Title	Recommended Action and Rationale
D-165.950	Educating the American People About Health System Reform	Rescind. Superseded by Policy H-165.838.
D-165.994	Status Report on the Uninsured	Retain. Still relevant.
D-165.996	Expanding Patient Choice in the Private Sector	Retain. Still relevant.
D-180.985	Health Plan and Insurer Transparency	Rescind. Superseded by Policy D-155.987.
D-185.988	Assuring Continued Coverage for Patients Transitioning Between Insurance Products	Rescind. Superseded by Policy H-165.838.
D-225.997	Medical Records Signature	Rescind. Superseded by Policy H-225.965.
D-285.995	Coordination of Information on Third Party Relations Activities	Retain. Still relevant.
D-330.924	Reform the Medicare System	Retain-in-part. Policy D-330.937 has been rescinded. Policy should be amended to read:  D-330.924 Reform the Medicare System Our AMA will renew its commitment for total reform of the current Medicare system by making it a high priority on the AMA

Policy #	Policy Title	Recommended Action and Rationale
		legislative agenda beginning in 2009 and the AMA's reform efforts will be centered on our long-standing policy of pluralism (AMA Policy H-165.844), freedom of choice (H-165.920, H-373.998, H-390.854), <del>defined contribution (D-330.937)</del> , and balance billing (D-380.996, H-385.991, D-390.969).
D-330.930	Deemed Participation and Misleading Marketing by Medicare Advantage Private Fee for Service Plans	Retain-in-part. The AMA completed the investigation into and reported to CMS any insurers claiming to have "deemed" panels of physicians who have agreed to accept Medicare Advantage private fee-for-service plan enrollees. Policy should be amended to read:  Our AMA will (1) <del>investigate, and report to the Centers for Medicare and Medicaid Services, any insurers claiming to have</del> "deemed" panels of physicians who have agreed to accept Medicare Advantage private fee for service (PFFS) plan enrollees; (2) continue its efforts to educate physicians and the general public on the implications of participating in <del>PFFS plans and other</del> programs offered under Medicare Advantage; and (3) <del>educate physicians and the public about the lack of secondary coverage (Medigap policies) with Medicare Advantage plans and how this may affect enrollees.</del>
D-330.996	Support for an Open Medicare Coverage Process	Retain. Still relevant.
D-385.966	Appropriate Payment for Mandated Benefits	Retain. Still relevant.
D-385.976	Published Reimbursement Schedules by Private Insurers	Retain. Still relevant.
D-390.989	Equal Pay for Equal Work	Retain. Still relevant.
D-390.997	CMS Practice Expense Formula	Retain. Still relevant.
D-400.989	Equal Pay for Equal Work	Retain. Still relevant.
H-110.996	Cost of Prescription Drugs	Rescind. Superseded by Policies H-110.997, H-110.990 and H-110.991.
H-130.939	Emergency Department Readiness to Care for Children	Retain-in-part. Change " <del>Guidelines for Care of Children in the Emergency Department</del> " to " <u>Guidelines for Pediatric Readiness in the Emergency Department</u> " to reflect the title of the revised guidelines.
H-130.940	Emergency Department Boarding and Crowding	Retain. Still relevant.
H-140.920	Socioeconomic Factors Influencing the Patient-Physician Relationship	Retain. Still relevant.
H-155.957	Geographic Variation in Health Care Cost and Utilization	Retain. Still relevant.
H-160.927	Coerced Employment of Physicians	Retain. Still relevant.
H-165.844	Educating the American People About Health System Reform	Retain. Still relevant.
H-165.916	Government Controlled Medicine	Retain. Still relevant.
H-180.950	Gender Rating and Discrimination Based on Prior Cesarean Section	Retain. Still relevant.
H-180.981	Rating or Rejection of Applicants for Health Policies	Rescind. Superseded by Policies H-165.825, H-165.838 and H-165.856.
H-185.945	Medical Foods	Retain. Still relevant
H-185.946	Gender Rating and Discrimination Based on Prior Cesarean Section	Rescind. Superseded by Policies H-165.838 and H-165.856.
H-185.963	Insurance Coverage for Adults with Childhood Diseases	Retain. Still relevant.
H-185.976	Insurance Discrimination Against Victims of Domestic Violence	Retain. Still relevant.
H-185.989	Continuity of Insurance Coverage	Rescind. Superseded by Policies H-165.838 and H-165.856.

Policy #	Policy Title	Recommended Action and Rationale
H-190.964	Electronic Claims	Retain. Still relevant.
H-190.994	Misleading Explanation of Benefits Language by Insurance Carriers	Retain. Still relevant.
H-215.963	Increasing Transparency of Hospital Contracts for Clinical and Non-Clinical Services	Retain. Still relevant.
H-215.979	Unilateral Imposition of Employee Status on Physicians by Hospitals	Retain. Still relevant.
H-220.943	Medical Staff Self-Governance	Retain. Still relevant.
H-220.961	Hospital Boards of Trustees	Retain. Still relevant.
H-220.988	Hospital Admitting Privileges	Retain-in-part. Rescind (1) as it is superseded by Policy H-235.963.
H-225.953	Principles for Developing a Sustainable and Successful Hospitalist Program	Retain. Still relevant.
H-225.954	Payment for In-House Coverage	Retain. Still relevant.
H-230.954	Privileging Physicians with Low Volume Hospital Activity	Retain. Still relevant.
H-230.992	Hospital Admitting Privileges	Retain. Still relevant.
H-235.963	Credentialed Physician Membership in Organized Medical Staff	Retain. Still relevant.
H-235.967	Medical Staff Legal Counsel and Conflict of Interest	Retain. Still relevant.
H-235.989	Medical Staff Bylaws	Retain. Still relevant.
H-235.992	Legal Counsel for Medical Staffs	Retain. Still relevant.
H-240.966	Reimbursement to Physicians and Hospitals for Government Mandated Services	Retain. Still relevant.
H-240.996	Cost Shifting	Retain. Still relevant.
H-265.999	Legal Reports on Physician-Hospital Relationships	Retain. Still relevant.
H-280.955	Surveys in Nursing Facilities	Retain. Still relevant.
H-285.912	Web-Based Prior Authorization Process	Rescind. Superseded by Policies D-190.974 and H-320.944.
H-285.926	Clinical and Professional Impacts of Cost Containment Efforts	Retain. Still relevant.
H-285.930	Pharmacy Benefit Risk-Sharing by Physicians	Retain. Still relevant.
H-290.997	Medicaid - Towards Reforming the Program	Retain. Still relevant.
H-320.983	Mandatory Second Opinion	Rescind. No longer relevant.
H-330.912	Appropriate Medical Coverage for Medicare Beneficiaries	Retain. Still relevant.
H-330.913	Medicare Managed Care Opt Out Rules	Retain-in-part. Change title to read “Medicare Advantage Managed Care Opt Out Rules.” Modify policy by replacing “Medicare Managed Care” with “Medicare Advantage.”
H-330.916	Legislation for Assuring Equitable Participation of Physicians in Medicare-Sponsored Managed Care Organizations	Retain-in-part. Change title to read “Legislation for Assuring Equitable Participation of Physicians in Medicare-Sponsored Managed Care Organizations Medicare Advantage.” Modify policy by replacing “Medicare+Choice” with “Medicare Advantage.”
H-330.924	Changes in COBRA Federal Regulations	Retain. Still relevant.
H-330.938	Extension of Medicare Price Controls to the Federal Employees Health Benefit Program	Retain. Still relevant.
H-335.992	Modifying the Medicare Unnecessary Services Program	Retain. Still relevant.
H-335.993	Medicare Part B Appeals - Telephone Hearings	Retain. Still relevant.
H-335.996	Spurious Medical Necessity Denials	Retain. Still relevant.
H-375.967	Supervision and Proctoring by Facility Medical Staff	Retain. Still relevant.
H-375.968	Supervision and Proctoring by Facility Medical Staff	Retain. Still relevant.
H-375.974	Clinical Proctoring	Retain. Still relevant.

Policy #	Policy Title	Recommended Action and Rationale
H-385.920	Condemnation and Reporting of Unilateral Physician Fee Reduction by Oxford	Rescind. Representatives of AMA, MSSNY, CSMS and MSNJ met with Oxford to address its payment policies including frequently varied co-payments and lack of detail on its EOBs. Oxford agreed to participate in future meetings with MSSNY, CSMS and MSNJ to review the content of its EOBs; take steps to improve the transparency of its electronic and paper remittance process; review its annual co-payment change instructions; share co-payment change information with relevant state medical associations; and, develop FAQs for its web site.
H-385.935	Medicare National Physician Payment Schedule	Retain. Still relevant.
H-385.952	Appropriate Physician Reimbursement by Centers for Medicare & Medicaid Services	Retain. Still relevant.
H-385.977	Counseling - Serious Medical Problems	Retain. Still relevant.
H-385.998	Reimbursement for Diagnostic or Therapeutic Procedures	Retain. Still relevant.
H-390.848	Medicare Coverage of Avastin for Intravitreal Use	Retain. Still relevant.
H-390.896	Payment for Case Management Services	Rescind. There is an assigned payment schedule for E/M.
H-390.945	Legal Action to Resolve Medicare Reimbursement Disparities	Retain. Still relevant.
H-390.961	Opposition to Mandatory Acceptance of Medicare	Retain. Still relevant.
H-400.952	Consolidation of Medicare Fee Schedule Areas	Retain. Still relevant.
H-400.972	Physician Payment Reform	Retain. Still relevant.
H-400.980	Behavioral Adjustments on Physician Payments	Retain. Still relevant.
H-400.990	Refinement of Medicare Physician Payment System	Retain. Still relevant.
H-406.992	The AMA's Medical Practice Survey Research Program	<p>Retain-in-part. The AMA conducts Physician Practice Benchmark Surveys—which are nationally representative samples of non-federal physicians who provide care to patients at least 20 hours per week—every other year. These surveys do not collect income data. Policy should be amended to read:</p> <p>Our AMA: (1) continues to be the world's leader in obtaining, synthesizing and disseminating information on medical practice to physicians by continually evaluating and considering enhancements to its <del>Socioeconomic Monitoring System data collection program</del> <u>Physician Practice Benchmark Survey</u>; and (2) continues to monitor and study the impact of changes in the socioeconomic environment on physicians and medical practices; (3) <del>continues to pursue proactive news management to mitigate negative press treatment of physician income data;</del> (4) <del>considers studying the impact of changes in the socioeconomic environment on women, minorities, and physicians in settings not currently covered by the Socioeconomic Monitoring System survey;</del> and (5) <del>will survey separate family practice from general practice physician data.</del></p>
H-425.981	Reimbursement of Screening Bone Densitometry	Retain. Still relevant.
H-510.991	Veterans Administration Health System	Retain. Still relevant.

## **2. COVERING THE UNINSURED UNDER THE AMA PROPOSAL FOR REFORM (RESOLUTION 108-A-18)**

*Reference committee hearing: see report of Reference Committee A.*

**HOUSE ACTION: RECOMMENDATIONS ADOPTED  
IN LIEU OF RESOLUTIONS 108-A-18 AND 116  
REMAINDER OF REPORT FILED**

*See Policies H-165.824, H-165.842, H-290.965, H-290.971, H-290.976, H-290.982,  
D-165.942, D-290.979 and D-290.982*

At the 2018 Annual Meeting, the House of Delegates referred Resolution 108, “Expanding AMA’s Position on Healthcare Reform Options,” which was sponsored by the Medical Student Section. Resolution 108-A-18 asked that our American Medical Association (AMA) remove references in AMA policy to opposing single-payer health care by rescinding Policies H-165.844 and H-165.985; amending Policy H-165.888 by deletion to remove “1(b) Unfair concentration of market power of payers is detrimental to patients and physicians, if patient freedom of choice or physician ability to select mode of practice is limited or denied. Single-payer systems clearly fall within such a definition and, consequently, should continue to be opposed by the AMA. Reform proposals should balance fairly the market power between payers and physicians or be opposed;” and amending Policy H-165.838 by deletion to remove “12. AMA policy is that creation of a new single-payer, government-run health care system is not in the best interest of the country and must not be part of national health system reform.” The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2019 Annual Meeting.

This report provides background on health care coverage and costs in the US; summarizes potential approaches to cover the uninsured and achieve universal coverage; outlines factors to evaluate in proposals to expand coverage; and presents policy recommendations.

### **BACKGROUND**

The health insurance coverage environment in the US for the nonelderly population heavily relies on the provision of employer-sponsored insurance, with nongroup coverage, Medicaid and other public programs covering smaller shares of the population. In 2017, 57 percent of the nonelderly population was covered by employer-sponsored health insurance coverage, with Medicaid and the Children’s Health Insurance Program (CHIP) covering 22 percent, non-group plans covering eight percent, and other public plans covering three percent. Of concern, 27.4 million nonelderly individuals (10 percent) remained uninsured, an increase of 700,000 from 2016.<sup>1</sup>

The income demographic of the uninsured population is concentrated below 400 percent of the federal poverty level (FPL), with 82 percent of the uninsured with income below that threshold in 2017. Almost one-fifth of the uninsured population had incomes below the poverty line in 2017,<sup>2</sup> which in 2019 is \$12,490 for an individual and \$25,750 for a family of four.<sup>3</sup> Significantly, more than three-quarters of the nonelderly uninsured had at least one full-time worker in their family.<sup>4</sup>

At the same time, \$3.5 trillion was spent on health care in the US in 2017, an increase of 3.9 percent from 2016 – amounting to \$10,739 per person. Hospital care made up 33 percent of total health care spending, with spending on physician and clinical services amounting to 20 percent, and retail prescription drugs 10 percent. Overall, health care spending made up 17.9 percent of the gross domestic product (GDP) in 2017.<sup>5</sup>

Health care is financed by a variety of entities in the US, via dedicated taxes and/or general revenues, or by contributions made to health insurance premiums and out-of-pocket costs. In 2017, the federal government and households each accounted for 28 percent of health care spending. Health care spending by private businesses amounted to 20 percent of spending, with state and local spending following at 17 percent.<sup>6</sup>

### **MOVING FORWARD: APPROACHES TO COVER THE UNINSURED**

The uptick in the uninsured rate, coupled with increasing pressures relating to health care costs, has caused momentum to build in support of action to cover the remaining uninsured. There have been two main approaches outlined in legislation and organizational policy proposals to date to improve the coverage climate in the US. First, legislation

and organizational proposals have been put forward to build upon and fix the Affordable Care Act (ACA) to cover more people. As an alternative, other proposals have been introduced to use Medicare as the foundation to cover all US residents, or allow Medicare or Medicaid buy-ins.

### *The AMA Proposal for Reform*

Expanding health insurance coverage and choice have been long-standing goals of the AMA. The approach to coverage as outlined under the AMA proposal for reform supports health system reform alternatives that are consistent with AMA policies concerning pluralism, freedom of choice, freedom of practice, and universal access for patients. Notably, the AMA health system reform proposal has been extensively deliberated by the House of Delegates over the past 20 years. Based principally on recommendations developed by the Council on Medical Service, beginning in 1998, the AMA proposal for covering the uninsured and expanding choice advocates for the promotion of individually selected and owned health insurance using refundable and advanceable tax credits that are inversely related to income so that patients with the lowest incomes will receive the largest credits (Policies H-165.920 and H-165.865). Policy H-165.920 also supports and advocates a system where individually purchased and owned health insurance coverage is the preferred option, but employer-provided coverage is still available to the extent the market demands it. AMA policy also underscores that in the absence of private sector reforms that would enable persons with low-incomes to purchase health insurance, our AMA supports eligibility expansions of public sector programs, such as Medicaid and CHIP, with the goal of improving access to health care coverage to otherwise uninsured groups (Policy H-290.974). AMA policy has long supported the creation of basic national standards of uniform eligibility for Medicaid (Policy H-290.997), and at the invitation of state medical societies, the AMA will work with state and specialty medical societies in advocating at the state level to expand Medicaid eligibility to 133 percent FPL as authorized by the ACA (Policy D-290.979). Addressing a public option, Policy H-165.838 states that insurance coverage options offered in a health insurance exchange 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.

Since the enactment of the ACA, the House of Delegates has been very proactive in and responsive to the evolving coverage environment to ensure that AMA policy is able to address how to best cover the remaining uninsured. Under the ACA, eligible individuals and families with incomes between 100 and 400 percent FPL (between 133 and 400 percent FPL in Medicaid expansion states) are being provided with refundable and advanceable premium credits that are inversely related to income to purchase coverage on health insurance exchanges. In addition, individuals and families with incomes between 100 and 250 percent FPL (between 133 and 250 percent FPL in Medicaid expansion states) also qualify for cost-sharing subsidies if they select a silver plan, which leads them to face lower deductibles, out-of-pocket maximums, copayments and other cost-sharing amounts. At the time that this report was written, 36 states and the District of Columbia have adopted the Medicaid expansion provided for in the ACA, which extended Medicaid eligibility to individuals with incomes up to 133 percent FPL.<sup>7</sup>

Significantly, the House of Delegates has adopted a multitude of policies that address coverage for the remaining uninsured in the ACA environment:

- *8.2 million individuals who are eligible for premium tax credits but remain uninsured:*<sup>8</sup> Policy H-165.824 supports adequate funding for and expansion of outreach efforts to increase public awareness of advance premium tax credits, and providing young adults with enhanced premium tax credits while maintaining the current premium tax credit structure which is inversely related to income.
- *1.9 million individuals who are ineligible for premium tax credits due to income higher than 400 percent FPL:*<sup>9</sup> AMA policy supports expanding eligibility for premium tax credits up to 500 percent FPL, encouraging state innovation with reinsurance (H-165.824), and establishing a permanent federal reinsurance program (H-165.842).
- *3.8 million individuals who are ineligible for premium tax credits to purchase coverage on health insurance exchanges because they have an offer of "affordable" employer coverage:*<sup>10</sup> Policy H-165.828 supports legislation or regulation, whichever is relevant, to fix the ACA's "family glitch," and supports lowering the threshold that determines whether an employee's premium contribution is "affordable," measured by comparing the employee's share of the premium to their income.

- *6.8 million individuals who are eligible for Medicaid or CHIP but remain uninsured:*<sup>11</sup> AMA policy supports efforts to expand coverage to uninsured children who are eligible for CHIP and Medicaid through improved and streamlined enrollment mechanisms and educational and outreach activities aimed at Medicaid-eligible and CHIP-eligible children. In addition, Policy H-290.961 opposes work requirements as a criterion for Medicaid eligibility.
- *2.5 million individuals with incomes below 100 percent FPL who fall into the “coverage gap” due to their state’s decision not to expand Medicaid:*<sup>12</sup> Policy D-290.979 states that our 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 (138 percent FPL including the income disregard) of FPL as authorized by the ACA.
- *Individuals who may choose not to get covered resulting from the elimination of the federal individual mandate penalty:* Policy H-165.824 encourages 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. This policy builds upon Policy H-165.848, which 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.

#### *Building Upon and Improving the Affordable Care Act*

Legislative and organizational proposals to build upon and fix the ACA, on both the federal and state levels, generally include one or more of the following provisions:

- Increasing the amount of and expanding eligibility for premium tax credits, including removing the “subsidy cliff;”
- Providing “enhanced” tax credits to young adults;
- Increasing amounts of cost-sharing reductions received by individuals who qualify for them;
- Extending eligibility for cost-sharing reductions beyond 250 percent FPL;
- Establishing a reinsurance program;
- Fixing the “family glitch;”
- Establishing a state individual mandate and/or auto-enrollment program; and
- Restricting the availability of short-term limited duration insurance (STLDI) plans and association health plans.

These proposals are generally targeted at the populations that remain uninsured under the law, as well as to address the reasons individuals are uninsured or underinsured in the current environment. For example, in 2017, 45 percent of uninsured nonelderly adults reported that they were uninsured because the cost was too high.<sup>13</sup> Increasing the amount of and expanding eligibility for premium tax credits and cost-sharing reductions addresses concerns with both high premiums and cost-sharing requirements.

#### *Expanding Medicare or Medicaid to Cover the Uninsured*

Legislation has also been introduced to use Medicare or Medicaid as vehicles to expand coverage. “Medicare-for-All” legislation has been introduced in the US House of Representatives and the Senate: S 1129, the Medicare for All Act of 2019 (Senator Bernie Sanders, I-VT), and HR 1384, the Medicare for All Act of 2019 (Representative Pramila Jayapal, D-WA). These bills call for the replacement of employer-sponsored insurance, individual market coverage, and most public programs, including Medicaid, Medicare and CHIP, with Medicare-for-All. The new Medicare-for-All program would have no premiums, and in general no cost-sharing, with the exception of S 1129 giving the Secretary of Health and Human Services (HHS) the authority to allow for cost-sharing for prescription drugs, up to \$200 per year. The new Medicare-for-All program would cover all medically necessary services in outlined benefit categories, dental and vision services, with coverage of long-term services and supports varying based on the legislation. These proposals would establish a global budget for all health spending. A fee schedule would be established for physicians, guided by Medicare rates.<sup>14, 15, 16</sup>

As an alternative to the traditional Medicare-for-All proposals, “Medicare for America” legislation was expected to be reintroduced this session of Congress at the time that this report was written. Of note, there may be differences between the legislation introduced this Congress and that introduced last Congress. Unlike Medicare-for-All, Medicare for America as introduced during the 115<sup>th</sup> Congress would allow large employers to continue providing health insurance to their employees, if they provide gold-level coverage (80 percent of benefits costs covered). Alternatively, they can direct their contributions toward paying for premiums for Medicare for America. If employers continue to offer health insurance to their employees, employees would have the ability to choose Medicare for America coverage instead of their employer coverage. There would also be premiums and cost-sharing under Medicare for America. Premiums would be on a sliding scale based on income, with individuals with incomes below 200 percent FPL having no premium, deductible or out-of-pocket costs. Premiums overall would be capped at no more than 9.69 percent of monthly income. Individuals and families with incomes between 200 and 600 percent FPL would be eligible to receive subsidies to lower their premium contributions, with current Medicare beneficiaries either paying the premium for which they are responsible under Medicare, or that of Medicare for America, whichever is less expensive. Out-of-pocket maximums would also be applied on a sliding scale based on income, with the caps being \$3,500 for an individual and \$5,000 for families. Provider payment under Medicare for America would be based largely on Medicare rates, with increases in payment for primary care, mental and behavioral health, and cognitive services, and the Secretary being given the authority to establish a rate schedule for services currently not paid for under Medicare. Participating providers under Medicare or Medicaid would be considered to be participating providers under Medicare for America. Notably, as a condition of participation in the program, providers would accept Medicare for America rates paid by employer-sponsored insurance plans and Medicare Advantage plans.<sup>17,18</sup>

Smaller scale proposals have also been introduced to allow older individuals to buy in to Medicare starting at age 50; establish a public option that would be offered through the exchanges based on Medicare; and allow individuals to buy in to Medicaid. Senator Debbie Stabenow (D-MI) has introduced S 470, the Medicare at 50 Act, and Representative Brian Higgins (D-NY) has introduced HR 1346, the Medicare Buy-In and Health Care Stabilization Act of 2019, which would enable individuals to buy in to Medicare at age 50. 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 for the buy-in population. Notably, individuals enrolled in the buy-in would receive financial assistance similar to that which they would have received had they purchased a qualified health plan through the marketplace.<sup>19,20</sup>

Senator Brian Schatz (D-HI) and Representative Ben Ray Lujan (D-NM) introduced S 489/HR 1277, the State Public Option Act. If enacted into law, the legislation which 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.<sup>21,22</sup> In addition, several states are considering a Medicaid buy-in or public option, including New Mexico, Colorado, Minnesota, New Jersey, Connecticut, Washington and Maine.<sup>23</sup> Some state proposals would use Medicaid provider rates as the basis for payment levels, whereas others would use Medicare or other approaches.

Legislative proposals have also been put forward in Congress to establish a public option on the exchanges that rely on components of the Medicare program in program structure and to keep plan costs down. The public option, available to individuals and/or small employers eligible to purchase such coverage, would require Medicare participating providers to participate in the public option. Proposals differ in their approaches to provider opt-out provisions, and whether providers in Medicaid would also be required to participate in the public option. Such public option proposals would also base provider payment rates on Medicare, either extending Medicare payment rates or using Medicare rates as a guide to establish payment levels. Individuals who qualify for premium tax credits and cost-sharing subsidies could use such subsidies to purchase the public option. All public option proposals would at a minimum cover essential health benefits as required under the ACA, with some proposals covering more benefits.

### *International Approaches to Universal Coverage*

Countries that have achieved universal coverage show that there is no “one-size-fits-all” approach to covering the uninsured and health system financing. Health system financing varies from country to country. While some countries can fall into one overarching financing model, others may incorporate multiple financing models in their health systems. Such models include a single-payer system financed through taxes, and employer-sponsored insurance and coverage provided by nonprofit, private insurers.



Many countries finance their health systems generally through taxes, with the government serving as single-payer. For example, in Denmark, health care is financed predominantly through a national health tax, equal to eight percent of taxable income. In the United Kingdom, the majority of financing for the National Health Service comes from general taxation and a payroll tax. Partly as a result of the level of health care benefits provided by the government, countries with single-payer systems tend to have higher tax rates and social insurance contributions. Overall, taxes that fund social insurance programs are often higher in other developed countries than in the United States.

Other countries have employer-sponsored insurance and coverage provided through nonprofit, private insurers. For example, health insurance in Germany is mandatory for all citizens and permanent residents, and is primarily provided by competing “sickness funds,” not-for-profit, nongovernmental health insurance funds. Sickness funds are financed by mandatory contributions imposed as a percentage of employees’ gross wages up to a ceiling. High-income individuals can choose to opt out and instead purchase substitutive private coverage. Switzerland requires residents to purchase mandatory statutory health insurance, which is offered by competing nonprofit insurers. Direct financing for health care providers, predominantly for hospitals providing inpatient acute care, comes from tax-financed government budgets. Residents pay premiums for statutory health insurance coverage; premiums are redistributed among insurers by a central fund, adjusted for risk. In the Netherlands, all residents are required to purchase statutory health insurance from private insurers. Its statutory health insurance is financed through a combination of a nationally defined, income-related contribution; a government grant for insured individuals under the age of 18; and community-rated premiums set by each insurer. Such contributions are collected centrally and allocated to insurers according to a risk-based capitation formula.<sup>24</sup>

In its analysis of international health systems, the Council noted that private insurance can play a supplementary and/or substitutive role to public health insurance options. Based on the country, premiums for private coverage can be paid by individuals and/or employers, unions or other organizations. Supplementary insurance, available in several countries, covers services that are excluded or not fully covered in the statutory plan, which could include prescription drug, dental and/or vision coverage. It can also build off the statutory coverage provided to improve coverage and can provide increased choice of or faster access to providers. For example, private health insurance in Australia and Norway offers more choice of providers, as well as expedited access to nonemergency care. Substitutive insurance is duplicative of coverage offered in the statutory plan, and could be available to populations not covered by or those who opt out of the statutory plan. In Germany, many young adults with higher incomes take advantage of substitutive private health insurance, because health insurers offer them coverage for a more extensive range of services, as well as lower premiums.<sup>25</sup>

The role of patient out-of-pocket payments in contributing to health care financing varies from country to country. In Canada, there is no patient cost-sharing for publicly insured physician, diagnostic and hospital services. In the United Kingdom, there is limited cost-sharing for publicly covered services. In countries where for many services patients have no cost-sharing, patients may have out-of-pocket responsibilities for outpatient prescription drugs, dental care and vision care. In many cases, vulnerable groups in these countries are either exempt from or face lower prescription drug copayments.<sup>26</sup>

Residents of Switzerland have similar types of cost-sharing exposures as privately insured individuals in the US. Insured adults are responsible for deductibles for statutory health insurance coverage, which can be lower, closer to \$235, or higher, more than \$1,900, depending on patient choice. After the deductible is met, individuals pay 10 percent coinsurance for all services, up to an annual maximum of approximately \$550 for adults, with the cap for children being roughly half of that for adults. Low-income individuals are eligible for premium subsidies, and regional governments or municipalities cover the health insurance expenses of individuals receiving social assistance benefits or supplementary old age and disability benefits.<sup>27</sup>

Overall, several other countries, while requiring deductibles and/or copayments, also impose caps on cost-sharing, which limit patient out-of-pocket responsibilities. There are also exemptions from cost-sharing for vulnerable populations. For example, in Germany, there is an annual cap on cost sharing for adults equal to two percent of household income; the cap is equal to one percent of household income for chronically ill individuals. In Sweden, annual out-of-pocket payments for health care visits are capped below \$200.<sup>28</sup>

Finally, approaches to paying providers vary, and are not wholly dependent on a country’s health care financing model. Physicians can be salaried, or be paid via fee-for-service and capitation. Payments to physicians can also depend on whether patients have registered with and/or received a referral from their primary care physician. Physician fee

schedules can be regulated or set by national, regional or local health authorities, negotiated between national medical societies/physician trade unions and the government, or negotiated/set by sickness funds or health plans. Physicians in some countries can also receive performance-based payments. Patient out-of-pocket payments contribute varying levels to physician payment, depending on cost-sharing responsibilities.

## CONSIDERATIONS IN EVALUATING PROPOSALS TO EXPAND COVERAGE

### *Coverage Impacts*

None of the legislative proposals to expand coverage highlighted in this report have been formally scored by the Congressional Budget Office to assess their impacts on coverage. That being said, proposals that would establish a single-payer system that would enroll all US residents into a single plan would be expected to lead to universal coverage. The coverage impacts of other proposals to expand coverage via a public plan available to all lawfully present individuals in the US would depend on whether individuals are able to opt out of the coverage, and what other provisions are included to maximize coverage rates. Some proposals would achieve universal coverage for legal residents, but not for undocumented individuals. Others, including public option proposals, would be expected to increase coverage, but at much lower rates.

The coverage impacts of proposals that aim to build upon and fix the ACA will depend on whether provisions to improve upon and/or expand premium tax credits and cost-sharing reductions; improve access to premium tax credits and cost-sharing reductions for those who find their employer-sponsored coverage unaffordable; and/or establish a federal reinsurance program are coupled with mechanisms to maximize coverage rates, such as meaningful individual mandate penalties or an auto-enrollment mechanism. Also, additional states expanding their Medicaid programs would positively impact coverage rates, as 2.5 million of the nonelderly uninsured have incomes below 100 percent FPL and fall into the “coverage gap” due to their state’s decision not to expand Medicaid.<sup>29</sup> Of note, certain policy options to improve the ACA have been evaluated to assess their potential impacts on overall coverage rates. For example, researchers from RAND Corporation modeled the impact of increasing the generosity of premium tax credits and extending eligibility for premium tax credits beyond 400 percent FPL, and concluded that implementing those policy options would increase the number of total insured by 2.4 million people in 2020. In addition, RAND modeled the impact of a generous reinsurance program, estimated to lead to an additional 2 million individuals having health insurance coverage in 2020.<sup>30</sup>

The Urban Institute also estimated the coverage impacts of reform proposals to build upon and fix the ACA, including:

- Reinstating the ACA’s individual mandate penalties and cost-sharing reduction payments and prohibiting the expanded availability of STLDI plans;
- Expanding Medicaid eligibility in all remaining states, with full federal financing of the Medicaid expansion for all states; and
- Improving marketplace assistance, including the enhancement of the ACA’s premium tax credit and cost-sharing subsidy schedules; tying ACA financial assistance to gold instead of silver level coverage; and establishing a permanent federal reinsurance program.

The Urban Institute assumed that 32.2 million nonelderly people would be uninsured in 2020. If these proposals to build upon and fix the ACA were enacted into law, the Urban Institute projected that number would drop to 21.1 million people in 2020 – a decrease of 11.1 million.<sup>31</sup>

### *Patient Choice of Health Plan*

The ability of and degree to which patients would be able to choose their health plan would vary greatly under proposals put forth to cover the uninsured. Some Medicare-for-All proposals would not allow individuals with employer-sponsored coverage to keep their coverage; other proposals, including Medicare for America and proposals that build upon the ACA, would, to varying degrees. Depending on the proposal that builds upon Medicare to cover all US residents, patient choice of health plan would depend on whether the structure of the public plan is indeed a singular public plan in which everyone enrolls, or if it would follow a structure similar to Medicare Advantage. Under Medicare buy-in proposals, individuals starting at age 50 would have a choice between their existing mode of coverage and buying in to Medicare. Medicaid buy-in and other public option proposals are generally adding another plan to pick from on the marketplaces. The Council notes that if Medicaid buy-in and other public options are able to offer

coverage at much lower premiums than existing marketplace plans, that could impact the size of premium tax credits available to individuals, which are pegged to the second lowest cost silver plan on the marketplace. If premium tax credit amounts are lower, individuals may have a choice of health plan, but may be able to afford fewer coverage options on the marketplaces.

### *Scope of Benefits*

The scope of benefits under proposals introduced to cover the uninsured vary in terms of comprehensiveness of benefits and cost-sharing. Medicare-for-All proposals that have been introduced at the time that this report was written would cover medically necessary services in outlined benefit categories, dental and vision services, and long-term services and supports. Generally, there would be no cost-sharing for these services, with the exception of S 1129, the Medicare for All Act of 2019, introduced by Senator Sanders, which would give the Secretary of HHS the authority to allow for cost-sharing for prescription drugs, up to \$200 per year. Medicare for America would cover benefits determined to be medically necessary, including long-term services and supports for the elderly and individuals with disabilities, with cost-sharing responsibilities varying by income. Under the Medicare buy-in proposal for older individuals starting at age 50, such individuals would be entitled to the same benefits under Medicare Parts A, B and D as current Medicare beneficiaries. Public option proposals, including Medicaid buy-ins, generally follow the ACA's essential health benefits requirements, with cost-sharing dependent on income.

### *Impacts on Patient Access*

Proposals to expand health insurance coverage can be expected to vary also in their impacts on patient access to care. Overall, increased demand for services would depend on how many individuals would become insured under the proposal. In addition, patient demand for services would vary based on the level of cost-sharing required under the proposal in question. For example, under traditional Medicare-for-All proposals, cost-sharing would generally be eliminated, which would be expected to lead to an increased utilization of medical services, as well as those services not typically covered under traditional health insurance (e.g. dental, vision, hearing). On the other hand, individuals use less care if cost-sharing is higher. As such, if patients were still responsible for a certain level of cost-sharing, the effect on demand for services would be expected to be more modest.

Provider supply and participation in any new public health insurance option can be expected to be impacted by the level at which providers are paid (e.g., Medicare or some variation thereof, Medicaid, new negotiated rates). For Medicare and Medicaid buy-in proposals as well as others that would create a public option, requiring provider participation could also impact whether providers continue to participate in traditional Medicare and/or Medicaid, potentially impacting current beneficiary access to care. In assessing the Medicare for All Act of 2017 as introduced by Senator Bernie Sanders, a working paper released by the Mercatus Center at George Mason University stated that “it is not precisely predictable how hospitals, physicians, and other health care providers would respond to a dramatic reduction in their reimbursements under M4A, well below their costs of care for all categories of patients combined.”<sup>32</sup> In addition, RAND Corporation recently analyzed a single-payer plan for the state of New York, and an assumption incorporated into its modeling was that “providers reduce supply of services when payment levels decrease or financial risk increases.”<sup>33</sup> Another RAND report assessing national health spending estimates under Medicare-for-All stated that “providers’ willingness and ability to provide health care services including the additional care required by the newly insured and those benefiting from lower cost sharing would likely be limited.”<sup>34</sup>

Of concern to the Council are those proposals that would greatly increase demand for services, while containing provisions expected to negatively impact provider supply. In detailing its methods for assessing the presidential campaign proposal of Senator Sanders in 2016, Urban Institute stated that “the Sanders plan would increase demand for health services by eliminating individuals’ direct contributions to care (i.e., by eliminating deductibles, copayments, and coinsurance), but not all increased demand could be met because provider capacity would be insufficient.”<sup>35</sup> The Mercatus Center study of the Medicare for All Act of 2017 stated that while some practices and facilities would be able to continue to operate, others would not, “thereby reducing the supply of health care services at the same time M4A sharply increases health care demand. It is impossible to say precisely how much the confluence of these factors would reduce individuals’ timely access to health care services, but some such access problems almost certainly must arise.”<sup>36</sup> RAND’s report on national health spending estimates under Medicare-for-All stated “[t]he extent and distribution of unmet care would depend on providers’ payer mix under current law and their responses to Medicare-for-All payment levels. For example, some providers may elect to not participate in a Medicare-for-All plan (and instead enter in private contracts with individuals, an arrangement permitted in some single-payer bills), providers

may alter when they retire, and potential medical students and trainees could change their career choices. As a result, some patients might experience longer wait times for care or face unmet needs.”<sup>37</sup>

Concerns regarding wait times also echo data comparing health systems of different countries. For example, while 51 percent of patients in the United States were able to get an appointment the same or next day, that number falls to 49 percent in Sweden and 43 percent in Canada, and is 57 percent in the United Kingdom. Only six percent of patients in the US had a wait time of two months or longer to access a specialist, whereas wait times to see a specialist were significantly longer in countries with systems classified in the study as national health service and single-payer. Thirty-nine percent of patients in Canada had wait times of two-months or longer to see a specialist, with 19 percent of patients in the United Kingdom and Sweden facing such specialist wait times. Health systems in countries classified to be “insurance-based” (e.g. Germany, Switzerland, Netherlands, France) have more comparable wait times to the US.<sup>38</sup>

### *Other Impacts on Physician Practices*

Health reform proposals that have been introduced have the potential to impact physicians and their practices in a multitude of ways, based on factors that include practice size and specialty; physician employment status; geography; and the payer mix of patients. As previously noted, transitioning the entire US population to a plan that pays Medicare rates, or has rates closely tied to that of Medicare, is expected to negatively impact practices that cannot cover their costs of care based on Medicare rates. Importantly, the Council notes innovation and practice enhancements can be undermined if practices were solely to rely on Medicare payment rates, therefore stifling delivery reform that promises to lower costs and improve care while maintaining access. Some Medicaid buy-in proposals raise similar concerns, especially those that use Medicaid payment rates in the buy-in program. On the other hand, proposals to build upon and fix the ACA would maintain the variety in the potential payer mix for physician practices.

The choices physicians currently have in their practice of medicine would be more limited under proposals that would enroll all US residents in a single public health insurance plan. That being said, it will be important to monitor if supplemental or substitutive private insurance would be allowed in such proposals, which would either replace the statutory coverage, or build off of the statutory coverage provided to improve coverage and provide increased choice of or faster access to providers. The Council notes that there may be an additional opportunity for physicians to participate in a parallel private market if it is allowed under such proposals.

Requirements for provider participation must be assessed in any proposal that would establish a public option or allow individuals to buy into Medicare or Medicaid. Such proposals assume physician participation in these plans if they participate in traditional Medicare and/or Medicaid. Under such proposals, if there is no provider opt-out provision, physicians would be expected to differ in their willingness to continue their participation in the existing traditional Medicare and Medicaid programs, as well as in their decisions on whether to accept new patients. Any proposal that ties physician participation in Medicare and/or Medicaid to a new public insurance option would also have the potential to significantly impact the payer mix of physician practices. The Council notes that Policies H-285.989 and D-383.984 oppose “all products” clauses or linking a physician’s participation in one insurance product to that physician’s participation in any other insurance product.

Health reform proposals that drastically impact physician practice payer mix could also impact practice efficiency. While proposals that build upon the ACA would continue the practice of physicians interacting with a variety of health plans, transitioning all US residents into one public health insurance plan could mean that physicians only interact with one plan, with the same benefits package and payment rates, as well with one set of rules governing the use of utilization management practices.

### *Cost and Financing*

The Council notes that none of the outlined legislative proposals to expand coverage have been formally scored by the Congressional Budget Office to assess their costs. That being said, think tanks and other entities have provided estimates of certain proposals. Medicare-for-All proposals that cover a comprehensive set of benefits with no cost-sharing are expected to incur the largest increases in federal spending. Recent analyses of Medicare-for-All proposals have been based on the Medicare for All Act of 2017 as introduced by Senator Sanders, his 2016 Medicare-for-All presidential campaign proposal, or a general Medicare-for-All proposal that would provide comprehensive health coverage, including long-term care benefits, with no-cost sharing. Of note, none of these analyses specifically measure

the effects of S 1129, the Medicare for All Act of 2019, introduced by Senator Sanders in April of 2019. These analyses, published by the Urban Institute, the Mercatus Center at George Mason University, Kenneth Thorpe of Emory University and RAND Corporation, projected that Medicare-for-All proposals would require a large increase in federal spending. However, there are important differences among the analyses; as a result, they are not directly comparable. First, while Mercatus estimated the effects of the Medicare for All Act of 2017 as introduced, Urban Institute and Kenneth Thorpe evaluated Senator Sanders' 2016 presidential campaign proposal. As a result, the Mercatus Center assumed a four-year phase in of Medicare-for-All, but did not include an expansion in long-term services and supports – both differences between the 2017 version of the legislation and the campaign proposal. RAND, on the other hand, provided estimates of a more generic Medicare-for-All proposal. Of note, all of these studies made their cost projections over different time periods. The studies also did not have the same assumptions of the level at which providers would be paid under Medicare-for-All.<sup>39,40</sup>

The Mercatus Center estimated that the Medicare for All Act of 2017 would increase federal spending by approximately \$32.6 trillion from 2022 to 2031, assuming a four-year phase-in period beginning in 2018.<sup>41</sup> The Urban Institute projected that federal spending under the 2016 presidential campaign proposal would increase by \$32 trillion between 2017 and 2026.<sup>42</sup> The estimate of the campaign proposal put forth by Kenneth Thorpe was lower – closer to \$25 trillion over the period from 2017 to 2026.<sup>43</sup> After the release of the Mercatus Center estimate, the Urban Institute noted that its estimates would differ if it were to standardize the assumptions between the two estimates. For example, Urban stated that if its estimate were over the same period as the Mercatus Center, and still included expansion of long-term services and supports, its estimate would be closer to \$40 trillion.<sup>44</sup> RAND Corporation estimated that Medicare-for-All would increase federal health spending in 2019, rather than projecting a 10-year estimate, by 221 percent, from \$1.09 trillion to approximately \$3.5 trillion.<sup>45</sup>

All analyses estimating the cost of Medicare-for-All note that it would necessitate a complete change in how health care is financed in the US. Nearly all current national spending on health care by households, private businesses, and state and local governments would shift to the federal government. How these entities fare after a transition to Medicare-for-All would ultimately depend on the pay-fors of the proposal. For example, in introducing the Medicare for All Act of 2019, Senator Sanders also released a white paper that laid out potential funding options, which included:

- Creating a 4 percent income-based premium paid by employees, exempting the first \$29,000 in income for a family of four;
- Imposing a 7.5 percent income-based premium paid by employers, exempting the first \$2 million in payroll to protect small businesses;
- Eliminating health tax expenditures;
- Making the federal income tax more progressive, including a marginal tax rate of up to 70 percent on those making above \$10 million, taxing earned and unearned income at the same rates, and limiting tax deductions for filers in the top tax bracket;
- Making the estate tax more progressive, including a 77 percent top rate on an inheritance above \$1 billion;
- Establishing a tax on extreme wealth;
- Closing the “Gingrich-Edwards Loophole;”
- Imposing a fee on large financial institutions; and
- Repealing corporate accounting gimmicks.<sup>46</sup>

Transitioning to the Medicare for America proposal, the Council notes that while the exact cost of the legislation is not yet known, it is expected to be significant, but cost less than the aforementioned Medicare-for-All proposals due to differences in plan premiums and cost-sharing requirements, and the role of employers. Of note, the sponsors of the bill put forward the following options to pay for the proposal as introduced during the 115<sup>th</sup> Congress:

- Sunsetting the Republican tax bill;
- Imposing a 5 percent surtax on adjusted gross income (including on capital gains) above \$500,000;
- Increasing the Medicare payroll tax and the net investment income tax;
- Increasing the excise taxes on all tobacco products, beer, wine, liquor, and sugar-sweetened drinks; and
- Incentivizing states to make maintenance of effort payments equal to the amounts they currently spend on Medicaid and CHIP.<sup>47</sup>

The cost of proposals to build upon the ACA depends on the comprehensiveness of the proposal, and whether provisions are coupled with a mechanism to maximize coverage rates, such as an individual mandate or auto-

enrollment system, as well as restrictions on short-term limited duration plans and association health plans. RAND Corporation estimated the impact on the federal deficit in 2020 of some potential proposals to improve coverage in the individual market under the ACA:

- Providing young adults with enhanced premium tax credits: \$1.1 billion;
- Increasing the generosity of premium tax credits: \$6.4 billion;
- Extending eligibility for premium tax credits beyond 400 percent FPL: \$9.9 billion;
- Increasing and extending eligibility for premium tax credits: \$18.8 billion; and
- Establishing a reinsurance program: Savings of \$2.3 billion to \$8.8 billion depending on generosity.<sup>48</sup>

The Urban Institute also estimated the impact of proposals to build upon and fix the ACA on federal spending on acute health care for the nonelderly in 2020:

- Reinstating the ACA's individual mandate penalties and cost-sharing reduction payments and prohibiting the expanded availability of STLDI plans: Savings of \$11.4 billion;
- Expanding Medicaid eligibility in all remaining states, with full federal financing of the Medicaid expansion for all states (when added to the previous bullet): \$68.1 billion; and
- Improving marketplace assistance, including enhancing the ACA's premium tax credit and cost-sharing subsidy schedules; tying ACA financial assistance to gold instead of silver level coverage; and establishing a permanent federal reinsurance program (added to the two previous bullets): \$131 billion.<sup>49</sup>

The cost of public option proposals, as well as Medicare and Medicaid buy-ins, depends on several factors. First, the rate upon which provider payments are based will impact the cost, whether provider rates are tied to Medicare or a variation thereof, Medicaid, or another payment mechanism entirely. The cost of such proposals will also depend on whether they would be required to be financially self-sufficient and not depend on the traditional Medicare or Medicaid programs for parts of their financing. It will be paramount to assess the impact of any proposal that builds upon the Medicare program, or relies on Medicare program financing in part, on the solvency of the Medicare Trust Fund.

## DISCUSSION

The AMA has long supported health system reform alternatives that are consistent with AMA policies concerning pluralism, freedom of choice, freedom of practice, and universal access for patients. To expand coverage to all Americans, the AMA has advocated for the promotion of individually selected and owned health insurance; the maintenance of the safety net that Medicaid and CHIP provide; and the preservation of employer-sponsored coverage to the extent the market demands it. On the whole, the AMA proposal for reform recognizes that many individuals are generally satisfied with their coverage, but provides affordable coverage options to those who are uninsured or are having difficulties affording coverage options, including employer-sponsored, for which they are eligible.

While the ACA has made great strides in covering the uninsured, the Council is concerned with the recent uptick in the uninsured rate, as well as future coverage impacts of zeroing out the federal individual mandate penalty, the expanded provision of STLDI, and other proposals put forward that could likely undermine the progress made to date. That being said, the ACA is not broken, but it is imperfect. Instead of abandoning the ACA and threatening the stability of coverage for those individuals who are generally satisfied with their coverage, the Council believes that now is the time to invest not only in fixing the law, but improving it. Improving the ACA appropriately targets providing coverage to the uninsured population, rather than upending the health insurance coverage of most Americans. Modifications to the law could also improve the coverage options for many who are underinsured and/or cite costs as a barrier to accessing the care they need. In addition, focusing the efforts of our AMA on improving the ACA helps promote physician practice viability by maintaining the variety in the potential payer mix for physician practices. Importantly, the Council is concerned about the cost of proposed Medicare-for-All proposals, and how the proposals' pay-fors would impact patients and physicians.

The AMA proposal for reform, based on AMA policy, is still the right direction to pursue in order to cover the uninsured, and is cognizant that, in this environment, the ACA is the vehicle through which the AMA proposal for reform can be realized. As such, by putting forward new proposals to build upon and fix the ACA, as well as reaffirming existing policies adopted by the House of Delegates, the AMA proposal for reform as follows has the potential to make significant strides in covering the remaining uninsured and providing health insurance to millions more Americans:

- Premium tax credits would be available to all individuals without an offer of “affordable” employer coverage.
- Individuals currently caught in the “family glitch” and unable to afford coverage offered through their employers for their families would become eligible for ACA financial assistance based on the premium for family coverage of their employer plan.
- To help people currently having difficulties affording coverage, the threshold used to determine the affordability of employer coverage would be lowered, which would make more people eligible for ACA financial assistance based on income.
- The generosity of premium tax credits would be increased to improve premium affordability, by tying premium tax credit size to gold-level instead of silver-level plan premiums, and/or lowering the cap on the percentage of income individuals are required to pay for premiums of the benchmark plan.
- Young adults facing high premiums would be eligible for “enhanced” tax credits based on income.
- Eligibility for cost-sharing reductions would be increased to help more people with the cost-sharing obligations of the plan in which they enroll.
- The size of cost-sharing reductions would be increased to lessen the cost-sharing burdens many individuals with low incomes face, which impacts their ability to access and afford the care they need.
- A permanent federal reinsurance program would be established, to address the impact of high-cost patients on premiums.
- State initiatives to expand their Medicaid programs will continue to be supported. To incentivize expansion decisions, states that newly expand Medicaid would still be eligible for three years of full federal funding.
- To maximize coverage rates, the AMA would continue to support reinstating a federal individual mandate penalty, as well as state efforts to maximize coverage, including individual mandate penalties and auto-enrollment mechanisms.
- To improve coverage rates of individuals eligible for either ACA financial assistance or Medicaid/CHIP but who remain uninsured, the AMA would support investments in outreach and enrollment assistance activities.
- States would continue to have the ability to test different innovations to cover the uninsured, provided such experimentations 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.

Importantly, the Council stresses that our AMA proposal for reform provides a strong policy foundation to use in evaluating health reform proposals as they get introduced in the coming years, regardless of whether they are tied to the ACA. As such, the Council does not support the policy rescissions proposed in referred Resolution 108-A-18. While the Council continues to believe that AMA should not support single-payer proposals, there is the potential for other health reform proposals to be put forward in the future that could be consistent with AMA policy. The Council underscores that the AMA will continue to thoughtfully engage in discussions of health reform proposals, which will vary greatly in their structure and scope. Opposing single-payer proposals does not preclude that engagement, nor mean that the AMA will not evaluate health reform proposals that are introduced. Ultimately, our AMA, guided by policy, will continue forward in its efforts to advocate for coverage of the uninsured.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 108-A-18, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support eliminating the subsidy “cliff”, thereby expanding eligibility for premium tax credits beyond 400 percent of the federal poverty level (FPL).
2. That our AMA support increasing the generosity of premium tax credits.
3. That our AMA support expanding eligibility for cost-sharing reductions.
4. That our AMA support increasing the size of cost-sharing reductions.
5. That our AMA reaffirm Policy H-165.828, which supports legislation or regulation, whichever is relevant, to fix the Affordable Care Act (ACA’s) “family glitch”; and capping the tax exclusion for employment-based health insurance as a funding stream to improve health insurance affordability.

6. That our AMA reaffirm Policy H-165.842, which supports the establishment of a permanent federal reinsurance program.
7. That our AMA reaffirm Policy H-165.824, which supports providing young adults with enhanced premium tax credits while maintaining the current premium tax credit structure which is inversely related to income; encourages 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; and supports adequate funding for and expansion of outreach efforts to increase public awareness of advance premium tax credits.
8. That our AMA reaffirm Policy D-290.979, which states that our 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 [(138 percent federal poverty level (FPL) including the income disregard)] FPL as authorized by the ACA.
9. That our AMA reaffirm Policy H-290.965, which supports extending to states the three years of 100 percent federal funding for Medicaid expansions that are implemented beyond 2016.
10. That our AMA reaffirm Policies H-290.976, H-290.971, H-290.982 and D-290.982, which support educational and outreach efforts targeted at those eligible for Medicaid and Children's Health Insurance Program, as well as improved and streamlined enrollment mechanisms for those programs.
11. That our AMA reaffirm Policy D-165.942, which 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.

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### 3. MEDICARE COVERAGE FOR DENTAL SERVICES (RESOLUTION 111-A-18)

*Reference committee hearing: see report of Reference Committee A.*

**HOUSE ACTION: RECOMMENDATIONS ADOPTED  
IN LIEU OF RESOLUTION 111-A-18  
REMAINDER OF REPORT FILED**  
*See Policies H-330.872 and D-160.925*

At the 2018 Annual Meeting, the House of Delegates referred Resolution 111, “Medicare Coverage for Dental Services,” which was sponsored by the American College of Cardiology. Resolution 111 asked the American Medical Association (AMA) to (1) reaffirm appreciation and gratitude for the valuable contributions dental health professionals make to Americans’ health and well-being as members of our health care team, and (2) promote and support legislative and administrative action to include preventive and therapeutic dental services as a standard benefit for all Medicare recipients. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates at the 2019 Annual Meeting.

This report examines the unmet dental care needs of many Medicare beneficiaries, seniors’ current options for obtaining dental health insurance and/or discounted care, the various challenges that would need to be overcome to create a Medicare benefit for dental services, and initiatives that are already underway to work towards better meeting the dental care needs of American seniors.

#### BACKGROUND

Medicare was created in 1965 as the federal health insurance program for people ages 65 and over, regardless of income or health status.<sup>1</sup> Medicare was later expanded to cover individuals under age 65 who are eligible for Social Security due to blindness or disability, or who have End Stage Renal Disease (ESRD) or Amyotrophic Lateral Sclerosis (ALS). Medicare covers approximately 59 million people who meet one of the criteria for eligibility.<sup>2</sup> Notably, however, traditional Medicare does not include coverage for routine oral health care like checkups, cleanings, and x-rays, or restorative procedures (fillings, crowns, bridges, and root canals), tooth extractions, and dentures.<sup>3</sup> While some Medicare beneficiaries may be able to obtain dental coverage through other sources, the scope of dental benefits varies widely by geography and across plans. As a result, it is estimated that 70 percent of seniors lack or have limited dental insurance and fewer than half access dental care each year.<sup>4</sup>

Accordingly, Medicare beneficiaries have high out-of-pocket expenses when they do access dental care. For example, a 2016 analysis found that nearly one-fifth of the Medicare beneficiaries who received dental care paid more than \$1,000 out-of-pocket.<sup>5</sup> For context, it has been reported that half of all Medicare beneficiaries live on annual incomes below \$26,200, and one-quarter have incomes below \$15,250.<sup>6</sup> The lack of dental coverage and high out-of-pocket costs can lead to patients delaying or forgoing dental care due to cost, as well as higher expenditures for medical and emergency care associated with untreated dental problems. However, while cost is often cited as a top reason for patients not going to the dentist, it is only one of many challenges senior citizens face as they seek dental care. Additional significant factors include: fear of the dentist, inconvenient appointment times or locations, dental health professional shortages, transportation challenges, and health literacy issues.<sup>7</sup>

At the same time, Medicare beneficiaries may have medical conditions and medications that worsen their oral health, or oral health issues that exacerbate or complicate treatment of their other medical conditions. Tooth decay and other oral diseases, when untreated, can cause pain, chronic and acute infection, tooth fractures and loss, compromised oral function, and impaired quality of life. Dental problems can make it difficult to eat, leading to poor nutrition, weight loss or gain, and exacerbation of chronic conditions like hypertension, diabetes, and hyperlipidemia – conditions which are common later in life. In addition, oral infections can be especially dangerous for older adults with weakened immune systems.<sup>8</sup> Recognizing that dental care is integral to overall well-being, many within the medical, dental, and patient advocacy communities have suggested that Medicare begin including dental care as a standard benefit. However, there is considerable agreement that adding the benefit would be very expensive and politically challenging.

## CURRENT OPTIONS FOR DENTAL COVERAGE FOR SENIORS

It is important to recognize that the scope of dental coverage and affordability of dental care is an issue for people of all ages. The scope of covered benefits, cost-sharing rules, and annual dollar limitations that apply to private dental insurance plans can lead patients of all ages to face high out-of-pocket costs for dental treatment, and this issue extends to Medicare beneficiaries.<sup>9</sup> Medicare coverage policy for dental care is not completely clear, and the Medicare program is reviewing its authority to provide additional services. Currently, dental-related Medicare coverage includes:

- Dental services that are an integral part of a covered procedure;
- Extractions performed in preparation for radiation treatment for cancers involving the jaw;
- Oral examinations (but not treatment) preceding kidney transplants or heart valve replacements; and
- Hospital care resulting from complications of a dental procedure (but excluding the cost of the dental care).<sup>10</sup>

While traditional Medicare does not cover routine oral health care or restorative procedures, seniors have some options for obtaining some level of dental insurance coverage and/or discounted dental care. Medicare Advantage (MA) plans have been an option for seniors, as an alternative to enrolling in traditional Medicare, since the 1970s.<sup>11</sup> Virtually all Medicare beneficiaries have access to at least one MA plan in their area, and in 2018, the average Medicare beneficiary could choose among 21 MA plans offered by six insurers. MA plans provide all Medicare-covered services (except hospice), and they typically provide additional benefits, including dental care. For example, in 2018, approximately two-thirds of MA beneficiaries were enrolled in plans that offer some dental coverage. Beginning in 2019, MA plans will be able to provide targeted services for beneficiaries with chronic conditions. MA continues to be an increasingly popular option among Medicare beneficiaries: enrollment in MA plans has more than tripled, with 6 million beneficiaries in 2005 and 20 million reported in a 2018 study. Its popularity is expected to continue to grow – in 2018, 34 percent of the Medicare population was enrolled in MA, and that figure is projected to rise to 42 percent by 2028. However, as with insurance for other populations, some MA plans charge an additional premium for dental benefits, cost-sharing requirements vary by plan and geography, and dollar limitations on coverage commonly apply.<sup>12</sup>

In addition to MA plans being available, some Medicare beneficiaries receive dental coverage via Medicaid, employer-sponsored retiree health plans, or individually purchased dental plans.<sup>13</sup> Again, however, the scope of dental benefits varies widely. Seniors must meet qualification criteria for Medicaid benefits, and not all states' Medicaid programs offer dental benefits.<sup>14</sup> Seniors (like other individuals) with employer-provided dental coverage must purchase their dental health plan separately from their medical insurance. Additionally, seniors can choose to purchase individual dental insurance plans through a variety of commercial insurance companies, or they can buy into a program that provides access to discounted dental care. However, given that these plans and programs carry sometimes significant monthly costs and can impose restrictive annual maximums on coverage (for example, a \$1,000 annual maximum in some dental PPOs<sup>15</sup>), seniors must carefully consider whether such options are cost effective for them. Finally, some dental offices offer their own in-office dental plan (also known as a “dental membership savings plan” or “direct primary care agreement”).<sup>16</sup> Patients participating in such plans pay their dentist/dental office a fixed amount per month or per year, and then they generally receive preventive services at no charge and discounts on other procedures.

## CHALLENGES TO CREATING A NEW MEDICARE DENTAL BENEFIT

While it is clear that seniors need better access to affordable dental care, it is not clear how to provide that needed service via a new Medicare standard dental benefit. First, as a general matter, the Medicare program is already struggling under profoundly challenging finances. The 2018 Medicare Trustees Report (the 2018 Report) explains that Medicare Part B and Part D, which together comprise the Supplementary Medical Insurance Trust Fund (SMI), will continue to place a significant burden on the finances of taxpayers and Medicare beneficiaries. SMI costs are projected to demand an increasing proportion of beneficiaries' incomes, and SMI costs are projected to increase significantly as a share of GDP over the next 75 years, from 2.1 percent to 4.0 percent.<sup>17</sup> Yet, adding a comprehensive benefit for dental coverage to Medicare Part B has been estimated to cost approximately \$32.3 billion.<sup>18</sup> Policymakers considering a new dental benefit would have to weigh significant competing demands to reduce growth in Medicare spending for currently covered benefits while also addressing the need for a very expensive additional benefit. It is also important to avoid jeopardizing funding for current Medicare benefits. This complicated policy decision must be made in the context of the broader solvency issues facing the Medicare program. The 2018 Report indicated that the Hospital Insurance Trust Fund (HI) component of Medicare has an estimated depletion date of 2026, which is three years earlier than in last year's report.<sup>19</sup> As in past years, the Trustees determined that the fund is not adequately

financed over the next 10 years. In fact, the Trustees project deficits in all future years until the trust fund becomes depleted in 2026.

Second, creating a new Medicare benefit for dental care would require legislative and regulatory action. A statutory exclusion in Section 1862(a)(12) of the Social Security Act prevents inclusion of dental benefits in Medicare.<sup>20</sup> Congress would need to act to remove that exclusion, and additional statutory changes, such as establishing a scope of services and structuring provider payment, would be required to ensure a smooth integration of dental benefits into Medicare. Additionally, the Centers for Medicare & Medicaid Services (CMS) would need authority to promulgate new regulations to implement and administer Medicare dental health benefits.

Even if a new Medicare dental benefit were enacted, it is not clear that dentists would be sufficiently interested in participating to provide good access to dental care for Medicare patients. With 40 percent of national health expenditures for dental care being paid by patients out-of-pocket, dentists have been less reliant on third-party payer financial support for their practices than have physicians.<sup>21</sup> Additionally, dental fee-for-service models typically include unique costs such as dental laboratory material and supplies within the fee for a given procedure, and comprehensive dental practices often house significant equipment that contributes to large overhead costs. The extent to which a newly created Medicare dental benefit covers these costs is likely to influence dental practices' decisions about whether to participate in a Medicare dental benefit.

## PROPOSALS FOR IMPROVING ACCESS TO DENTAL CARE FOR SENIORS

A variety of policy options could be considered to expand access to dental care for Medicare beneficiaries. As “America’s leading oral health advocate,” the American Dental Association (ADA) is deeply committed to advocating for public policies “affecting the practice of dentistry and the oral health of the American public.”<sup>22</sup> The ADA recognizes senior citizens’ compelling need for dental care and continues to study methods for improving seniors’ access to dental care, to explore the possibility of a Medicare dental benefit, and to advocate on behalf of the dental community and its patients. The ADA recently contributed to a multi-disciplinary collaboration that included representatives from the Center for Medicare Advocacy, Oral Health America, Families USA, Justice in Aging, and the Santa Fe Group and resulted in a white paper analyzing a potential oral health benefit in Medicare Part B. While the resulting white paper advocates for inclusion of an oral health benefit in Medicare Part B, the ADA has not reached that conclusion. Instead, the ADA’s position has been one of thoughtful engagement, without endorsing a new Medicare dental care benefit. The ADA contributed data to the white paper, explaining that, “The ADA Board of Trustees determined that it was critical for the ADA to educate this coalition to ensure that the dentist perspective on this national health policy issue is represented and understood.”<sup>23</sup> Critically, however, the ADA stated that “the Association’s input does not constitute endorsement of inclusion of a dental benefit under Medicare at this time.”<sup>24</sup> Instead, the ADA explained, “Ultimately, success depends on establishing a sustainable program that will actually increase oral health for seniors.”<sup>25</sup> As of July 2018, the ADA’s Council on Dental Benefit Programs has been “studying this issue [of a Medicare dental benefit] in order to make an informed recommendation for the profession.”<sup>26</sup> More recently, when the ADA House of Delegates met in October 2018, it adopted policy that “calls for the ADA president to appoint an ad hoc committee to review and update existing policy. . . and to identify an implementation plan and timeline to address elder care including Medicare.”<sup>27</sup> AMA staff communications with ADA staff indicate that the ADA is carefully studying the issue of senior oral health and Medicare coverage for dental services, and it plans to issue further guidance in the near future, potentially as soon as late 2019.

In addition to the proposal to add a dental benefit to Medicare Part B, others have proposed an optional supplementary Medicare benefit to provide coverage for dental, vision, and hearing services, similar to the Medicare Part D benefit. The optional benefit package would be mostly funded through premiums (with income-based subsidies that follow the design of the Part D subsidy potentially available). At the same time, the study authors acknowledge that calculating the cost of such a benefit package is challenging and dependent upon many assumptions, and they describe their policy option as a starting point for discussion and more extensive modeling.<sup>28</sup> Other policy options include the contention by some advocates that CMS has the authority to cover oral health care when it is medically necessary for the treatment of Medicare-covered diseases, illnesses, and injuries, and CMS is reviewing this question.<sup>29</sup>

Each of these policy options raises questions about budget, scope of coverage, cost-sharing, provider payment, and administration. To inform the policy debate, further studies of possible Medicare benefit plan design, impacts on clinical outcomes, and cost effectiveness are needed. For example, researchers could study outcomes and impacts reported from MA plans offering varying degrees of dental coverage to inform optimal benefit design. Additionally,

clinical and comparative effectiveness research from the National Institute of Dental and Craniofacial Research (NIDCR) could inform future analyses.

As the specific debate surrounding a Medicare dental benefit continues to unfold, the ADA is also engaged in broader efforts to examine barriers to dental care and expand access. As part of a series on Access to Oral Health, the ADA issued a report on the role of finance in breaking down barriers to oral health for all Americans. The ADA emphasized that “adequate funding should be made available through both public and private financing mechanisms. Financial barriers to care must be removed or lessened to increase the utilization of dental services.”<sup>30</sup> However, the ADA explained that “increased funding alone cannot ‘fix’ a dental financing system that is rife with inefficiencies and shifting policies. . . Funding alone will not guarantee other needed improvements in the system.”<sup>31</sup> Since 2014, the ADA has led a community-based, grassroots movement called Action for Dental Health. Action for Dental Health aims to provide care for people who suffer from untreated dental disease, to strengthen and expand the public/private safety net, and to bring disease prevention and education into communities. This movement advocates for increased dental health protections under Medicaid, providing dental care for seniors in nursing homes with funding through Medicaid, training other health professionals to provide basic dental health education and recognize conditions that need to be referred to a dentist, and providing free dental care to underserved populations.<sup>32</sup> The Action for Dental Health movement recently won a significant victory with the enactment of the Action for Dental Health Act (the Act) which aims to improve access to oral health care for underserved Americans.<sup>33</sup> Specifically relevant to the issue of senior dental care, the Act supports the development of models for the provision of dental services (such as dental homes) for children and adults including the elderly, blind, individuals with disabilities, and individuals living in long-term care facilities. The Act will also support initiatives to reduce the use of emergency departments by individuals seeking dental services that would be more appropriately provided in a dental primary care setting.<sup>34</sup>

#### AMA POLICY

AMA policy emphasizes the important role of oral health in overall patient care. Policy D-160.925 recognizes the importance of managing oral health and access to dental care as a part of optimal patient care. The policy also states that the AMA will explore opportunities for collaboration with the ADA on a comprehensive strategy for improving oral health care and education for clinicians. Additional policy supports providing coverage for dental care for medical residents and fellows in training (Policies H-295.873 and H-310.912) and for individuals with developmental disabilities (Policy H-90.968).

Policy regarding insurance coverage for hearing aids is also instructive, as hearing aids constitute another category of care that is not covered by traditional Medicare, but that is critical to patient well-being. Policy H-185.929 encourages private health plans to offer optional riders that allow their members to add hearing benefits to existing policies to offset the costs of hearing aid purchases, hearing-related exams, and related services. The policy also supports coverage of hearing tests administered by a physician or physician-led team as part of Medicare’s benefit.

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

Extensive AMA policy emphasizes the importance of collaboration with health care community stakeholders and national medical specialty societies. Several policies support continued collaboration with national medical specialty societies, interest groups, and other stakeholders to develop clinical guidelines for preventive services; encourage coverage for evidence-based recommendations regarding preventive services, especially for populations at high risk for a given condition; and promote to the public and the profession the value of Medicare-covered preventive services (Policies D-330.935, D-330.967, H-425.987, and H-425.988). Similarly, Policy D-185.979 encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services.

#### DISCUSSION

The Council commends the sponsors of referred Resolution 111-A-18 for highlighting the inextricable link between oral health and overall health and well-being and the dental care needs of Medicare beneficiaries. In light of the AMA’s policy commitment to collaborating with the ADA, the critical importance of the dental profession’s perspective on

the issue of creating a Medicare benefit for dental care, and the currently evolving research on this issue, the Council believes that the AMA should continue to explore opportunities to work with the ADA to improve access to dental care for Medicare beneficiaries. As part of this collaboration, the AMA should continue to monitor and evaluate the ADA's research and policy recommendations regarding a Medicare benefit for dental care and the broader challenge of meeting the oral health care needs of America's senior citizens. In addition, the Council believes that the AMA should support initiatives to expand health services research regarding expanding affordable access to dental care for Medicare beneficiaries. This research could include studies of the effectiveness of expanded dental coverage in improving health and preventing disease in the Medicare population, the optimal dental benefit plan designs for improving health and preventing disease in the Medicare population, and the impact of expanded dental coverage on health care costs and utilization. Finally, to underscore the importance of the goals articulated through Resolution 111-A-18 and the AMA's commitment to working with the ADA to achieve these goals, the Council recommends reaffirming Policy D-160.925, which recognizes the importance of managing oral health, access to dental care as a part of optimal patient care, and collaboration with the ADA.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 111-A-18 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy D-160.925, which recognizes the importance of managing oral health, access to dental care as a part of optimal patient care, and collaboration with the American Dental Association (ADA).
2. That our AMA support continued opportunities to work with the ADA and other interested national organizations to improve access to dental care for Medicare beneficiaries.
3. That our AMA support initiatives to expand health services research on the effectiveness of expanded dental coverage in improving health and preventing disease in the Medicare population, the optimal dental benefit plan designs to cost-effectively improve health and prevent disease in the Medicare population, and the impact of expanded dental coverage on health care costs and utilization.

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#### APPENDIX - Policy Recommended for Reaffirmation

Policy, D-160.925 Importance of Oral Health in Patient Care

Our AMA: (1) recognizes the importance of (a) managing oral health and (b) access to dental care as a part of optimal patient care; and (2) will explore opportunities for collaboration with the American Dental Association on a comprehensive strategy for improving oral health care and education for clinicians. (Res. 911, I-16)

### 4. RECLASSIFICATION OF COMPLEX REHABILITATION TECHNOLOGY (RESOLUTION 117-A-18)

*Reference committee hearing: see report of Reference Committee A.*

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS  
IN LIEU OF RESOLUTION 117-A-18  
REMAINDER OF REPORT FILED  
*See Policy H-330.871***

At the 2018 Annual Meeting, the House of Delegates referred Resolution 117-A-18, “Supporting Reclassification of Complex Rehabilitation Technology (CRT),” which was introduced by the Texas Delegation. The Board of Trustees assigned this item to the Council on Medical Service for a report back at the 2019 Annual Meeting. Resolution 117-A-18 asked that our American Medical Association (AMA) “advocate for the Centers for Medicare & Medicaid Services (CMS) to reclassify CRT as a separate and distinct payment category to improve access to the most appropriate and necessary equipment to allow individuals with significant disabilities and chronic medical conditions

to increase their independence, reduce their overall health care expenses and appropriately manage their medical needs.”

In this report, the Council explains complex rehabilitation technology, discusses legislation that has impacted funding for CRT, summarizes competitive bidding in this context, and highlights relevant AMA policy. The Council concurs with the intent of Resolution 117-A-18, and recommends minimal modifications to avoid potential unintended consequences of the reclassification.

## BACKGROUND

Resolution 117-A-18 identifies challenges with the current classification of CRT within the broader category of durable medical equipment (DME) under Medicare’s payment rules. The resolution explains that the DME category used by CMS does not distinguish technological differences between CRT and other DME. CRT is often required for optimal ongoing mobility at home as well as in daily living activities for individuals with debilitating chronic illnesses. The resolution also notes that long-term care facilities may not provide medically necessary CRT due to the cost or lack of experience with CRT configuration.

CRT can include specialized devices and services that meet the needs of beneficiaries with complex, long-term or permanent, mobility and other impairments. CRT consists of individually configured manual and power wheelchairs, seating and positioning systems, and other adaptive equipment such as standing devices and gait trainers. The specialization inherent in CRT contrasts with the far less complex mobility devices under the DME benefit, which typically serve a short-term, post-hospitalization beneficiary population in need of DME while recovering in the home. In 2014, CRT power wheelchairs and accessories accounted for two percent (about 13,000) of all Medicare wheelchair utilization and 22 percent (about \$69 million) of wheelchair expenditures.<sup>1</sup>

## COMPETITIVE BIDDING

The Medicare Durable Medical Equipment, Prosthetics, Orthotics, & Supplies (DMEPOS) Competitive Bidding Program was enacted with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which required Medicare to implement a competitive bidding process for selected DMEPOS items to reduce beneficiary out-of-pocket expenses and save the Medicare program money.<sup>2</sup>

Under competitive bidding, suppliers compete in established competitive bidding areas by submitting bids for selected products. Not all products or items are subject to competitive bidding. Bids are evaluated based on the supplier’s eligibility, its financial stability and the bid price. Contracts are awarded to the Medicare suppliers who offer the best price and meet applicable quality and financial standards. Contract suppliers must agree to accept assignment on all claims for bid items and will be paid the single payment amount.

Notably, CRT power wheelchairs, but not other CRT products, were excluded from competitive bidding with the passage of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. An exceptionally costly unanticipated expense, such as for CRT, can consume a large portion of the budgets of CRT device and service vendors, creating price pressures and/or potentially hindering beneficiary access. A July 2018 GAO report<sup>3</sup> found that competitive bidding of DME reduced payment levels substantially, with average reduction of 46 percent across the top 53 items. Rural areas are largely excluded from coverage in the bidding areas. DME vendors can compete in those non-bid areas and also refuse to provide services and products to those areas.

MIPPA acknowledged that complex rehabilitative power wheelchairs were unique and different from standard DME. However, the law did not establish a separate benefit/payment category for these wheelchairs and is limited in scope to apply only to certain complex rehabilitative power wheelchairs. Legislation would be needed to require that CMS create a separate and distinct classification for all products and services that are classified as CRT.

## RELEVANT AMA POLICY AND ADVOCACY

Policy D-330.907 strongly encourages CMS to refrain from implementing policies that would curtail access to CRT wheelchairs and accessories by applying competitively bid prices to these specialized devices. If CMS does not refrain from implementing policies limiting access to CRT wheelchairs, the policy states that the AMA will encourage



Congress to support legislation (e.g., HR 3229) that would provide a technical correction to federal law to clarify that CMS cannot apply Medicare competitive bidding pricing to CRT wheelchairs.

Policy H-185.963 (1) urges public and private third party payers to increase access to health insurance products for adults with congenital and/or childhood diseases that are designed for the unique needs of this population; and (2) emphasizes that any health insurance product designed for adults with congenital and/or childhood diseases include the availability of specialized treatment options, medical services, medical equipment and pharmaceuticals, as well as the accessibility of an adequate number of physicians specializing in the care of this unique population.

Policy H-330.955 states that the AMA (1) continues to voice its objection to CMS and other insurers regarding onerous requirements for the prescription of durable medical equipment; (2) advocates that additional members of a physician-led health care team be permitted to complete the certification of medical necessity form for durable medical equipment, according to their education, training and licensure and at the discretion of the physician team leader, but require that the final signature authorizing the prescription for the durable medical equipment be the responsibility of the physician; (3) calls for CMS to revise its interpretation of the law, and advocates for other insurers, to permit that the physician's prescription be the only certification of medical necessity needed to initiate an order for and to secure Medicare or other insurer payment for durable medical equipment; and (4) calls on physicians to be aware of the abuses caused by product-specific advertising by manufacturers and suppliers of durable medical equipment, the impact on the consumers of inappropriate promotion, and the contribution such promotion makes to unnecessary health care expenditures.

Policy H-390.835 supports: (1) additional reimbursement for evaluation and management services for patients who require additional time and specialized equipment during medical visits due to severe mobility-related impairments; (2) that no additional cost-sharing for the additional reimbursement will be passed on to patients with mobility disabilities, consistent with Federal Law; (3) that primary and specialty medical providers be educated regarding the care of patients with severely impaired mobility to improve access to care; and (4) additional funding for payment for services provided to patients with mobility related impairments that is not through a budget neutral adjustment to the physician fee schedule.

In accordance with Policy D-330.907, the AMA submitted a letter to the Secretary of Health and Human Services on June 9, 2016, urging CMS to revoke the application of competitive bidding to complex rehabilitation wheelchairs.

## DISCUSSION

Referred Resolution 117-A-18 is consistent with AMA policy and past advocacy urging the CMS to rescind the decision to apply the competitive bidding pricing program to CRT wheelchairs and wheelchair accessories and instead develop alternative approaches that consider beneficiary access.

Accordingly, the Council recommends the essence of Resolution 117-A-18, while noting that accomplishing the request of the resolution will require legislation and regulation. Because CMS cannot enact legislation, the Council recommends supporting reclassification without referring to CMS as the necessary change agent. Once legislation is enacted, the Council's recommended policy statement of support for reclassification would direct the AMA to advocate for CMS implementation. The Council also recommends supporting the efforts of Federation partners to accomplish adequately funded CRT reclassification.

If CRT is categorized as a distinct category it should be adequately funded. In addition, to address concerns that prices for CRT products and services could increase significantly within a distinct category, the Council believes that it would be appropriate for CMS to develop additional requirements and/or regulations beyond those that currently exist for the fitting and prescribing of CRT under DME regulations. Such possible requirements/regulations could include, but not be limited to competitive bidding of CRT, coverage policies, and quality standards.

Finally, the Council encourages the ongoing involvement of appropriate stakeholders to accomplish the adequately funded reclassification of CRT, such as pain physicians, physical therapists, occupational therapists.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 117-A-18, and the remainder of the report be filed:

1. That our American Medical Association (AMA) support the reclassification of complex rehabilitation technology (CRT) as a separate, distinct, and adequately funded payment category to improve access to the most appropriate and necessary equipment to allow individuals with significant disabilities and chronic medical conditions to increase their independence, reduce their overall health care expenses and appropriately manage their medical needs.
2. That our AMA support state medical association and national medical specialty society efforts to accomplish adequately funded reclassification of CRT.
3. That our AMA support, upon reclassification of CRT as a distinct category, the development by the Centers for Medicare & Medicaid Services, with the advice of physicians with appropriate training and expertise, of appropriate, simplified and streamlined requirements specific to CRT that reduce the administrative burden on physicians.

## REFERENCES

1. US Government Accountability Office. "Medicare: Utilization and Expenditures of Complex Wheelchair Accessories." June 1, 2016. Retrieved from <https://www.gao.gov/assets/680/677602.pdf>. Accessed February 19, 2019.
2. Centers for Medicare & Medicaid Services. DMEPOS Competitive Bidding. Retrieved from <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html>. Accessed February 20, 2019.
3. US Government Accountability Office. "Medicare Fee-For-Service: Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment." July 2018. Retrieved at <https://www.gao.gov/assets/700/693412.pdf>. Accessed on February 21, 2019.

## 5. THE IMPACT OF PHARMACY BENEFIT MANAGERS ON PATIENTS AND PHYSICIANS

*Reference committee hearing: see report of Reference Committee A.*

### HOUSE ACTION: RECOMMENDATIONS ADOPTED REMAINDER OF REPORT FILED

*See Policies H-125.979, H-285.965, H-320.939, H-320.958, D-110.987 and D-330.910*

At the 2018 Annual Meeting, the House of Delegates adopted Policy D-120.933, "Pharmacy Benefit Managers Impact on Patients." The Board of Trustees assigned the following provisions of the policy to the Council on Medical Service for a report back to the House of Delegates at the 2019 Annual Meeting:

Our American Medical Association (AMA) will: (1) gather more data on the erosion of physician-led medication therapy management in order to assess the impact pharmacy benefit manager (PBM) tactics may have on patient's timely access to medications, patient outcomes, and the physician-patient relationship; and (2) examine issues with PBM-related clawbacks and direct and indirect remuneration (DIR) fees to better inform existing advocacy efforts.

This report provides background on PBM operations and market conditions, outlines issues of concern for patients and physicians with respect to PBM operations; and presents policy recommendations.

### BACKGROUND: PHARMACY BENEFIT MANAGER OPERATIONS AND MARKET CONDITIONS

PBMs represent payers, including health insurers and self-insured employers, to negotiate discounts on the prices of prescription drugs and rebates based on volume of sales with pharmaceutical companies. In turn, payers determine which drugs to cover and how much patients pay. The role of PBMs as "middlemen" among payers, pharmaceutical companies and pharmacies goes beyond the negotiation of drug prices on behalf of their clients. PBMs are more

frequently fully administering the drug benefit of their clients, creating formularies, making coverage decisions, and determining medical necessity using utilization management tools. They also create networks of pharmacies and negotiate reductions in dispensing fees.

In general, PBMs have three primary revenue sources:

1. Fees from payers for claims administration and drug dispensing;
2. A percentage of the savings secured from rebates and discounts negotiated from pharmaceutical companies; and
3. Fees and savings associated with maintaining pharmacy networks.

The PBM market is highly concentrated: three PBMs – Express Scripts, CVS Caremark and OptumRx – control more than 70 percent of the market.<sup>1</sup> These three PBMs, by representing so many covered lives, have substantial bargaining power in their negotiations with drug manufacturers. Complicating the market concentration is the trend toward PBMs merging with health insurers, and how that could impact pharmacy networks available to patients. CVS-Aetna announced their proposed merger in December of 2017. The US Department of Justice (DOJ) has approved the CVS-Aetna merger, contingent on a federal court approving a settlement in which Aetna has agreed to divest its Medicare Part D prescription drug plan business. At the time this report was written, a federal court is reviewing that settlement. Cigna-Express Scripts announced their intention to combine in March of 2018. The Cigna-Express Scripts merger has been approved and is being consummated. Pertaining to PBM operations, the health insurers in these instances are trying to merge with the entity that is providing them with PBM and pharmacy services. Concerns have been raised by the AMA and others that the CVS-Aetna merger could substantially lessen competition in PBM services, health insurance, retail pharmacy, Medicare Part D, and specialty pharmacy.<sup>2</sup>

#### OPERATIONS OF PHARMACY BENEFIT MANAGERS: ISSUES OF CONCERN FOR PATIENTS AND PHYSICIANS

##### *Insufficient Regulation*

While most states have laws that regulate various aspects of PBM operations, such laws are rather limited in nature, and do not necessarily reflect the roles that PBMs have assumed in fully administering the drug benefit of their clients. State laws that regulate aspects of PBM operations generally fall into the following categories:

- Requiring a PBM to register with or be licensed by the state, in order to conduct business in the state;
- Specifying pharmacy audit procedures by PBMs, including outlining audit appeals mechanisms, audit notification requirements, how frequently audits can occur and what can be audited;
- Outlining conflict of interest provisions with respect to pharmacy and therapeutics (P&T) committees and other areas;
- Requiring transparency in the development and utilization of maximum allowable cost (MAC) lists, which list the maximum amount a PBM will pay for drugs;
- Prohibiting “gag clauses” in PBM-pharmacy contracts;
- Enacting “anti co-pay clawback” provisions that aim to prevent patient co-payments from exceeding the full cost of the drug;
- Imposing a fiduciary duty on a PBM to the entity with which it contracts; and
- Imposing a performance duty on a PBM, which requires a PBM to operate in good faith with the entity with which it contracts.

On the federal level, the function PBMs have assumed in administering the drug benefit of their clients raise the issue of if, and to what extent, PBMs are currently subject to federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity. Concerns have been raised that clarity is needed in this regard, as while they are not a health plan, they are operating very much like one pertaining to drug benefits.

### AMA Policy and Advocacy Regarding Regulation

Policy D-185.995 puts PBMs on the same footing as public and private sector payers, by stating that our AMA will (1) advocate our policies related to health plan coverage of prescription drugs to PBMs, as well as to public and private sector payers; and (2) advocate for the enactment of legislation consistent with AMA policies related to health plan coverage of prescription drugs. Accordingly, the multitude of AMA policies addressing formulary requirements and transparency, utilization management, mental health parity and other issues are applicable to PBMs in addition to health plans.

Policy H-125.986 provides significant guidance with respect to federal regulation of PBM operations. The policy: 1) encourages the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) to continue monitoring the relationships between pharmaceutical manufacturers and PBMs, especially with regard to manufacturers' influences on PBM drug formularies and drug product switching programs, and to take enforcement actions as appropriate; 2) states that certain actions/activities by PBMs and others constitute the practice of medicine without a license and interfere with appropriate medical care to our patients; 3) supports efforts to ensure that reimbursement policies established by PBMs are based on medical need; these policies include, but are not limited to, prior authorization, formularies, and tiers for compounded medications; and 4) encourages the FTC and FDA to monitor PBMs' policies for potential conflicts of interest and anti-trust violations, and to take appropriate enforcement actions should those policies advantage pharmacies in which the PBM holds an economic interest.

In its comments in response to the *American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint)* in July of 2018, the AMA outlined its support for regulating PBMs, stating that the benefit management of PBMs now resembles the typical role of insurers, and they should be treated as such by regulators. Also in July, the AMA submitted a letter in support of the efforts of the National Council of Insurance Legislators (NCOIL) in developing a draft state model act to require licensure of PBMs in the state and allow for oversight by the department of insurance or other equivalent regulatory agency. Additionally, the AMA has advocated for the National Association of Insurance Commissioners (NAIC) to include in its pharmacy benefit model legislation the regulation of PBM activities.

### *Lack of Transparency*

The Council recognizes that the ability of patients and physicians to have the information they need to make key decisions regarding medication, and of policymakers to craft viable solutions to high and escalating pharmaceutical costs, has been hampered by the often byzantine and confidential arrangements that are driving increased medication prices without a clear and justifiable reason. The opaque nature of PBM negotiations of drug prices has raised questions whether the rebate process results in list prices above what they would be absent rebates, as neither PBMs nor drug manufacturers currently have an incentive to lower list prices. In addition, there is a lack of transparency regarding what percent of the savings associated with rebates are passed through to patients or payers. The degree to which savings are passed on to payers and patients impacts health plan premiums as well as cost-sharing requirements.

Concerns have also been raised by physicians and their patients pertaining to transparency in formularies, prescription drug cost-sharing requirements, and utilization management requirements. This lack of transparency makes it exceedingly difficult for physicians to determine what treatments are preferred by a particular payer at the point-of-care, what level of cost-sharing their patients will face, and whether medications are subject to any step therapy or other utilization management requirements. For patients, lack of transparency in their drug coverage may lead to delays in necessary medication treatment, as well as being unaware of their formulary and cost-sharing responsibilities, which can lead to an inability to afford the medications they need. Such lack of transparency is exacerbated when formularies are changed mid-year, which can have negative effects on patients and can have a major impact on health care costs. Actions of PBMs to remove a medication from a patient's formulary during the middle of the plan year and replace it with another medication that is not effective for the patient – or which the patient has previously tried and not done well on – could result in potential trips to the emergency room and/or hospitalizations, increased out-of-pocket costs if the patient is responsible for paying for the drug, and potential physician and patient resources spent on appeals and alternative solutions.

### AMA Policy and Advocacy regarding Transparency

The AMA has been highly engaged in efforts to promote the transparency of PBM practices and operations, resulting from the adoption of Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs and health insurance companies. Addressing mid-year formulary changes specifically, Policy H-125.979 states that drugs may not be removed from the formulary nor moved to a higher cost tier within a patient's health plan policy term. To expose the opaque process that pharmaceutical companies, PBMs, and health insurers engage in when pricing prescription drugs and to rally grassroots support to call on lawmakers to demand transparency, the AMA launched a grassroots campaign and website, TruthinRx.org, in 2016. At the time this report was written, more than 338,000 individuals have signed a petition to members of Congress in support of greater drug pricing transparency, with the campaign also generating more than one million messages sent to Congress demanding drug price transparency.

PBM transparency has also been a key theme highlighted in federal advocacy efforts related to drug pricing. In its comments in response to the proposed rule *Removal of Safe Harbor Protections for Rebates Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection for Certain Point-Of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees* in April 2019, the AMA supported applying manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale, and requiring PBMs to disclose a wide range of information, including additional information about their fee arrangements. In its statement for the record to the US House of Representatives Committee on Oversight and Reform on examining the actions of drug companies in raising prescription drug prices in January 2019, the AMA supported requiring PBMs to apply manufacturer rebates and pharmacy price concessions to drug prices at the point-of-sale to ensure that patients benefit from discounts as well as eliminate some incentives for higher drug list prices; requiring increased transparency in formularies, prescription drug cost-sharing, and utilization management requirements for patients and physicians at the point-of-prescribing as well as when beneficiaries make annual enrollment elections; and prohibiting removal of drugs from a formulary or moving to a higher cost tier during the duration of the patient's plan year unless a change is made for safety reasons. These concerns were echoed in the comments of the AMA submitted in response to *American Patients First, The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint)* in July 2018.

In addition, in August 2018, the AMA submitted a letter in support of S 2554, the "Patient Right to Know Drug Prices Act," which has since become law. The law prohibits health insurers and PBMs from using "gag clauses" that prevent pharmacists from sharing with patients the lower cost options when patients are purchasing medically necessary medication. In addition, the law will ensure that the FTC will have the necessary authorities to combat anti-competitive pay-for-delay settlement agreements between manufacturers of biological reference products and follow-on biologics.

In March 2019, the AMA submitted a letter that supported HR 1781, the Payment Commission Data Act of 2019. If enacted into law, the bill would provide access to essential data that the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) need to evaluate the practices of various entities within the pharmaceutical supply chain that are either not readily available or not available at all for independent analysis, including drug pricing and rebate data. In its letter, the AMA noted that the lack of independent, data driven, third-party analysis of drug pricing and rebate data continues to hamstring additional efforts needed to combat anti-competitive business practices that undermine affordability and harm patients.

Concerning state-level advocacy, 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), which addresses the issues of stabilized formularies and cost transparency. In particular, the AMA Model Act requires PBMs operating in the state to disclose any discounts or other financial consideration they received that affect the price and cost-sharing of covered medicines placed on a formulary. In addition, the AMA has model state legislation that prohibits clawbacks and standard gag clauses in pharmacy-PBM contracts.

### *PBM Clawbacks and Direct and Indirect Remuneration Fees*

DIR is a term used by the Centers for Medicare & Medicaid Services (CMS) to refer to compensation Medicare Part D plan sponsors or their PBMs receive after the point-of-sale, including rebates provided by drug manufacturers and concessions paid by pharmacies. Concessions paid by pharmacies – which can include dispensing physicians and

practice-based pharmacies – can comprise of network participation fees and reimbursement reconciliations. Such additional compensation after the point-of-sale, therefore, changes the final cost of drugs for payers, or the prices paid to pharmacies for drugs. In Part D, DIR impacts Medicare payments to Part D plans. However, DIR fees or similar fee mechanisms are being used in the commercial marketplace as well.

The concern raised in Policy D-120.933, was directed not toward the role of DIR in capturing rebates from pharmaceutical companies, but the impact of DIR fees on pharmacies. The Council recognizes that such fees have negatively impacted some physicians who conduct in-office dispensing and/or have practice-based pharmacies. If DIR fees are not collected from pharmacies on a real-time basis, but rather after transactions take place, pharmacies and affected physician specialties have raised concerns that there exists a lack of clarity regarding their true reimbursement rates. In addition, such entities have cited a need for additional transparency regarding how DIRs are determined and calculated.

In November 2018, the Centers for Medicare & Medicaid Services issued a proposed rule, “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,” that contains potential policy recommendations that would respond to the concerns raised in Resolution 225-A-18 concerning the impact of DIR fees on pharmacies. The proposed rule considers having DIR fees be accounted for and applied at the point-of-sale, which impacts the predictability of pharmacy reimbursement rates as well as patient cost-sharing.<sup>3</sup>

#### AMA Policy and Advocacy regarding Clawbacks and DIR Fees

Policy H-110.991 states that our AMA will 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 PBMs that bar pharmacists from telling consumers about less-expensive options for purchasing their medication. Accordingly, in January 2019, the AMA submitted comments in response to the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule. In its comments, the AMA supported the proposed changes to the definition of “negotiated price” and other related changes that were outlined to ensure reduction in cost burden by beneficiaries at the point-of-sale for Part D prescription drugs, increased transparency, and enhanced competition among Part D plan sponsors. Further, the AMA noted that “when all pharmacy price concessions are not reflected in the price of a drug at the point-of-sale, beneficiaries do not benefit through a reduction in the amount that they must pay in cost-sharing and pay a larger share of the actual cost of a drug.”

#### *Utilization Management Requirements*

When PBMs administer the drug benefits of payers, they have the ability to make coverage decisions and implement utilization management requirements that interfere with patients receiving the optimal treatment selected in consultation with their physicians. At the very least, utilization management requirements can delay access to needed care; in some cases, the barriers to care imposed by prior authorization and step therapy may lead to the patient receiving less effective therapy, no treatment at all, or even potentially harmful therapies. For physician practices, utilization management requirements often involve very manual, time-consuming processes that can divert valuable and scarce physician resources away from direct patient care.

The 2018 AMA Prior Authorization Physician Survey provides insight into the impact that PBM utilization management requirements can have on patients and physician practices. In response to the survey, more than nine in 10 physicians (91 percent) responded that the prior authorization process delays patient access to necessary care, and three-quarters of physicians (75 percent) report that prior authorization can at least sometimes lead to patients abandoning a recommended course of treatment. In addition, more than nine in 10 physicians (91 percent) reported that prior authorization programs have a negative impact on patient clinical outcomes. Of significant concern, 28 percent of physicians reported that prior authorization led to a serious adverse event for a patient in their care. The survey findings also showed that every week, a medical practice completes an average of 31 prior authorization requirements per physician, which take the equivalent of nearly two business days (14.9 hours) of physician and staff time to complete. To keep up with the administrative burden, more than a third of physicians (36 percent) employ staff members who work exclusively on tasks associated with prior authorization.<sup>4</sup>

In addition, a US Department of Health and Human Services (HHS) Office of Inspector General (OIG) review of Medicare Advantage service denials in 2014-2016 reinforces the point that utilization management requirements can

prevent patients from receiving medically necessary care. The OIG found that more than 116,800 prior authorization requests that were initially denied were eventually overturned on appeal. These overturned denials represent specific drugs/services that were medically necessary and the patient needed the treatment. The Council notes that this figure is particularly concerning because beneficiaries and providers appealed only one percent of denials.<sup>5</sup>

#### AMA Policy and Advocacy regarding Utilization Management Requirements

Policy H-320.939 supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm. Policy H-285.965 outlines AMA policy objectives addressing managed care cost containment involving prescription drugs. Policy D-330.910 states that our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the CMS and other appropriate organizations to resolve them. Policy H-320.958 states that our AMA will advocate strongly for utilization management and quality assessment programs that are non-intrusive, have reduced administrative burdens, and allow for adequate input by the medical profession.

To educate the general public about the problems associated with prior authorization and to gather stories from physicians and patients about how they have been affected by it, the AMA launched a grassroots website, FixPriorAuth.org, in July 2018. At the time that this report was written, there have been 10 million social media impressions, more than 500 patient and physician stories have been captured, and approximately 90,000 petitions have been signed.

In addition, the AMA has been very active in advocating for a reduction in both the number of physicians subjected to prior authorization and the overall volume of prior authorizations. In January 2017, the AMA and a coalition of state and specialty medical societies, national provider associations, and patient organizations developed and released a set of 21 Prior Authorization and Utilization Management Reform Principles intended to ensure that patients receive timely and medically necessary care and medications and reduce the administrative burdens. More than 100 other health care organizations have supported those principles. In January 2018, the AMA joined the American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association and Medical Group Management Association in a Consensus Statement outlining a shared commitment to industry-wide improvements to prior authorization processes and patient-centered care. Additionally, the AMA has model legislation addressing prior authorization and utilization management programs that are often employed by PBMs, and works closely with many state and specialty medical societies to enact legislation each year.

Concerning federal advocacy, the AMA submitted comments in response to the *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses* proposed rule, and raised significant concerns with the proposal to allow Part D plans to apply more prior authorization and step therapy requirements to protected class drugs. In its comments submitted in November 2018 in response to the proposed rule to modify Medicare regulations to promote program efficiency, transparency, and burden, the AMA urged CMS to reinstate its 2012 policy prohibiting Medicare Advantage plans from using step-therapy protocols for Part B physician-administered medications; and to carefully consider the care delays associated with prior authorization and the resulting impact on beneficiaries and their health and well-being when evaluating any additional prior authorization requirements for the Medicare program.

#### DISCUSSION

The Council recognizes that PBMs no longer simply negotiate drug prices on behalf of their clients, but rather fully administer the drug benefit creating formularies, making coverage decisions, and determining medical necessity with utilization management tools. The Council believes that PBMs' role managing drug benefits now resembles the typical role of insurers, and they should be treated as such by regulators. Overall, regulators must better understand and control the costs to patients and the systems that are resulting from PBM practices. As such, the Council recommends that PBMs be actively regulated under state departments of insurance. To implement this new policy, the Council believes that our AMA should develop model state legislation addressing state regulation of PBMs. On the federal level, the Council believes that PBMs, like health plans, should be subject to federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.

The Council recognizes that the negative fluidity of the drug benefit is largely a result of the rebate system and the constant negotiations that take place to advance the interests of many drug benefit stakeholders – but not patients. The Council is concerned that the rebate process results in list prices above what they would be absent rebates, as neither PBMs nor manufacturers currently have an incentive to lower list prices. As such, the Council questions whether rebates that are being negotiated by PBMs are resulting in any true savings. Moreover, the Council notes there is insufficient evidence regarding what percent of the savings associated with rebates are being passed through to patients or to payers.

To improve transparency in this space, the disclosure of rebate and discount information, financial incentive information, and P&T committee information would constitute critical steps forward. The Council also believes that manufacturer rebates and pharmacy price concessions should be applied to drug prices at the point-of-sale. This policy, which also applies directly to DIR fees, would add much needed transparency and ensure that beneficiaries benefit from discounts, and dispensing physicians and practice-based pharmacies have more clarity regarding their true reimbursement rates. As these policy changes are implemented, the Council believes that it will be essential to monitor their impact on premiums, medication list prices, and the discount/rebate structure.

In order to maintain cost transparency for patients and keep patients stable on their medications, the Council urges improved transparency in formularies, prescription drug cost-sharing, and utilization management requirements. Requirements and restrictions should be easily accessible by patients and prescribers and unless a change is made for safety reasons, PBMs and health plans should be prohibited from making changes during the duration of the patient's plan year. As such, the Council recommends the reaffirmation of Policy H-125.979.

Utilization management practices employed by PBMs can undermine the ability of patients to have timely access to the medically necessary treatment that they need. The Council notes that reaffirming existing AMA policies helps to highlight the need for new and additional efforts to track and quantify the impact of PBMs' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm. Existing AMA policies also aim to protect patients in managed care cost containment practices involving prescription drugs, and state that our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the CMS and other appropriate organizations to resolve them.

## 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 the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
2. That our AMA develop model state legislation addressing the state regulation of PBMs, which shall include provisions to maximize the number of PBMs under state regulatory oversight.
3. That our AMA support requiring the application of manufacturer rebates and pharmacy price concessions, including direct and indirect remuneration (DIR) fees, to drug prices at the point-of-sale.
4. That our AMA support efforts to ensure that PBMs are subject to state and federal laws that prevent discrimination against patients, including those related to discriminatory benefit design and mental health and substance use disorder parity.
5. That our AMA support improved transparency of PBM operations, including disclosing:
  - Utilization information;
  - Rebate and discount information;
  - Financial incentive information;
  - Pharmacy and therapeutics (P&T) committee information, including records describing why a medication is chosen for or removed in the P&T committee's formulary, whether P&T committee members have a financial or other conflict of interest, and decisions related to tiering, prior authorization and step therapy;



- Formulary information, specifically information as to whether certain drugs are preferred over others and patient cost-sharing responsibilities, made available to patients and to prescribers at the point-of-care in electronic health records;
  - Methodology and sources utilized to determine drug classification and multiple source generic pricing; and
  - Percentage of sole source contracts awarded annually.
6. That our AMA encourage increased transparency in how DIR fees are determined and calculated.
  7. That our AMA reaffirm Policy H-125.979, which aims to prohibit drugs from being removed from the formulary or moved to a higher cost tier during the duration of the patient's plan year.
  8. That our AMA reaffirm Policy H-320.939, which supports efforts to track and quantify the impact of health plans' prior authorization and utilization management processes on patient access to necessary care and patient clinical outcomes, including the extent to which these processes contribute to patient harm.
  9. That our AMA reaffirm Policy H-285.965, which outlines AMA policy objectives addressing managed care cost containment involving prescription drugs.
  10. That our AMA reaffirm Policy D-330.910, which states that our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the Centers for Medicare & Medicaid Services and other appropriate organizations to resolve them.
  11. That our AMA reaffirm Policy H-320.958, which states that our AMA will advocate strongly for utilization management and quality assessment programs that are non-intrusive, have reduced administrative burdens, and allow for adequate input by the medical profession.

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### 6. PREVENTIVE PROSTATE CANCER SCREENING (RESOLUTION 226-A-18)

*Reference committee hearing: see report of Reference Committee A.*

#### **HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 226-A-18 REMAINDER OF REPORT FILED**

*See Policies H-185.939, H-373.997, H-425.966, H-425.997, H-450.938, D-185.979,  
D-185.980 and D-450.957*

At the 2018 Annual Meeting, the House of Delegates referred Resolution 226, "Model State Legislation for Routine Preventive Prostate Cancer Screening," which was sponsored by the American Urological Association (AUA), the American Association of Clinical Urologists, and the Virginia Delegation. Resolution 226 asked that the American Medical Association (AMA) develop model state legislation for screening of asymptomatic men ages 55-69 for prostate cancer after informed discussion between patients and their physicians without annual deductible or co-pay. The Board of Trustees assigned this item to the Council on Medical Service (CMS) for a report back to the House of Delegates at the 2019 Annual Meeting.

This report examines prostate cancer screening in the context of general costs of care concerns, the legal basis for coverage of preventive services without patient cost-sharing, whether prostate cancer screening has been shown to meet the criteria for benefits provided without patient cost-sharing, key clinical practice guidelines for prostate cancer screening, and the AMA's approach to cancer prevention and expanding affordable access to care.

## BACKGROUND

Prostate cancer is one of the most common types of cancer that affects men.<sup>1</sup> In the United States, men's lifetime risk of being diagnosed with prostate cancer is approximately 11 percent and their lifetime risk of dying of prostate cancer is 2.5 percent.<sup>2</sup> African-American men and men with a family history of prostate cancer have an increased risk of prostate cancer compared with other men. In fact, older age, African-American race, and family history of prostate cancer are the most important risk factors for the development of prostate cancer.<sup>3</sup> As highlighted in the I-18 Joint Report of CMS and the Council on Science and Public Health (CSAPH), "Aligning Clinical and Financial Incentives for High-Value Care," more must be done to align incentives to support early prevention, detection, and treatment of disease, including cancer.

To ensure that patients get the medical care they need, they must be able to afford the full spectrum of care that they could require, from risk factor identification, to screening, to preventive interventions, to treatment of diagnosed disease. Even when a service is covered by a health plan, patients may incur significant costs in the form of co-payments, coinsurance, and/or large medical bills that they must pay before meeting their deductible. Such costs have been shown to cause people, especially those in low-income and vulnerable populations, to forgo not only unnecessary but also necessary care.<sup>4</sup> Cost-related non-adherence (CRN) refers to a state in which patients are unable to pursue recommended medical care due to financial barriers.<sup>5</sup> Sub-optimal use of evidence-based medical services can lead to negative clinical outcomes, increased disparities, and in some cases, higher aggregate costs.<sup>6</sup> CRN has been identified across the entire continuum of clinical care – physician visits, preventive screenings, prescription drugs, etc. – and it is especially problematic for vulnerable populations, such as those with multiple chronic conditions, and for socioeconomically and racially disparate populations.<sup>7</sup>

## ACA REQUIREMENTS & PREVENTIVE SERVICES BENEFIT MANDATES

A factor mitigating patient concerns about the cost of preventive care is the Affordable Care Act's (ACA) requirement that health plans cover select preventive services without any patient cost-sharing (zero-dollar). CMS and CSAPH recently examined the ACA's zero-dollar preventive services requirement in three joint reports:

- A-17, "Value of Preventive Services" (A-17 Joint Report);
- A-18, "Coverage for Colorectal Cancer Screening" (A-18 Joint Report); and
- I-18, "Aligning Clinical and Financial Incentives for High-Value Care" (I-18 Joint Report).

As detailed in the A-17 Joint Report, the ACA required all private, non-grandfathered health insurance plans to provide zero-dollar coverage for the preventive services recommended by four expert organizations: the United States Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Women's Preventive Services Initiative, and Bright Futures (collectively, the Expert Organizations). The report also described the varied methods used by the Expert Organizations for developing preventive service guidelines. The A-17 report established Policy H-460.894, which encouraged the Expert Organizations to develop their recommendations with transparency, clarity and specificity.

The A-18 Joint Report on colorectal cancer screening is highly relevant in the current context as another close examination of a cancer screening that has been recently evaluated by the USPSTF and other medical guideline issuing organizations. Notably, the USPSTF had already recommended colorectal cancer screening with an "A" grade, making the screening eligible for zero-dollar coverage for some patients with ACA-compliant health plans. A critical challenge addressed in the A-18 Joint Report was inconsistency in ACA-compliant and Medicare coverage. Accordingly, the A-18 Joint Report established Policy H-330.877, which supports Medicare coverage for colorectal cancer screenings consistent with ACA-compliant plan coverage requirements.

The I-18 Joint Report explored various challenges that the health care industry has faced in implementing the zero-dollar coverage requirement, and it established Policy D-185.979 to help address those challenges. Specifically, Policy D-185.979 supports clinical nuance in value-based insurance design (VBID) to respect individual patient needs,

aligning financial incentives across physician payment initiatives and benefit design initiatives, and encouraging national medical specialty societies to identify high-value services and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services.

The ACA's mandated zero-dollar coverage for select preventive services enjoys strong bipartisan support. A recent poll found that the ACA provision eliminating out-of-pocket costs for certain preventive services was favored by 83 percent of Americans.<sup>8</sup> However, before a service is mandated as a zero-dollar benefit in accordance with the ACA, it must be recommended by one of the Expert Organizations based on their review of the scientific evidence.

#### *Meaning of USPSTF Recommendation Grading*

Critically, to qualify for mandated zero-dollar coverage based on a USPSTF recommendation, a health care service must receive an "A" or "B" recommendation. Services that receive a "C" recommendation are supported by the USPSTF for certain patients, but they do not qualify for the ACA's zero-dollar coverage. The evidence supporting a given service determines the recommendation grade it receives. "A," "B," and "C" recommendations from the USPSTF all encourage provision of the service at issue, to some extent, with the recommendations varying based on the strength of the evidence in support of the service:

- "A" recommendations mean: "The USPSTF recommends the service. There is high certainty that the net benefit is substantial." Accordingly, the USPSTF recommends that practitioners, "offer or provide this service."
- "B" recommendations mean: "The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial." As with an A recommendation, the USPSTF recommends that practitioners, "offer or provide this service."
- "C" recommendations are a bit more nuanced, and notably, the USPSTF's approach to "C" recommendations has evolved over the past two decades. Currently, a "C" recommendation means: "The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small." Accordingly, the USPSTF recommends that practitioners, "Offer or provide this service for selected patients depending on individual circumstances." In describing the evolution of the "C" recommendation, the USPSTF explains, "Grade C recommendations are particularly sensitive to patient values and circumstances. Determining whether or not the service should be offered or provided to an individual patient will typically require an informed conversation between the clinician and patient."<sup>9</sup>

The USPSTF can also issue a negative recommendation, a "D" recommendation, meaning: "The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits." Accordingly, the USPSTF recommends that practitioners, "Discourage the use of this service."<sup>10</sup>

Finally, the USPSTF can issue an "I" statement which means, "The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined." For these services, the USPSTF recommends that providers, "Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms."<sup>11</sup>

#### *Few Cancer Screenings are Eligible for Zero-Dollar Coverage*

Resolution 226-A-18 asserts that, "screening for breast cancer and colonoscopies are covered preventive services for patients without an annual deductible or co-pay." While that is true for some patients screened for breast and colorectal cancer, it is not true for many patients. Some cancer screenings (such as breast and colorectal cancer) for some patient populations have received an "A" or "B" recommendation from the USPSTF and are therefore provided for some patients without patient cost-sharing. This zero-dollar coverage, however, only results from the fact that the USPSTF has found evidence supporting an "A" or "B" level recommendation, indicating the net benefit of those services, for those populations. Accordingly, the cancer screenings that are provided without patient cost-sharing are limited to those for which the existing evidence meets the USPSTF's standards.

As a result, many services that may be valuable to patients are not provided without cost-sharing when the existing evidence does not demonstrate that the net benefit is substantial or moderate leading to an "A" or "B" recommendation

from the USPSTF. Prostate cancer screening is an excellent example. In assigning prostate cancer screening in men aged 55 to 69 years a “C” recommendation, the USPSTF explained that prostate cancer screening is recognized as valuable for some patients, but the evidence of benefits may not outweigh the potential harms for other patients.<sup>12</sup> Other critical services falling into the USPSTF’s C recommendation category include screening mammography in women prior to age 50 years<sup>13</sup> and screening for colorectal cancer in adults aged 76 to 85 years.<sup>14</sup> Moreover, when the evidence for cancer screenings is lacking, the screenings receive an “I” recommendation from the USPSTF. Currently, these services include adult skin cancer,<sup>15</sup> bladder cancer,<sup>16</sup> and oral cancer.<sup>17</sup>

Currently, the only cancer prevention services with an “A” or “B” recommendations for any patient population are:

- Aspirin Use to Prevent Cardiovascular Disease and Colorectal Cancer,<sup>18</sup>
- BRCA-Related Cancer: Risk Assessment, Genetic Counseling, and Genetic Testing,<sup>19</sup>
- Breast Cancer: Medications for Risk Reduction,<sup>20</sup>
- Breast Cancer: Screening,<sup>21</sup>
- Cervical Cancer: Screening,<sup>22</sup>
- Colorectal Cancer: Screening,<sup>23</sup>
- Lung Cancer: Screening,<sup>24</sup> and
- Skin Cancer Prevention: Behavioral Counseling (only applies to young adults, adolescents, children, and parents of young children).<sup>25</sup>

Moreover, among the cancer prevention services with “A” or “B” recommendations which are provided without cost-sharing, the recommendations are limited to specific patient populations. Accordingly, some patients for whom physicians would recommend these services fall outside the scope of the USPSTF recommendations, and therefore, the zero-dollar benefits do not apply to them. Relevant examples that the Council has examined in the A-18 and I-18 Joint Reports are:

- Breast cancer screening – “B” rating only applies to average risk women at certain ages. Screening for younger women is assigned a “C” recommendation, much like prostate cancer screening.<sup>26</sup> Moreover, women at heightened risk do not fall within the scope of the “B” recommendation. Accordingly, while some women will qualify for zero-dollar mammograms, others will not.
- Colorectal cancer screening – “B” rating only applies to average risk adults at certain ages.<sup>27</sup> Screening for older adults is assigned a “C” recommendation, and adults at heightened risk are outside the scope of the “B” recommendation. Once again, some adults will be able to receive a zero-dollar colorectal cancer screening, but others will not.
- Skin cancer prevention – the recommended scope of this cancer prevention service is even more limited. The USPSTF’s “B” recommendation only applies to counseling, not screening, and for individuals aged 6 months to 24 years (or their parents). The USPSTF issued a “C” recommendation regarding counseling for adults with fair skin older than 24 years.<sup>28</sup> As a result, some patients can receive zero-dollar counseling regarding skin cancer prevention, but all skin cancer screenings would incur cost-sharing.

These examples illustrate that cost-sharing remains a concern not only for prostate cancer screening, but for other cancer screenings, too. At the same time, while cost-sharing is required, health insurance coverage for cancer screenings can help to defray the cost for insured patients.

## RECOMMENDATIONS REGARDING PROSTATE CANCER SCREENING

The USPSTF’s recommendations regarding prostate cancer screening are well-aligned with those of key medical specialty societies and other health care organizations. Prostate cancer screening has been reviewed repeatedly by the USPSTF,<sup>29</sup> and their most recent assessment is consistent with that of the AUA – both organizations recommend discussions of this service between a patient and his physician, and both recommend informed decision-making regarding whether to proceed with testing. Neither organization categorically recommends prostate cancer screening. For the AUA, this recommendation equates to a B on the AUA’s scale,<sup>30</sup> while for the USPSTF, this recommendation equates to a C on the USPSTF’s scale. These recommendations are also consistent with that of the American Cancer Society (ACS).<sup>31</sup> In addition to providing clinical guidelines, the ACS also takes an advocacy position supporting “insurance coverage” for prostate cancer screening, though it does not specifically call for zero-dollar coverage.<sup>32</sup> Notably, none of these three expert guidelines recommend universally screening any men of any age or risk category,

and none of these evidence-based specialty guidelines justify a benefit mandate of zero-dollar coverage for prostate cancer screening in asymptomatic men ages 55-69.

## EVIDENCE FOR CLINICAL GUIDELINES THAT INFORM COVERAGE DECISIONS

While the current evidence-based guidelines do not categorically recommend prostate cancer screening, the USPSTF has repeatedly highlighted evidence gaps, and with additional evidence, new, more precise recommendations, could be issued. When the USPSTF issued its 2018 recommendations on prostate cancer screening,<sup>33</sup> it explained that to update its 2012 recommendation, it commissioned two new reviews: a systematic review of the evidence regarding the benefits and harms of prostate-specific antigen (PSA)-based screening for prostate cancer and subsequent treatment of screen-detected prostate cancer, and a review of multiple contextual questions, including a review of existing decision analysis models and what they suggest about the potential for mitigating the harms of screening and treatment and the overdiagnosis rate of PSA-based screening. These studies also examined the effectiveness and harms of PSA-based screening in patient subpopulations at higher risk of prostate cancer, including older men, African American men, and men with a family history of prostate cancer. In addition, the USPSTF reviewed evidence from three randomized controlled trials (RCTs) studying PSA-based screening for prostate cancer: the US-based Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial, the European Randomized Study of Screening for Prostate Cancer (ERSPC), and the Cluster Randomized Trial of PSA Testing for Prostate Cancer (CAP). These trials used varying screening intervals (from 1-time screening to every 1 to 4 years) and PSA thresholds (2.5 to 10.0 ng/mL) for diagnostic biopsy. These RCTs each had at least a decade of median follow-up.

Even with this additional research, the USPSTF emphasized that there are many areas in need of research to improve the evidence-base for screening and treatment of prostate cancer, including:

1. Comparing different screening strategies;
2. Developing, validating, and providing longer-term follow-up of screening and diagnostic techniques;
3. Screening for and treatment of prostate cancer in African American men, and specifying that given the large disparities in prostate cancer mortality in African American men, this research should be a national priority;
4. How to better inform men with a family history of prostate cancer about the benefits and harms of PSA-based screening for prostate cancer;
5. How to refine active prostate cancer treatments to minimize harms; and
6. How to improve informed decision-making.<sup>34</sup>

The USPSTF highlighted these critical research gaps in its November 2018 Report to Congress on *High-Priority Evidence Gaps for Clinical Preventive Services*.<sup>35</sup> Notably, screening for prostate cancer, especially among African-American men and men with a family history, is one of only three high-priority cancer-related evidence gaps that the USPSTF highlighted in 2018. This USPSTF report also explains that the National Institutes of Health (NIH) reviews the research gaps identified by the USPSTF and utilizes the information in developing future funding opportunities.

In addition, growing from a desire to find prostate cancer screening tools that better identify clinically significant prostate cancer, research into improved screening modalities is rapidly evolving. A variety of companies are developing urine or blood-based risk assays using precision medicine to identify aggressive cases of prostate cancer, with some products already available to physicians and patients.<sup>36</sup> For example, ExoDx Prostate (IntelliScore) (EPI) is a non-invasive urine-based liquid biopsy for prostate cancer which can accurately identify high-grade prostate cancer at the time of biopsy and at surgery.<sup>37</sup> As a “rule out” test, EPI is designed to more accurately predict whether a patient presenting for an initial biopsy does not have a high-grade prostate cancer, and therefore could be monitored while avoiding a biopsy at that time.<sup>38</sup> Similarly, MDx Health offers physicians and patients SelectMDx, an epigenetic urine test for prostate cancer risk stratification.<sup>39</sup> Additionally, prostate magnetic resonance imaging (MRI) prior to prostate biopsy can be used to help reduce overdiagnosis of insignificant cancer and improve detection of clinically significant cancer. Recent clinical studies<sup>40</sup> and a consensus statement of the AUA and the Society of Abdominal Radiology (SAR)<sup>41</sup> support the use of high-quality prostate MRI in detecting prostate cancer. However, some experts have raised concerns about both the appropriateness and practicality of advocating for widespread use of MRI to detect prostate cancer, emphasizing that more research is needed to evaluate the relative aggressiveness of high-grade tumors missed by prostate MRI, and that both the costs and the subspecialist expertise required to successfully perform MRI for prostate cancer detection may make widespread implementation of this tool impractical.<sup>42</sup> Currently, insurance coverage for precision medicine<sup>43</sup> and prostate MRI<sup>44</sup> can pose challenges for patients and their physicians. Accordingly, continued research into the efficacy of new and evolving screening and detection methods will be

essential to inform clinical guidelines and standards of care, which can in turn influence insurance coverage determinations.

## INSURANCE COVERAGE FOR PROSTATE CANCER SCREENING

The ACS explains that while some states have slightly different prostate cancer screening coverage requirements, “most state laws assure annual coverage for men ages 50 and over and for high-risk men [African-American men and/or men with a family history of prostate cancer], ages 40 and over.”<sup>45</sup> Additionally, Medicare covers the PSA blood test and a digital rectal exam (DRE) once a year for all male beneficiaries age 50 and over. There is no co-insurance and no Part B deductible for the PSA test. Unlike some cancers where the costs associated with merely screening for the cancer can be prohibitively expensive (e.g., the myriad fees associated with colonoscopies or the potential for multiple different imaging fees associated with breast cancer screenings), the cost associated with a PSA test is relatively minimal. A 2013 study found, “During 2007–2009, the average annual prostate cancer screening cost per beneficiary was \$36.”<sup>46</sup> Similarly, the Medicare 2019 Clinical Lab Fee Schedule Payment for PSA is approximately \$20. While \$20-36 is certainly a barrier for some patients, it pales in comparison to the costs patients could later face if their PSA test is positive, and it pales in comparison to the cost of a colonoscopy.

As explored in the A-18 and I-18 Joint Reports, the current health care system does not successfully identify all high-value preventive services that are worthy of reduced patient cost-sharing, and VBID presents an opportunity for physicians to help shape the identification of additional high-value preventive services. The I-18 Joint Report established Policy D-185.979 which encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. Prostate cancer screening could be an excellent example. Given the research gaps that will take time to fill and the powerful first-hand experience that physicians can share, physicians and payers could collaboratively evaluate prostate cancer screening to determine whether it should qualify as a high-value service, at least for certain patients, and be covered with reduced patient cost-sharing to encourage its utilization.

## AMA POLICY

Many AMA policies support cancer prevention education, awareness, access and/or general insurance coverage, but they do not seek mandated zero-dollar coverage for specific cancer screening services. Key examples include:

- Breast and Cervical Cancers: Policies D-55.997, H-525.994, H-440.872, H-525.993, H-55.971, and H-525.977;
- Colorectal and Anal Cancers: Policies H-55.981, D-55.998, and H-460.913;
- Lung Cancer: Policy H-185.936;
- Skin Cancer: Policy H-55.972; and
- Prostate Cancer: Policies H-425.980 and D-450.957.

AMA policies that call for coverage with no cost-sharing broadly address categories of benefits, rather than individual disease states, including Policy H-185.969 regarding immunizations, Policy D-330.935 regarding Medicare preventive service benefits, and Policy H-290.972 regarding preventive coverage for health savings account holders in the Medicaid program. One exception, where AMA policy does seek zero-dollar coverage for a cancer screening, is for colorectal cancer screening (Policies H-185.960 and H-330.877). Critically, however, Policies H-185.960 and H-330.877 do not seek to establish a new zero-dollar benefit mandate; rather, they build on an ACA benefit mandate, seeking Medicare coverage on par with ACA-recognized evidence-based guidelines.

Longstanding AMA policy supports well-informed physician-patient shared decision-making regarding whether to pursue prostate cancer screening (Policy H-425.980), which is consistent with USPSTF, AUA, and ACS prostate cancer screening recommendations, as well as with AMA policy regarding many other cancer prevention efforts. Additionally, Policy H-373.997 sets forth core elements of physician-patient shared decision-making, and Policy H-450.938 sets forth the principles to guide physician value-based decision-making, including providing physicians with easy access to costs of care at the point of decision-making.

Extensive AMA policy supports insurance coverage for evidence-based preventive services (including Policies H-165.840, H-425.997, H-165.848, H-390.849, and H-185.954). Additionally, strong policy supports coverage and

payment policies for evidence-based genetic/genomic precision medicine and encouraging national medical specialty societies develop clinical practice guidelines incorporating evidence-based precision medicine (Policy D-185.980).

Extensive AMA policy emphasizes the importance of collaboration with national medical specialty societies. Policies D-330.967 and H-425.987 support continued collaboration with national medical specialty societies and interest groups to encourage coverage for evidence-based recommendations regarding preventive services, especially for populations at high risk for a given condition. Similarly, Policy D-185.979 encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. Policy H-425.988 supports continuing collaboration with the federal government, specialty societies, and others, to develop guidelines for, and effective means of delivery of, clinical preventive services.

Long-standing AMA policy opposes benefit mandates. Policy H-165.856 sets forth principles to guide health insurance market regulation and states that the regulatory environment should enable rather than impede private market innovation in product development and purchasing arrangements, and that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options. At the same time, AMA policy strongly supports the provision of evidence-based preventive services without patient cost-sharing. AMA policy does recognize the limitations of the USPSTF and emphasizes the importance of relevant specialty physician input in guideline development. Policy D-425.992 expresses concern regarding the effect that USPSTF recommendations can have on limiting access to preventive care for Americans (e.g., regarding access to screening mammography and prostate specific antigen screening) and encourages the USPSTF to implement procedures that allow for meaningful input on recommendation development from specialists and stakeholders in the topic area under study. Similarly, Policy D-450.957 specifically focuses on prostate cancer and the importance of including relevant specialty societies in guideline development.

Finally, AMA policy strongly supports VBI and innovative insurance design. Policy H-450.938 provides principles to guide physician value-based decision-making. Policy H-155.960 supports value-based decision-making and encourages third-party payers to use targeted benefit design, whereby patient cost-sharing is determined based on the clinical value of a health care service or treatment, with consideration given to tailoring cost-sharing to patient income and other factors known to impact compliance. Policy H-185.939 supports flexibility in the design and implementation of VBI programs and outlines guiding principles, including that VBI consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements. Finally, Policy D-185.979 supports clinical nuance in VBI to respect individual patient needs.

## DISCUSSION

The Council lauds the sponsors of referred Resolution 226-A-18 for highlighting the importance of prostate cancer screening and shares the goal of increasing access to this preventive service for appropriate patient populations. The Council is committed to developing AMA policy regarding prostate cancer screening that is consistent with the existing evidence-base, current clinical guidelines, and AMA policy. To accomplish this goal, the Council believes that the AMA should encourage public and private payers to ensure coverage for prostate cancer screening when the service is deemed appropriate following informed physician-patient shared decision-making. Such policy would be consistent with the ACS recommendations for prostate cancer screening and AMA policy regarding various common cancers (Policies H-185.936, H-525.993, and H-55.981), as well as AMA policy regarding shared and value-based decision-making (Policies H-373.997 and H-450.938). Moreover, the resolution sponsors, the ACS, and the USPSTF all emphasize the importance of informed physician-patient shared decision-making in the context of prostate cancer screening, and the Council believes that the AMA should similarly emphasize this service. National medical specialty societies can play a critical role in promoting public education around the importance of informed physician-patient shared decision-making regarding prostate cancer screening, and the Council encourages them to do so. In addition, the Council believes that, coupled with the new policies recommended in this report, reaffirming Policies H-373.997 and H-450.938 will help to emphasize the importance of well-informed shared physician-patient decision-making. Recognizing that the evidence-base for prostate cancer screening is rapidly evolving, and that more research is needed to better understand which patients should be screened, at which intervals, and with which tools, the Council recommends that Policy D-450.957 (see Appendix) be amended to change the title to read, “Clinical Guidelines and Evidence Regarding Benefits of Prostate Cancer Screening and Other Preventive Services,” and to add a new subsection (3) encouraging scientific research to address the evidence gaps highlighted by organizations making evidence-based recommendations about clinical preventive services.

In addition, as improved, evidence-based methods for detecting clinically significant prostate cancer evolve, it will be essential that insurance coverage for medically necessary tests keep pace. Accordingly, the Council recommends reaffirming Policies D-185.980 and H-425.997 which support coverage for evidence-based genetic/genomic precision medicine and evidence-based, cost-effective preventive services. Moreover, prostate cancer screening, a service that is highly valuable to some patients and less necessary for others, is an outstanding example of how clinical nuance can be deployed through VBID to align clinical and financial incentives around care that is high-value for individual patients, consistent with Policy D-185.979. As also noted in Policy D-185.979, national medical specialty societies should play a key role in helping to shape VBID plans that decrease cost-sharing to encourage utilization of high-value services, and the Council recommends reaffirming that policy. Similarly, the Council believes that reaffirming Policy H-185.939 will emphasize the importance of VBID plans explicitly considering the clinical benefit of a given service when determining cost-sharing or other benefit design elements.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 226-A-18 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) encourage public and private payers to ensure coverage for prostate cancer screening when the service is deemed appropriate following informed physician-patient shared decision-making.
2. That our AMA encourage national medical specialty societies to promote public education around the importance of informed physician-patient shared decision-making regarding medical services that are particularly sensitive to patient values and circumstances, such as prostate cancer screening.
3. That our AMA amend Policy D-450.957 to change the title to read, “Clinical Guidelines and Evidence Regarding Benefits of Prostate Cancer Screening and Other Preventive Services,” and to add a new subsection, “(3) encouraging scientific research to address the evidence gaps highlighted by organizations making evidence-based recommendations about clinical preventive services.”
4. That our AMA reaffirm Policy D-185.979 regarding aligning clinical and financial incentives for high-value care and highlighting the role national medical specialty societies can play in helping to shape value-based insurance design (VBID) plans that decrease cost-sharing to encourage utilization of high-value services.
5. That our AMA reaffirm Policy H-185.939 which supports VBID plans that explicitly consider the clinical benefit of a given service when determining cost-sharing structures or other benefit design elements.
6. That our AMA reaffirm Policy H-373.997, which sets forth core elements of physician-patient shared decision-making and Policy H-450.938, which sets forth the principles to guide physician value-based decision-making, including providing physicians with easy access to costs of care at the point of decision-making.
7. That our AMA reaffirm Policy D-185.980, which supports coverage for evidence-based genetic/genomic precision medicine and Policy H-425.997, which supports insurance coverage for evidence-based, cost-effective preventive services.

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#### APPENDIX - Policies Recommended for Amendment or Reaffirmation

##### Policy D-185.979, Aligning Clinical and Financial Incentives for High-Value Care

1. Our AMA supports Value-Based Insurance Design (VBID) plans designed in accordance with the tenets of “clinical nuance,” recognizing that (a) medical services may differ in the amount of health produced, and (b) the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided.
2. Our AMA supports initiatives that align provider-facing financial incentives created through payment reform and patient-facing financial incentives created through benefit design reform, to ensure that patient, provider, and payer incentives all promote the same quality care. Such initiatives may include reducing patient cost-sharing for the items and services that are tied to provider quality metrics.

3. Our AMA will develop coding guidance tools to help providers appropriately bill for zero-dollar preventive interventions and promote common understanding among health care providers, payers, patients, and health care information technology vendors regarding what will be covered at given cost-sharing levels.
4. Our AMA will develop physician educational tools that prepare physicians for conversations with their patients about the scope of preventive services provided without cost-sharing and instances where and when preventive services may result in financial obligations for the patient.
5. Our AMA will continue to support requiring private health plans to provide coverage for evidence-based preventive services without imposing cost-sharing (such as co-payments, deductibles, or coinsurance) on patients.
6. Our AMA will continue to support implementing innovative VBID programs in Medicare Advantage plans.
7. Our AMA supports legislative and regulatory flexibility to accommodate VBID that (a) preserves health plan coverage without patient cost-sharing for evidence-based preventive services; and (b) allows innovations that expand access to affordable care, including changes needed to allow High Deductible Health Plans paired with Health Savings Accounts to provide pre-deductible coverage for preventive and chronic care management services.
8. Our AMA encourages national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. (Joint CMS CSAPH Rep. 01, I-18).

Policy D-185.980, Payment and Coverage for Genetic/Genomic Precision Medicine

1. Our AMA encourages public and private payers to adopt processes and methodologies for determining coverage and payment for genetic/genomic precision medicine that:
    - a. Promote transparency and clarity;
    - b. Involve multidisciplinary stakeholders, including genetic/genomic medicine experts and relevant national medical specialty societies;
    - c. Describe the evidence being considered and methods for updating the evidence;
    - d. Provide opportunities for comment and review as well as meaningful reconsiderations; and
    - e. 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.
  2. Our AMA encourages coverage and payment policies for genetic/genomic precision medicine that are evidence-based and take into account the unique challenges of traditional evidence development through randomized controlled trials, and work with test developers and appropriate clinical experts to establish clear thresholds for acceptable evidence for coverage.
  3. Our AMA will work with interested national medical specialty societies and other stakeholders to encourage the development of a comprehensive payment strategy that facilitates more consistent coverage of genetic/genomic tests and therapeutics that have clinical impact.
  4. Our AMA encourages national medical specialty societies to develop clinical practice guidelines incorporating precision medicine approaches that support adoption of appropriate, evidence-based services.
  5. Our AMA supports continued research and evidence generation demonstrating the validity, meaningfulness, short-term and long-term cost-effectiveness and value of precision medicine.
- (Joint CMS / CSAPH Rep. 01, I-17 Reaffirmed: CMS Rep. 06, A-18)

Policy D-450.957, Draft Clinical Quality Measures Non-Recommended PSA-Based Screening

Our AMA will: (1) continue to advocate for inclusion of relevant specialty societies and their members in guideline and performance measure development, including in technical expert panels charged with developing performance measures; and (2) work with the federal government, specialty societies, and other relevant stakeholders to develop guidelines and clinical quality measures for the prevention or early detection of disease, such as prostate cancer, based on rigorous review of the evidence which includes expertise from any medical specialty for which the recommendation may be relevant to ultimately inform shared decision making. (Res. 225, I-15).

Policy 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). (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: Joint CMS/CSAPH Rep. 01, I-17 Reaffirmed: CMS Rep. 07, A-18 Reaffirmed: Joint CMS CSAPH Rep. 01, I-18)

#### Policy H-373.997, Shared Decision-Making

##### Our AMA:

1. recognizes the formal shared decision-making process as having three core elements to help patients become active partners in their health care: (a) clinical information about health conditions, treatment options, and potential outcomes; (b) tools to help patients identify and articulate their values and priorities when choosing medical treatment options; and (c) structured guidance to help patients integrate clinical and values information to make an informed treatment choice;
2. supports the concept of voluntary use of shared decision-making processes and patient decision aids as a way to strengthen the patient-physician relationship and facilitate informed patient engagement in health care decisions;
3. opposes any efforts to require the use of patient decision aids or shared decision-making processes as a condition of health insurance coverage or provider participation;
4. supports the development of demonstration and pilot projects to help increase knowledge about integrating shared decision-making tools and processes into clinical practice;
5. supports efforts to establish and promote quality standards for the development and use of patient decision aids, including standards for physician involvement in development and evaluation processes, clinical accuracy, and conflict of interest disclosures; and
6. will continue to study the concept of shared decision-making and report back to the House of Delegates regarding developments in this area. (CMS Rep. 7, A-10 Reaffirmed in lieu of Res. 5, A-12 Reaffirmation I-14)

#### Policy H-425.997, Preventive Services

1. Our AMA encourages the development of policies and mechanisms to assure the continuity, coordination and continuous availability of patient care, including professional preventive care and early-detection screening services, provided the services are cost effective.
2. It is the policy of the AMA that any preventive service that is being considered for inclusion in public or private sector insurance products have evidence-based data to demonstrate improved outcomes or quality of life and the cost effectiveness of the service.
3. Our AMA believes that preventive care should ideally be coordinated by a patient's physician.  
(BOT Rep. A, NCCMC Rec. 31, A-78 Reaffirmed: CLRPD Rep. C, A-89 Reaffirmed: Sunset Report and Reaffirmed and Appended: CMS Rep. 7, A-00 Reaffirmed in lieu of Res. 104, A-06 Reaffirmation A-07 Modified and Reaffirmed: Sub. Res. 101, A-08 Reaffirmed: CMS Rep. 03, I-16 Reaffirmed: CMS Rep. 03, I-17)

#### Policy H-450.938, Value-Based Decision-Making in the Health Care System

##### PRINCIPLES TO GUIDE PHYSICIAN VALUE-BASED DECISION-MAKING

1. Physicians should encourage their patients to participate in making value-based health care decisions.
2. Physicians should have easy access to and consider the best available evidence at the point of decision-making, to ensure that the chosen intervention is maximally effective in reducing morbidity and mortality.
3. Physicians should have easy access to and review the best available data associated with costs at the point of decision-making. This necessitates cost data to be delivered in a reasonable and useable manner by third-party payers and purchasers. The cost of each alternate intervention, in addition to patient insurance coverage and cost-sharing requirements, should be evaluated.
4. Physicians can enhance value by balancing the potential benefits and costs in their decision-making related to maximizing health outcomes and quality of care for patients.
5. Physicians should seek opportunities to improve their information technology infrastructures to include new and innovative technologies, such as personal health records and other health information technology initiatives, to facilitate increased access to needed and useable evidence and information at the point of decision-making.
6. Physicians should seek opportunities to integrate prevention, including screening, testing and lifestyle counseling, into office visits by patients who may be at risk of developing a preventable chronic disease later in life. (CMS Rep. 7, A-08 Reaffirmed in lieu of Res. 5, A-12 Reaffirmation I-14 Reaffirmation: I-17)

## **7. HOSPITAL CONSOLIDATION (RESOLUTION 235-A-18)**

*Reference committee hearing: see report of Reference Committee G.*

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS  
IN LIEU OF RESOLUTION 235-A-18  
REMAINDER OF REPORT FILED**

*See Policies H-215.960, H-215.969, H-220.937, H-225.947 and H-225.950*

At the 2018 Annual Meeting, the House of Delegates referred Resolution 235-A-18, “Hospital Consolidation,” which was introduced by the Washington Delegation. The Board of Trustees assigned this item to the Council on Medical Service for a report back at the 2019 Annual Meeting. Resolution 235-A-18 asked that our American Medical Association (AMA) actively oppose future hospital mergers and acquisitions in highly concentrated hospital markets, and study the benefits and risks of hospital rate setting commissions in states where highly concentrated hospital markets currently exist.

This report discusses horizontal and vertical hospital consolidation; outlines findings from a recent AMA analysis of hospital market concentration levels; highlights the role of states; describes alternative solutions that promote competition and choice in hospital markets; summarizes relevant AMA policy; and makes policy recommendations.

### **BACKGROUND**

Consolidation in health care markets includes both horizontal and vertical mergers of physicians, hospitals, insurers, pharmaceutical companies, pharmaceutical benefit managers, and other entities. As stated in [Council Report 5-A-17, “Hospital Consolidation,”](#) the AMA believes that health care entity mergers—including among hospitals—should be examined individually, taking into account the case-specific variables of market power and patient needs. The AMA strongly supports health care market competition as well as vigorous state and federal oversight of health care entity consolidation. Antitrust advocacy for physicians is a longstanding AMA priority, and close monitoring of health care markets is a key aspect of AMA antitrust activity.

#### *Horizontal Hospital Consolidation*

Although the AMA’s most visible health care consolidation efforts have focused on health insurance markets, the AMA has also analyzed hospital market concentration using 2013 and 2016 data from the American Hospital Association. In a 2018 analysis, the AMA looked at 1,946 hospitals in 363 metropolitan statistical area (MSA)-level markets in 2013 and 2,028 hospitals in 387 MSAs in 2016 and found that, in most markets, hospitals (or systems) have large market shares.<sup>1</sup> In terms of hospital market shares, the AMA found that in 95 percent of MSAs, at least one hospital or hospital system had a market share of 30 percent or greater in both 2013 and 2016. In 2016, 72 percent of MSAs were found to have a single hospital or system with a market share of at least 50 percent, and 40 percent of MSAs had a single hospital or system with a market share of 70 percent or more.<sup>2</sup> The AMA analysis also found that, in 2016, 92 percent of MSA-level markets were highly concentrated, and 75 percent of hospitals were members of hospital systems.<sup>3</sup>

Hospital markets are concentrated largely due to consolidation. There were 1,412 hospital mergers between 1998 and 2015—with 561 reported between 2010 and 2015—and an additional 102 and 115 mergers documented in 2016 and 2017, respectively.<sup>4,5</sup> Eleven of the transactions in 2017 were mega-deals involving sellers with net revenues of \$1 billion or more.<sup>6</sup>

There are potential benefits and harms resulting from horizontal hospital consolidation, with savings due to economies of scale and enhanced operational efficiencies cited as potential benefits. Hospitals acquiring market power through mergers may also increase prices for hospital care above competitive levels. Although not all hospital mergers impact competition, research has found that mergers in concentrated markets lead to price increases, and that the increases are significant when close competitors consolidate.<sup>7,8</sup> Studies have found little evidence of quality improvements post-merger, and lower quality in more concentrated hospital markets.<sup>9,10</sup> The evidence is more consistent for markets where prices are administered (e.g., Medicare). In markets where prices are market determined, consolidation can also

lead to lower quality, but the evidence is more mixed.<sup>11</sup> Highly concentrated hospital markets may also lessen the practice options available to physicians in communities dominated by large hospital systems.

### *Vertical Hospital Consolidation*

A hospital acquiring a physician practice is an example of vertical hospital consolidation. The AMA closely monitors trends in hospital acquisition of physician practices—which was the focus of [Council on Medical Service Report 2-A-15, “Expanding AMA’s Position on Healthcare Reform Options,”](#)—via biennial Physician Practice Benchmark Surveys (Benchmark Surveys), which are nationally representative samples of non-federal physicians who provide care to patients at least 20 hours per week. In 2018, the share of physicians who worked in practices that were at least partially owned by a hospital was 26.7 percent, up from 25.4 percent in 2016, 25.6 percent in 2014 and 23.4 percent in 2012.<sup>12</sup> The share of physicians who were direct hospital employees in 2018 was 8.0 percent, up from 7.4 percent in 2016, 7.2 percent in 2014 and 5.6 percent in 2012.<sup>13</sup>

Vertical hospital consolidation has been found to increase prices and, in markets where prices are administered (e.g., Medicare), to increase total spending.<sup>14,15</sup> Recent steps taken by the Centers for Medicare & Medicaid Services (CMS) to level the site-of-service playing field between physician offices and off-campus hospital provider-based departments may have diminished a crucial incentive for hospitals to purchase physician practices in the future. For many years, higher payments to hospital outpatient departments likely incentivized the sale of physician practices and ambulatory surgical centers (ASCs) to hospitals because acquired facilities meeting certain criteria (e.g., located within 35 miles of the hospital) were routinely converted to hospital outpatient departments and allowed to charge higher rates for services performed at these off-campus facilities. However, a provision in the Bipartisan Budget Act of 2015 (BBA) disallowed provider-based billing by hospitals for newly acquired physician practices and ASCs. Beginning in 2017, off-campus entities acquired after enactment of the BBA—in November 2015—were no longer permitted to bill for services under Medicare’s Outpatient Prospective Payment System (OPPS), and instead required to bill under the applicable payment system (Physician Fee Schedule). Since 2017, CMS has paid for services at non-excepted off-campus provider-based hospital departments using a Physician Fee Schedule relativity adjuster that is based on a percentage of the OPPS payment rate. CMS has since extended site-neutral payments to include clinic visits provided at off-campus provider-based hospital departments acquired prior to November 2015 that were previously excepted from the BBA provision.<sup>16</sup> The AMA will continue to monitor the impact of these changes on hospital markets.

### PROMOTING COMPETITION AND CHOICE

The AMA is aware of the potential effects of hospital consolidation on physicians and patients, including concerns about the loss of physician autonomy in clinical decision-making and preserving physician leadership in large systems, and also increased hospital prices in concentrated markets. The AMA also recognizes that employment preferences vary greatly among physicians, and that employment by large hospital systems or hospital-owned practices remains an attractive practice option for some physicians. A 2013 AMA-RAND study on professional satisfaction found that physicians in physician-owned practices were more satisfied than physicians in other ownership models (e.g., hospital or corporate ownership), but that work controls and opportunities to participate in strategic decisions mediate the effect of practice ownership on overall professional satisfaction.<sup>17</sup>

The AMA has long been a strong advocate for competitive health care markets and antitrust relief for physicians, and maintains that health care markets should be sufficiently competitive to allow physicians to have adequate choices and practice options. AMA efforts to obtain antitrust relief for physicians, maximize their practice options, and protect patient-physician relationships include legislative advocacy; advocacy at the Federal Trade Commission (FTC) and the US Department of Justice (DOJ); and the creation of practical physician resources.

State and federal antitrust enforcement for hospital consolidation has been somewhat limited and has had mixed results over the years, with some successes and also periods of intense merger activity.<sup>18</sup> Many mergers have proceeded unchallenged. Experts have also asserted that in hospital markets that are already highly concentrated, antitrust provides no remedy.<sup>19</sup> Accordingly, in addition to antitrust activities, the AMA has pursued alternative solutions that promote competition and choice, including: eliminating state certificate of need (CON) laws; repealing the ban on physician-owned hospitals; reducing the administrative burden to enable physicians to compete with hospitals; and achieving meaningful price transparency.



*Eliminating State CON Laws:* The AMA supports the elimination of state CON laws, which are barriers to market entry that harm competition, and supports state medical associations in their advocacy efforts to repeal them. CON laws require state boards to review all entities seeking to enter a health care market to provide care, including existing facilities seeking to offer new services or services in new locations. Thirty-five states and the District of Columbia currently administer CON programs.<sup>20</sup> As stated in Policy H-205.999, the AMA believes that there is little evidence to suggest that CON programs are effective in restraining health care costs or in limiting capital investment. In the absence of such evidence, AMA policy also opposes CON laws and the extension of CON regulations to private physician offices.

*Repealing the Ban on Physician-Owned Hospitals:* The AMA strongly advocates that Congress repeal limits to the whole hospital exception of the Stark physician self-referral law, which essentially bans physician ownership of hospitals and places restrictions on expansions of already existing physician-owned hospitals. Repealing the ban would allow new entrants into hospital markets, thereby increasing competition. Because physician-owned hospitals have been shown to provide the highest quality of care to patients, limiting their viability reduces access to high-quality care. The AMA firmly believes that physician-owned hospitals should be allowed to compete equally with other hospitals, and that the federal ban restricts competition and choice.

*Reducing Administrative Burdens:* Physicians are increasingly burdened by administrative tasks that are extremely costly to practices and reduce time with patients, yet increase the work necessary to provide medical services. Examples of these burdens include abiding by state and federal rules and regulations, meeting quality reporting requirements, managing electronic health records, and navigating a plethora of payer protocols and utilization management programs. Utilization management has become so burdensome that in 2018 the average physician reported completing 31 prior authorizations per week, a process that required 14.9 hours of work or the equivalent of two business days.<sup>21</sup> Taken together, these burdens make it difficult for physician practices—particularly smaller practices—to compete, which may lead physicians to consolidate with larger groups or hospitals.<sup>22</sup> The AMA conducts widespread prior authorization advocacy and outreach, including promoting Prior Authorization and Utilization Management Reform Principles, the Consensus Statement on Improving the Prior Authorization Process, model state legislation, the Prior Authorization Physician Survey, and the AMA Prior Authorization toolkit.

*Price Transparency:* The lack of complete, accurate and timely information about the cost of health care services prevents health care markets from operating efficiently. Patients are increasingly becoming active consumers of health care services rather than passive recipients of care in a market where price is often unknown until after the service is delivered. The AMA supports price transparency and recognizes that achieving meaningful price transparency may help lower health care costs and empower patients to choose low-cost, high-quality care. The AMA supports measures that expand the availability of health care pricing information, enabling patients and their physicians to make value-based decisions when patients have a choice of provider or facility.

## ROLE OF STATES

While it is recognized that most hospital markets are highly concentrated and do not work as well as they could, it is also recognized that hospital markets are local and that states play a significant role in regulating them. States have their own antitrust laws, and state attorneys general and other regulators have better access to the local market-level data needed to oversee and challenge proposed mergers in their states. States can take on mergers themselves or join federal antitrust efforts. Some states have approved mergers but established conditions that must be met, such as requiring merged hospitals to maintain charity care programs or capping price increases for a certain number of years. As discussed previously, states can also reduce barriers to new competitors in hospital markets by eliminating CON laws.

### *All-Payer Rate Setting for Hospitals (Maryland, Pennsylvania and Vermont)*

The approach to fostering competition cited in referred Resolution 235-A-18 is all-payer rate setting for hospitals, under which all payers (e.g., Medicare, Medicaid, private insurers and employer self-insured plans) pay hospitals the same price for services. Although-payer rate setting was popular in the 1970s, Maryland is the only state where it remains. Building on its all-payer rate setting approach, Maryland began implementing an all-payer global budgeting model for hospitals in 2014, while Pennsylvania began a similar model for rural hospitals in 2017. Vermont has developed an all-payer model for accountable care organizations (ACOs) that enables Medicare, Medicaid and private insurers to pay ACOs differently than through fee-for-service. These more recent all-payer payment models are still

in the early stages of implementation and continue to undergo refinements and ongoing evaluation. Hospitals under this model are exempt from Medicare's inpatient and outpatient prospective payment systems and instead are paid based on fixed annual budget amounts for inpatient and outpatient hospital services that are established in advance.

A federally-funded evaluation of the first three years of Maryland's all-payer model found that it reduced total expenditures and hospital expenditures for Medicare patients but did not impact total expenditures or hospital expenditures for privately insured patients.<sup>23</sup> The evaluation further found that hospitals have adapted to global budgets without being adversely impacted financially. Other studies have looked at hospitals in eight urban counties in Maryland and the state's earlier rural pilot program, and research is ongoing. Accordingly, the Council believes that it may be premature to draw meaningful conclusions about the potential impact of hospital rate-setting in states with highly concentrated hospital markets.

All-payer rate setting for hospitals is intended to increase price competition and lessen the bargaining power of dominant hospitals, and it moves hospitals away from fee-for-service. However, appropriate payment rates can be challenging to establish and the model can be costly for states to administer.<sup>24</sup> Strong state leadership as well as an established information technology infrastructure are needed for all-payer global budgeting to be successful.<sup>25</sup>

#### *Massachusetts Health Policy Commission*

The Massachusetts Health Policy Commission (HPC) is an independent state agency that monitors health care spending growth and makes policy recommendations regarding health care payment and delivery reforms. Among other responsibilities, the HPC—established in 2012—is charged with monitoring changes in the health care market. Massachusetts regulations stipulate that health care provider organizations with more than \$25 million in revenue must notify the HPC before consummating transactions for the purpose of enabling the state watchdog to conduct a “cost and market impact review.”<sup>26</sup> The HPC has conducted several such reviews of proposed hospital mergers over the years and made them available to stakeholders as well as the public, thereby increasing transparency surrounding these transactions. Notably, mergers may be allowed to move forward despite criticisms from the HPC.

#### AMA RESOURCES

Recognizing that physicians are increasingly becoming employed by hospitals and health systems, the AMA has developed several practical [tools](#) for physicians, including the Annotated Model Co-Management Service Line Agreement, Annotated Model Physician-Hospital Employment Agreement and the Annotated Model Physician-Group Practice Employment Agreement which assist in the negotiation of employment contracts. For physicians considering a practice setting change or looking for an alignment strategy with an integrated health system, the AMA developed [Joining or Aligning with a Physician-led Integrated Health System](#). The AMA has also made available a set of resources called “Unwinding Existing Arrangements” that guides employed physicians on how to “unwind” from their organization, factoring in operational, financial, and strategic considerations.

AMA principles for physician employment (Policy H-225.950) have been codified to address some of the more complex issues related to employer-employee relationships, and the AMA Physician's Guide to Medical Staff Bylaws is a useful reference manual for drafting and amending hospital medical staff bylaws. The AMA has also developed a series of model state bills, available from the AMA's Advocacy Resource Center, that are intended to address concerns expressed by employed physicians. Through these resources, the AMA is well-positioned to help employed physicians and those considering employment by hospitals or other corporations to preserve physician autonomy and independent decision-making and protect patient-physician relationships. The inviolability of the patient-physician relationship is a recurrent theme throughout the AMA Code of Medical Ethics, which also addresses mergers of secular and religiously affiliated health care institutions (Code of Medical Ethics Opinion 11.2.6). AMA staff are available to provide guidance and consultation on a range of issues related to employment and consolidation.

#### *Working Toward Integrated Leadership Structures*

Importantly, the AMA has always supported the ability of physicians to choose their mode of practice. The AMA promotes physician leadership in integrated structures and develops policy and resources intended to help safeguard physicians employed by large systems. The AMA has collaborated with hospitals, independent physician associations, large integrated health care systems' leaders and payers to cultivate successful physician leadership that improves the value of care for patients. Working with these stakeholders to bring clinical skills and business insights together at the



leadership level, the AMA is fostering a more cohesive and integrative decision-making process within hospitals and health care systems. To help hospitals and health care systems institute that kind of decision-making process, the American Hospital Association (AHA) and the AMA released “Integrated Leadership for Hospitals and Health Systems: Principles for Success” in June 2015. The “Principles” provide a guiding framework for physicians and hospitals that choose to create an integrated leadership structure but are unsure how to best achieve the engagement and alignment necessary to collaboratively prioritize patient care and resource management.

## RELEVANT AMA POLICY

Policy H-215.968 supports and encourages competition between and among health facilities as a means of promoting the delivery of high-quality, cost-effective health care. Antitrust relief for physicians that enables physicians to negotiate adequate payment remains a top priority of the AMA under Policies H-380.987, D-383.989, D-383.990 and H-383.992. Under Policy H-160.915, antitrust laws should be flexible to allow physicians to engage in clinically integrated delivery models without being employed by a hospital or ACO. Policy D-385.962 directs the AMA to support antitrust relief for physician-led accountable care organizations. Policy H-225.950 outlines AMA Principles for Physician Employment intended to assist physicians in addressing some of the unique challenges employment presents to the practice of medicine, including conflicts of interest, contracting, and hospital medical staff relations.

The AMA has substantial policy intended to protect medical staffs, including Policy H-220.937, which states that geographic disparities or differences in patient populations may warrant multiple medical staffs within a single hospital corporation, and that each medical staff shall develop and adopt bylaws and rules and regulations to establish a framework for self-governance of medical activities and accountability to the governing body. Policy H-215.969 provides that, in the event of a hospital merger, acquisition, consolidation or affiliation, a joint committee with merging medical staffs should be established to resolve at least the following issues: (a) medical staff representation on the board of directors; (b) clinical services to be offered by the institutions; (c) process for approving and amending medical staff bylaws; (d) selection of the medical staff officers, medical executive committee, and clinical department chairs; (e) credentialing and recredentialing of physicians and limited licensed providers; (f) quality improvement; (g) utilization and peer review activities; (h) presence of exclusive contracts for physician services and their impact on physicians’ clinical privileges; (i) conflict resolution mechanisms; (j) the role, if any, of medical directors and physicians in joint ventures; (k) control of medical staff funds; (l) successor-in-interest rights; and (m) that the medical staff bylaws be viewed as binding contracts between the medical staffs and the hospitals. Policy H-215.969 also states that the AMA will work to ensure, through appropriate state oversight agencies, that where hospital mergers and acquisitions may lead to restrictions on reproductive health care services, the merging entity shall be responsible for ensuring continuing community access to these services. Under Policy H-235.991, medical staff bylaws should include successor-in-interest provisions to protect medical staffs from a hospital ignoring existing bylaws and establishing new bylaws to apply post-merger, acquisition, affiliation or consolidation.

Policy H-225.947, which was established via [Council on Medical Service Report 5-A-15, “Hospital Incentives for Admission, Testing and Procedures,”](#) encourages physicians who seek employment as their mode of practice to strive for employment arrangements consistent with a series of principles including that: (a) physician clinical autonomy is preserved; (b) physicians are included and actively involved in integrated leadership opportunities; (c) physicians are encouraged and guaranteed the ability to organize under a formal self-governance and management structure; (d) physicians are encouraged and expected to work with others to deliver effective, efficient and appropriate care; (e) a mechanism is provided for the open and transparent sharing of clinical and business information by all parties to improve care; and (f) a clinical information system infrastructure exists that allows capture and reporting of key clinical quality and efficiency performance data for all participants and accountability across the system to those measures. Policy H-225.947 also encourages continued research on the effects of integrated health care delivery models that employ physicians on patients and the medical profession. Policy H-285.931 adopts principles for physician involvement in integrated delivery systems and health plans. Policy D-225.977 directs the AMA to continue to assess the needs of employed physicians and promote physician collaboration, teamwork, partnership, and leadership in emerging health care organizational structures.

AMA policy does not prohibit the application of restrictive covenants in the physician employment context generally, although Policy H-225.950, “Principles for Physician Employment,” discourages physicians from entering into agreements that restrict the physician’s right to practice medicine for a specified period of time or in a specified area upon termination of employment. AMA Code of Medical Ethics Opinion 11.2.3.1 states that covenants-not-to-compete restrict competition, can disrupt continuity of care, and may limit access to care. Accordingly, physicians

should not enter into covenants that: (a) unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship; and (b) do not make reasonable accommodation for patients' choice of physician. This opinion also states that physicians in training should not be asked to sign covenants not to compete as a condition of entry into any residency or fellowship program. Under Policy H-140.984, the AMA opposes an across-the-board ban on self-referrals, because of benefits to patients including increased access and competition.

## DISCUSSION

The Council shares the concerns among physicians regarding potential negative consequences for physicians and patients in highly concentrated hospital markets (e.g., increased prices, reduced choice, and fewer physician practice options). In addition to reviewing the literature, the Council received input from AMA antitrust experts during the development of this report, and notes that AMA staff are readily available to assist and advise AMA members and state medical associations with questions or concerns about physician-hospital relations or hospital consolidation. Nonetheless, the AMA does not have the resources to actively oppose all future hospital mergers in highly concentrated markets, as requested by Resolution 235-A-18. Attempting to address hospital mergers in the same manner that the AMA has addressed major health insurance mergers would place an undue burden on the organization's resources and may alienate many valued AMA members who work for hospitals and hospital systems.

Having prepared two reports on hospital consolidation in a two-year time period, the Council has a clear understanding of ongoing AMA efforts to monitor and respond to health care consolidation, including engaging with the FTC and the DOJ as well as state attorneys general and insurance commissioners. The Council further appreciates the abundance of AMA policy embracing competition and choice, and concludes that hospital consolidation is sufficiently addressed (and not prohibited) by existing policy. Accordingly, the Council developed a new policy recommendation that brings together existing AMA policy to affirm that: (a) health care entity mergers should be examined individually, taking into account case-specific variables of market power and patient needs; (b) the AMA strongly supports and encourages competition in all health care markets; (c) the AMA supports rigorous review and scrutiny of proposed mergers to determine their effects on patients and providers; and (d) antitrust relief for physicians remains a top AMA priority.

The Council also recognizes that most hospital markets are highly concentrated, and that hospital markets are predominantly local. The Council's review of the literature found that antitrust efforts may not be effective in hospital markets that are already highly concentrated, and that alternative solutions are warranted. Accordingly, the Council recommends that the AMA continue to support actions that promote competition and choice, including: (a) eliminating state CON laws; (b) repealing the ban on physician-owned hospitals; (c) reducing administrative burdens that make it difficult for physician practices to compete; and (d) achieving meaningful price transparency.

Because hospital markets are local, the Council further recommends encouraging state medical associations to monitor hospital markets and review the impact of horizontal and vertical health system integration on patients, physicians and hospital prices.

Having discussed the potential impact of hospital consolidation on medical staffs, and the need to protect affected medical staffs post-merger, the Council recommends reaffirmation of four policies intended to help guide medical staffs and physicians experiencing consolidation: Policy H-215.969, which provides that, in the event of a hospital merger, acquisition, consolidation or affiliation, a joint committee with merging medical staffs should be established to resolve critical issues; Policy H-220.937, which states that geographic disparities or differences in patient populations may warrant multiple medical staffs within a single hospital corporation; Policy H-225.950, which outlines AMA Principles for Physician Employment; and Policy H-225.947, which encourages physicians who seek employment as their mode of practice to strive for employment arrangements consistent with a series of principles that actively involve physicians in integrated leadership and preserve clinical autonomy.

The Council is intrigued by state efforts to promote competition, including Maryland's all-payer rate setting model and Massachusetts' HPC. The AMA will continue to monitor these and other models but, at this time, does not make recommendations regarding their widespread adoption.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 235-A-18, and the remainder of the report be filed:

1. That our American Medical Association (AMA) affirm that: (a) health care entity mergers should be examined individually, taking into account case-specific variables of market power and patient needs; (b) the AMA strongly supports and encourages competition in all health care markets; (c) the AMA supports rigorous review and scrutiny of proposed mergers to determine their effects on patients and providers; and (d) antitrust relief for physicians remains a top AMA priority.
2. That our AMA continue to support actions that promote competition and choice, including: (a) eliminating state certificate of need laws; (b) repealing the ban on physician-owned hospitals; (c) reducing administrative burdens that make it difficult for physician practices to compete; and (d) achieving meaningful price transparency.
3. That our AMA work with interested state medical associations to monitor hospital markets, including rural, state and regional markets, and review the impact of horizontal and vertical health system integration on patients, physicians and hospital prices.
4. That our AMA reaffirm Policy H-215.969, which provides that, in the event of a hospital merger, acquisition, consolidation or affiliation, a joint committee with merging medical staffs should be established to resolve at least the following issues: (a) medical staff representation on the board of directors; (b) clinical services to be offered by the institutions; (c) process for approving and amending medical staff bylaws; (d) selection of the medical staff officers, medical executive committee, and clinical department chairs; (e) credentialing and recredentialing of physicians and limited licensed providers; (f) quality improvement; (g) utilization and peer review activities; (h) presence of exclusive contracts for physician services and their impact on physicians' clinical privileges; (i) conflict resolution mechanisms; (j) the role, if any, of medical directors and physicians in joint ventures; (k) control of medical staff funds; (l) successor-in-interest rights; and (m) that the medical staff bylaws be viewed as binding contracts between the medical staffs and the hospitals.
5. That our AMA reaffirm Policy H-220.937, which states that geographic disparities or differences in patient populations may warrant multiple medical staffs within a single hospital corporation, and that each medical staff shall develop and adopt bylaws and rules and regulations to establish a framework for self-governance of medical activities and accountability to the governing body.
6. That our AMA reaffirm Policy H-225.950, which outlines AMA Principles for Physician Employment intended to assist physicians in addressing some of the unique challenges employment presents to the practice of medicine, including conflicts of interest, contracting, and hospital medical staff relations, and that discourage physicians from entering into agreements that restrict their right to practice medicine for a specified period of time or in a specified area upon termination of employment. and
7. That our AMA reaffirm Policy H-225.947, which encourages physicians who seek employment as their mode of practice to strive for employment arrangements consistent with a series of principles that actively involve physicians in integrated leadership and preserve clinical autonomy.

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## 8. GROUP PURCHASING ORGANIZATIONS AND PHARMACY BENEFIT MANAGER SAFE HARBOR (RESOLUTION 252-A-18)

*Reference committee hearing: see report of Reference Committee G.*

### HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 252-A-18 REMAINDER OF REPORT FILED

*See Policies H-100.956, H-110.992, H-125.986 and D-100.967*

At the 2018 Annual Meeting, the House of Delegates referred Resolution 252, which was introduced by the Organized Medical Staff Section and assigned for study to the Council on Medical Service with assistance from the Council on Legislation. Resolution 252-A-18 asked:

That our American Medical Association (AMA): (1) collaborate with medical specialty partners, patient advocacy groups, and other stakeholders to seek repeal of the 1987 Safe Harbor exemption to the Medicare Anti-Kickback Statute for Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs); (2) educate its

members on how safe harbor exemption for GPOs and PBMs affects drug prices and drug shortages; and (3) reaffirm Policy H-100.956, which states in part that “Our AMA will collaborate with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.”

This report provides background on GPOs, how they function, and the relevant federal anti-kickback statute; details how the GPO safe harbor is used by PBMs; outlines possible antitrust and anticompetitive concerns with the GPO safe harbor; specifies the possible legal and patient access implications of repeal of the safe harbor; and offers recommendations to refine the GPO safe harbor operations.

## BACKGROUND

At the 2016 Annual Meeting, Resolution 201-A-16, “Repeal of Anti-Kickback Safe Harbor for Group Purchasing Organizations,” sponsored by the Medical Student Section, asked the AMA to support the repeal of the Anti-Kickback safe harbor for GPOs. Resolution 201-A-16 was referred for decision by the House of Delegates. The Council on Legislation discussed and provided input for the Management Report for Board Action, which recommended not adopting Resolution 201-A-16. The Board voted that Resolution 201-A-16 not be adopted.

At the 2018 Annual Meeting, concern was raised during the reference committee hearing regarding Resolution 252-A-18 that its proposed solution of repealing the GPO safe harbor could be both ineffective and counterproductive in addressing the identified problems of drug shortages and pricing. With respect to GPO pricing incentives, testimony also stated that GPO contracts are voluntary in nature. GPO customers may have the ability to purchase products and services off-contract if they find a preferable or better-priced option. Testimony further indicated that GPO customers include not only hospitals, but also clinics, ambulatory surgery centers, and other provider arrangements. As such, physician-owned hospitals and other physician practice settings may be adversely impacted if the viability of the GPO business model is compromised.

## HOW A GPO FUNCTIONS

GPOs are organizations that act as purchasing intermediaries that negotiate contracts between their customers—health care providers—and vendors of medical products. A GPO is generally made up of provider-members, and such members may receive profits from the GPO. A provider joins a GPO to “incur a lower purchasing cost ... by buying through the GPO [rather] than by contracting for the same item directly with a manufacturer. GPOs assert that they are able to lower their provider-members’ price per unit by employing market intelligence and product expertise that no single member could afford, and by contracting for the group’s combined purchase quantity. GPOs are able to lower a provider’s contracting cost by spreading its own, presumably higher, fixed contracting cost over its many members.”<sup>1</sup> For example, AMA members can receive practice discounts through Henry Schein Medical for medical, surgical, pharmaceutical, and equipment purchases.<sup>2</sup> Henry Schein is partnered with GroupSource, a GPO serving the non-acute physician market, to offer physicians a wide range of products.<sup>3</sup>

GPOs earn revenue from several sources:

- Administrative fees paid by the manufacturer of products;
- Membership fees from provider-members;
- Administrative fees charged to distributors authorized to distribute products under a GPO’s contract;
- Miscellaneous service fees that are charged directly to provider-members; and
- Other sources of revenue like outside investments.

GPOs offer a variety of services that may be paid by the administration fees or through direct charging to provider members. The U.S. Government Accountability Office identifies the funding methods that GPOs reported using for the services they provided:<sup>4</sup>

**Table 3: The Six Largest Group Purchasing Organizations' (GPO) Reported Funding Methods for Services Provided in 2008**

Service <sup>a</sup>	Number of GPOs offering service	Number of GPOs funding only through administrative fees	Number of GPOs funding only through charges to customers	Number of GPOs using both funding methods
Custom contracting	6	2	2	2
Clinical evaluation and standardization	6	4	0	2
Technology assessments	6	5	1	0
Supply-chain analysis	5	1	1	3
Electronic commerce	5	2	0	3
Materials management consulting	5	1	1	3
Benchmarking data	5	1	1	3
Continuing medical education	5	4	0	1
Market research	4	2	2	0
Materials management outsourcing	3	0	3	0
Patient safety services	3	2	1	0
Marketing products or services	3	2	1	0
Insurance services	2	1	1	0
Revenue management	2	0	2	0
Warehousing	1	1	0	0
Equipment repair	1	1	0	0
Other <sup>b</sup>	3	2	0	1

## STATUTORY AND REGULATORY BACKGROUND ON THE FEDERAL ANTI-KICKBACK STATUTE

The federal anti-kickback statute provides *criminal* penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce business reimbursed under the Medicare or state health care programs.<sup>5</sup> The offense is classified as a felony, and is punishable by fines of up to \$100,000, imprisonment for up to 10 years, and subjects the offending party to false claims act liability. The Secretary of the US Department of Health and Human Services (HHS) delegated authority over the anti-kickback statute to the HHS Office of Inspector General (OIG).

This provision is extremely broad. The types of remuneration covered specifically include kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind. In addition, prohibited conduct includes not only remuneration intended to induce referrals of patients, but also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or state health care programs.

Because of the broad reach of the statute, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress provides statutory exceptions from illegal remuneration where the anti-kickback statute does not apply. In addition, Congress specifically required the development and promulgation of regulations, the so-called safe harbor provisions, that would specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute, even though they may potentially be capable of inducing referrals of business under federal health care programs.<sup>6</sup> In authorizing HHS to protect certain arrangements and payment practices under the anti-kickback statute, Congress intended that the safe harbor regulations be updated periodically to reflect changing business practices and technologies in the health care industry.

Accordingly, the legal framework governing the anti-kickback statute includes both statutory exceptions *and* regulatory safe harbors. The federal government considers the statutory exceptions and regulatory safe harbors as co-terminus, meaning that they cover the same conduct and the regulatory safe harbor is implementing the statutory safe harbor. Industry and the provider community have argued that they are distinct, separate protections. For example, a provider could receive protection under the statutory exception for discounts even if the arrangement would not fit within the counterpart regulatory safe harbor. Whether the protections are co-terminus or distinct is an open legal question that depends on the legal precedent of case law in each federal circuit (if a circuit has considered this specific issue).

This report will focus on three specific statutory exceptions and regulatory safe harbors that may cover the various funding mechanisms of GPOs: (1) GPO safe harbor; (2) discount safe harbor; and (3) personal services and management contracts safe harbor.

### *GPO Statutory Exception and Regulatory Safe Harbor*

With GPOs, Congress enacted section 9321 of the Omnibus Budget Reconciliation Act of 1986, which excludes from the definition of “remuneration” certain fees paid by vendors to GPOs from prosecution under the anti-kickback statute.<sup>7</sup> According to the legislative history, Congress believed that GPOs could “help reduce health care costs for the government and the private sector alike by enabling a group of purchasers to obtain substantial volume discounts on the prices they are charged.”<sup>8</sup>

In 1991, OIG issued a final rule implementing a GPO safe harbor to apply to payments from vendors to entities authorized to act as a GPO for individuals or entities who are furnishing Medicare or Medicaid services. The proposed safe harbor required a written agreement between the GPO and the individual or entity that specifies the amounts vendors will pay the GPO.

To qualify for protection under the GPO safe harbor, a GPO must have a written agreement with each individual or entity for which items or services are furnished. That agreement must either provide that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of three percent or less of the purchase price of the goods or services provided by that vendor or, in the event the fee paid to the GPO is not fixed at three percent or less of the purchase price of the goods or services, specify the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

Where the entity that receives the goods or services from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. As explained in the preamble to the final regulations, the safe harbor is not intended to protect fees to arrange for referrals or recommendations within a single entity.<sup>9</sup> Therefore, the safe harbor provides that “Group Purchasing Organization” means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid, or other federal health care programs, and who are neither wholly owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly owned entity).

Thus, if a GPO meets the above requirements, it fits within the GPO safe harbor and its administrative fees will not be subject to criminal prosecution under the anti-kickback statute. Of course, these administrative fees may cover a variety of services.

### *Discount Statutory Exception and Regulatory Safe Harbor*

The discount statutory exception applies to arrangements where there is a discount or other reduction in price that was obtained by a provider or other entity when such discounts are properly disclosed and reflected in the costs for which reimbursement could be claimed.<sup>10</sup> Congress included the discount exception to “ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal.”<sup>11</sup>

The regulatory discount safe harbor exempts from the definition of remuneration discounts on items or services for which the federal government may pay and certain disclosure requirements are met.<sup>12</sup> A discount means a reduction in the amount a buyer is charged for an item or service based on an arms-length transaction. In addition, rebates are also covered under the discount safe harbor to mean an amount that is described in writing at the time of the purchase but is not paid at the time of sale. The safe harbor also specifically excludes from the definition of a discount cash or cash-equivalents (except for rebates in the form of a check); certain swapping arrangements (e.g., induce purchasing one good for another good); exempted remuneration from other safe harbors (e.g., warranties); and other remuneration, in cash or in kind not explicitly described by the safe harbor.

The regulatory safe harbor disclosure requirements vary based on the type of entity—buyer, seller, offeror—in the discount arrangement. Moreover, a buyer’s disclosure requirements depend on whether the entity is (1) acting under a risk contract; (2) reports costs on a cost report; or (3) submits a claim or a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid, or other federal health care programs.<sup>13</sup>



Thus, a GPO's up-front discount is covered by the statutory exception and the regulatory safe harbor if properly disclosed, and it will not be subject to criminal prosecution under the anti-kickback statute.

#### *Personal Services and Management Contracts Regulatory Safe Harbor*

This safe harbor protects certain payments made by a principal to an agent as compensation for the agents' services. Protection applies only if certain standards are met that "limit the opportunity to provide financial incentives in exchange for referrals."<sup>14</sup> These standards include that aggregate compensation is set in advance, consistent with fair market value in an arms-length transaction, and not determined in a manner that takes into account the volume or value of any referrals or business generated between the parties.<sup>15</sup>

Thus, if a GPO offers additional services that go beyond the administration fees (i.e., direct charges to the provider-members), the GPO may be able to structure such fees under the personal services safe harbor and receive protection from criminal prosecution under the anti-kickback statute.

#### APPLICATION TO PHARMACY BENEFIT MANAGERS

Overall, the application of the anti-kickback safe harbors and exceptions to PBMs is difficult because PBMs and their current activities were not prevalent or existent when the safe harbors were created.

#### *GPO Statutory Exception and Regulatory Safe Harbor*

The OIG's only formal pronouncement on PBMs and the GPO regulatory Safe Harbor is found in sub-regulatory guidance: Compliance Program Guidance for Pharmaceutical Manufacturers issued in 2003.<sup>16</sup> "Any rebates or other payments by drug manufacturers to PBMs that are based on the PBM's customers' purchases potentially implicate the anti-kickback statute." Protection is available by structuring such arrangements to fit in the GPO safe harbor. That safe harbor requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer and to HHS upon request. In addition, Medicare Part D sponsors and other entities that provide PBM services are required to report various data elements to CMS. The statute specifies that this data is confidential and generally must not be disclosed by the government or by a plan receiving the information.<sup>17</sup>

The OIG potentially extended the GPO regulatory Safe Harbor, which is meant to cover administrative fees, to include "any rebates or other payments." Thus, PBMs can argue that fees and rebates have protection under the GPO Safe Harbor. However, PBMs would attempt to fit non-administrative fees within different safe harbors first and then potentially rely on GPO Safe Harbor as a backstop.<sup>18</sup>

#### *Discount Statutory Exception and Regulatory Safe Harbor*

On February 6, 2019, HHS issued a proposed rule to amend the safe harbor regulations concerning discounts.<sup>19</sup> HHS is proposing to disallow these traditional discount/rebate arrangements for plan sponsors under Part D and Medicaid Managed Care Organizations and attempt to instead pass any price concession directly to the beneficiary at the point-of-sale of the drug. To do this, they are proposing changes to the anti-kickback safe harbor regulation concerning discounts. Under the proposal, CMS would eliminate the current safe harbor protections for discounts paid by manufacturers directly to plan sponsors and PBMs. HHS also proposes the creation of two new safe harbor protections: protection for reductions in price at the point-of-sale and protection for fixed fees paid to PBMs for services rendered to manufacturers.<sup>20</sup>

In its formal response to the proposed rule, the AMA commented that OIG either needs to eliminate the application of the GPO regulatory safe harbor to PBMs or clarify its application only to administrative fees and define what services are covered. The AMA's comments went on to state that PBMs may be able to avail themselves to existing regulatory safe harbors including the GPO safe harbor, the personal services and management contracts safe harbor, managed care safe harbor, and the proposed certain PBM services safe harbor. The AMA requested that the Department clarify what PBM fees and services apply to both the proposed and existing safe harbors. Otherwise, the AMA is concerned that the lack of clarity may provide further opportunity for exploitation.



Moreover, on May 16, 2018, Secretary Azar noted: “We would welcome the PBM industry coming forth with broader proposals for moving away from today’s system, including a plan for implementation with the pharmaceutical industry. But we also have the administrative power to end this system ourselves—to eliminate rebates and forbid remuneration from pharmaceutical companies, align interests, and end the corrupt bargain that keeps driving list prices skyward.” In his comments before the Senate Health, Education, Labor & Pensions Committee, Secretary Azar went further, noting: “Rebates are allowed under an exception to the Anti-Kickback Statute, and that’s an exception that we believe by regulation we could modify.”

In the legal community, there is debate as to whether a PBM truly meets the definition of a “buyer” under the regulatory discount safe harbor considering PBMs do not take physical possession of the drugs. That said, most discount arrangements between PBMs and drug manufacturers (or other entities) are structured to fit within the discount safe harbor.

#### *Personal Services and Management Contracts Regulatory Safe Harbor*

As with GPOs, if a PBM offers additional services that go beyond the administration fees (e.g., data analytics, disease management), the PBM may be able to structure such fees under the personal services safe harbor and receive protection from criminal prosecution under the anti-kickback statute.

Summary Table

	GPO	PBM	Anti-Kickback Statute exception/safe harbor
Administrative Fees	~3%	~4.5-5% <sup>21</sup>	Protected by the GPO safe harbor
Type of Discount	Up front <u>discount</u> at time of purchase	After the purchase <u>rebate</u>	Protected by the Discount safe harbor
Other fees	Data analytics, market research, clinical evaluation, etc.	Data analytics, disease management	If applicable, protected by the Personal Services safe harbor

#### ANTITRUST AND COMPETITION CONCERNS

In response to antitrust concerns in the health care area, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) from 1993-1996 issued policy statements involving mergers and various joint activities in the health care arena.<sup>22</sup> Statement 7 discusses DOJ/FTC enforcement policy involving health care providers’ joint purchasing agreements, which includes GPOs. Generally, DOJ/FTC believe that most joint purchasing arrangements among hospitals or other health care providers do not raise antitrust concerns because the participants frequently can obtain volume discounts, reduce transaction costs, and have access to other services like consulting advice that may not be available to each participant on their own. Absent extraordinary circumstances, the agencies will not challenge any joint purchasing arrangement if it is in the “Antitrust Safety Zone.”

Two conditions must be present to enter the zone:

1. The purchases by the health care provider account for less than 35 percent of the total sales of the purchased product or services in the relevant market.
2. The cost of the products and services purchased jointly accounts for less than 20 percent of the total revenue from all products or services sold by each competing participant in the joint purchasing arrangements.

The agencies also listed certain safeguards that joint purchasing arrangements can adopt to minimize concerns including not requiring the use of arrangements for all services; having an independent employee or agent negotiate on behalf of the joint purchasing arrangement, and ensuring communications between the purchasing group and participants are kept confidential.

Since this guidance was issued, GPO market consolidation has increased and led to an oligopoly market structure for national GPOs. The five largest GPOs by purchasing volume have approximately 85-90 percent of the market<sup>23</sup> and in 2017 the top four GPOs reported a total purchasing volume of \$189 billion.<sup>24</sup>

Competition concerns are also raised when it comes to contracts between GPOs and vendors including sole-source contracting, minimum purchasing requirements that may cause overspending, length of the contract (5+ years in some instances), and bundling.

- **Sole-source contracts:** In a GAO report, all five major GPOs reported that they do negotiate sole-source contracts when it is advantageous to their customers, though some GPOs reported negotiating a higher proportion of sole source contracts than others. One GPO said that about 18 percent of its customers' spending through the GPO is through sole-source contracts. Three GPOs reported sole-source contracting for branded drugs and commodities, and four GPOs reported sole-source contracting for generic drugs, including generic injectable drugs.
- **Contracts that bundle related products:** GPOs report negotiating contracts that offer discounts based on the purchase of bundled products, but restricting bundling to products that are used together or are otherwise related in order to create efficiencies and help standardize products for their customers.
- **Long-term contracts:** GPOs report awarding longer terms for certain types of products, such as IV systems and laboratory products.

Alternatively, all GPO contracts are voluntary and the product of market negotiations. Hospitals and other health care providers are generally not required to only contract with one GPO and may belong to multiple GPOs. Vendors are not required to contract with GPOs and health care providers are not required to use the contracts negotiated by GPOs with their vendors. While GPOs may negotiate sole-source contracts, providers are generally not required to purchase through their GPO contracts but can instead purchase supplies "off contract" by negotiating their own prices directly with suppliers.<sup>25</sup> In economic models, on-contract prices are not necessarily the lowest available. In fact, off-contract prices are sometimes lower. However, off-contract prices could be lower than on-contract prices because of the presence of the GPO. Without the GPO, the off-contract price could potentially be higher.<sup>26</sup>

In addition to the above concerns related to GPO contracts, PBM contracting mechanism may also have an impact on competition. Complaints about the PBM contracting process include employers wanting an alternative to a rebate-driven approach to managing costs, PBMs lacking transparency about how they generate revenue, contracts being complicated and including clauses that benefit the PBM at the expense of the employer or patient, and rebates contributing to misaligned incentives that put PBM interests before patients or employers (no fiduciary obligation).<sup>27</sup>

### *Contributing Factors to Drug Shortages*

Drug shortages remain an ongoing public health concern in the United States. Although the rate of new shortages has decreased, long-term active and ongoing shortages have not been resolved and critical shortages continue to impact patient care and pharmacy operations. Several commonly used products required for patient care are in shortage including sterile infusion solutions (e.g., saline, amino acids, dextrose), as well as diazepam, lidocaine, hydromorphone, and morphine.

Proponents supporting the repeal of the GPO Safe Harbor state the root cause of drug shortages is the existence of the GPO Safe Harbor.<sup>28</sup> However, the drug shortage issue is multi-factorial and complex. Ongoing supply challenges of certain medications, typically injectable products that are off-patent and have few suppliers, persist. Causes of these shortages continue to remain largely unchanged:

- **Quality problems** – drug shortages are mostly triggered by quality problems during manufacturing processes which causes manufacturers to slow or halt production to address these problems.
- **Limited inventory** – widespread use of just-in-time inventory practices can increase the vulnerability of the supply chain to shortages.
- **Regulatory approval** – new manufacturers may not be able to quickly enter the market to produce a drug in shortage because the U.S. Food & Drug Administration's (FDA) approval is required. Existing manufacturers also need FDA approval of changes to manufacturing conditions or processes.
- **Production complexity** – costly, specialized equipment is required to manufacture drugs and maintaining sterility throughout the production process is challenging and may require facilities dedicated solely to those drugs.
- **Constrained manufacturing capacity** – in the generic sterile injectable market, the industry is concentrated and has limited manufacturing capacity. The pressures to produce many drugs on only a few manufacturing lines can leave manufacturers with little flexibility when one manufacturer ceases production of a particular drug.

With respect to GPOs, a 2014 GAO report in examining causes of drug shortages was inconclusive and, importantly, did not mention the GPO safe harbor as a causal factor of drug shortages.<sup>29</sup> Accordingly, while the presence of the GPO safe harbor may be a factor in drug shortages, drug shortages are multi-factorial, no consensus exists as to what percentage, if any, the safe harbor contributes to drug shortages, and no empirical evidence exists that the safe harbor is the root cause of drug shortages.

### *Contributing Factors to Drug Pricing*

Proponents supporting the repeal of the GPO Safe Harbor also state that the safe harbor causes unprecedented drug price spikes.<sup>30</sup> While impacted by supply chain dynamics, other contributing factors to pharmaceutical pricing include the type of pharmaceutical (generic, brand, biologic), level of negotiation authority of the purchasing entity, and market exclusivity and manipulations. At the front-end, pharmaceutical manufacturers set a drug's list price, which does not include discounts or rebates. The list price is set to cover costs of production, research and development, and profits. Patients who are uninsured and in high-deductible health plans have greater exposure to the list price; for other patients who are insured, it more represents a starting price in the distribution chain from wholesalers to pharmacies to patients, ultimately impacting patient cost-sharing levels. While concerns have been raised that the rebate process between pharmaceutical companies and PBMs results in list prices above what they would be absent rebates, other key factors foundationally impact a drug's list price.

When addressing the pricing of brand-name drugs, such factors include the number of individuals expected to use the drug, development costs, and competition in the marketplace. Brand-name drugs have 20 years of patent protection from the date of filing, and also enjoy a period of market exclusivity, depending on the type of drug. Orphan drugs – drugs to treat rare diseases or conditions affecting less than 200,000 individuals in the U.S., or affecting more than 200,000 individuals but for which there is not a reasonable expectation that the sales of the drug would recover the costs – have seven years of market exclusivity. Drugs deemed to be innovative products that include an entirely new active ingredient – a new chemical – have five years of market exclusivity. Six months of exclusivity are added to existing exclusivity periods once studies on the effects of a drug upon children are submitted for FDA review and meet the statutory requirements.<sup>31</sup>

Currently, biologic manufacturers have 12 years of market exclusivity for innovator products. Innovator biologics also have additional patent protection that generally exceeds the market exclusivity period by a few years. Overall prices for biologics are higher resulting from the high risk and expense of manufacturing these products, the special handling and administration required, and an overall lack of competition in the marketplace. Biosimilars can offer some cost savings in comparison with their originator equivalents, but thus far not at the level seen between traditional brand-name and generic drugs.

Brand-name drug manufacturers have also used various techniques to delay competition in the marketplace or lengthen patent protection. In reverse-payment patent litigation settlements, also known as “pay-for-delay” settlements, a brand-name drug manufacturer pays a potential generic competitor to abandon its patent challenge and delay offering a generic drug product for a number of years. Brand-name manufacturers can also attempt to effectively extend the term of patent protection for a single product by creating a patent portfolio, composed of patents with staggered terms for modified forms of the same drug, new delivery systems for that drug, or other variations of the original product, a practice known as “evergreening.” Examples of evergreening include reformulating a drug as extended release or changing the mix of chemical isomers. In situations where a newer version of an existing brand-name drug enters the marketplace, brand-name manufacturers can also choose to take the older drug off the market or restrict access to the older drug, including by limiting its distribution through select specialty pharmacies.

Several factors can impact the prices of generic drugs, including drug shortages, supply disruptions, limits in manufacturing capacity, and generic drug industry mergers and acquisitions. In addition, generic drug companies may transition to manufacture drugs recently off patent to gain early market share, while others have chosen to manufacture generic drugs that have been on the market for some time and no longer have ample competition.

Patient out-of-pocket costs for the same prescription drug can vary based on the health plan in which they are enrolled. Certain government programs, including Medicaid, the Veterans Affairs and Department of Defense, secure discounts and/or rebates on the price of prescription drugs. In most other coverage situations, patient cost-sharing levels result from insurer/PBM-pharmaceutical company negotiations, and depend on whether drugs are on their health plan formulary, and if so, at what cost-sharing tier.

Our AMA policies on drug shortages and pricing advocate pursuing a collaborative approach focused on finding the root causes of problems. Blaming GPOs for the complicated drug shortage problem risks compromising this solution-oriented strategy, especially without a current policy consensus on this point. With respect to GPO pricing incentives, it is important to keep in mind that GPO contracts are voluntary in nature. GPO customers retain the ability to purchase products and services off-contract if they find a preferable or better-priced option.

## DISCUSSION

Throughout the evolution of this report, the Council on Medical Service welcomed input from the Council on Legislation and thanks the Council on Legislation for its thoughtful comments throughout the drafting process. The Council on Medical Service is confident that the collaboration between the Councils was essential to the formulation of a measured report on a highly complex subject and the nuances therein.

The GAO has expressly declined to call for eliminating the safe harbor as the appropriate solution, noting that “a repeal of the safe harbor provision would require a clearer understanding of the impact of the GPO funding structure.” GAO emphasized, and the Council agrees, that eliminating the safe harbor could have unintended consequences, at least in the short term:

Some experts believe there is an incentive for GPOs to negotiate higher prices for products and services because GPO compensation increases as prices increase. However, other experts, as well as GPOs, stated that there is sufficient competition between them to mitigate any potential conflicts of interest. Almost 30 years after its passage, there is little empirical evidence to definitively assess the impact of the vendor-fee-based funding structure protected under the safe harbor. While repealing the safe harbor could eliminate misaligned incentives, most agree there would be a disruption while hospitals and vendors transitioned to new arrangements. Over the longer term, if the current trend of hospital consolidation continues, the concerns about these disruptions may be diminished to the extent that large hospital systems may be in a better position to pay GPOs directly for their services or negotiate contracts with vendors on their own. Furthermore, given that some hospitals are already paying a subsidiary of one GPO directly for access to vendor contracts, alternative approaches are possible.<sup>32</sup>

### *GPO Studies*

As mentioned by the GAO, the Council finds little empirical evidence exists to definitively assess the impact of the GPO safe harbor. Most research studies are funded by interested parties like the Healthcare Supply Chain Association. A limited economic model with no funding ties to GPOs, PBMs, or proponents of repeal, found that while removal of the safe harbor decreased providers’ nominal purchasing price, their total purchasing costs are the same as when the safe harbor was present. Thus, repeal would not affect any party’s profits or costs.<sup>33</sup> In a broader economic model, a study found that total purchasing cost of the providers is not affected by the presence of the GPO administration fees, although providers may experience higher unit prices.<sup>34</sup>

### *Legal Impact of Fitting GPOs or PBMs Within Personal Services Safe Harbor*

If the GPO safe harbor were repealed, the Council believes that GPOs and PBMs simply could shift fees into other forms, such as rebates or other fees, rather than lose their revenue stream. For example, the current administrative fee could fit within the personal services and management contracts safe harbor or fit within enough factors of the safe harbor that OIG would use its enforcement discretion and not pursue criminal charges against the GPO or PBM.<sup>35</sup> This safe harbor covers a wide variety of conduct. The Council notes that the personal services category covers many types of services provided in the health care industry including professional physician services provided under an independent contractor arrangement, a physician group providing medical services to a hospital, and medical director agreements. The management contracts category covers all non-professional services billing and collection, accounting, marketing, purchasing, staffing, recruiting, quality assurance, and facilities and personnel management.

In this case, the GPO Safe Harbor three percent or 4.5 - 5 percent administration fee could be repackaged under the personal services and management contracts safe harbor as a management contract. To fit within that safe harbor, a GPO or PBM would need to meet the following requirements:

1. Agreement in writing and signed;
2. Covers all of the services provided;

3. Not less than one year;
4. Aggregate compensation paid to the agent (GPO) over the term of the agreement is set in advance, is fair market value, and does not take into the volume or value of any referrals of federal health care program beneficiaries;
5. Arrangement does not violate any state or federal law;
6. Contracted services do not exceed what is reasonably necessary to accomplish the commercially reasonable business objective; and
7. If services are on a part-time basis (e.g., part-time housekeeping), lay out schedule of internals, precise length, and exact charge for such intervals.

Repackaging the administrative fee into the personal services and management contracts safe harbor may not squarely meet all of the safe harbor's requirements because a percentage may not be an aggregate compensation set in advance. OIG is silent on fixed percentages laid out in advance under this exception. OIG, in Advisory Opinions, does allow performance or other percent bonuses as compensation even if it does not fit squarely within the safe harbor. In those instances, OIG uses its enforcement discretion to decline to pursue (e.g., lack of intent). There is also a low risk that the compensation (three percent) was payment for patient referrals because the percentage does not directly vary with the number of patients treated. With determining fair market value, OIG would likely find the three percent GPO fee or the 4.5 percent PBM fee to be fair market value given the percentage of the market that uses these percentages in practice.

Moreover, specifically regarding PBMs, the Council notes that CMS Report 5-A-19, which is before the House of Delegates at this meeting, recommends supporting the active regulation of PBMs under state departments of insurance, supporting efforts to ensure that PBMs are subject to federal laws that prevent discrimination against patients, and supporting improved transparency in PBM operations including a list of disclosures.

#### *Impact on Patient Care*

The Council strongly believes that repeal of the GPO safe harbor may also have, at least in the short-term, widespread disruption of the supply chain and administrative challenges for not only hospitals (including physician-owned hospitals), but also clinics, ambulatory surgery centers, and other provider arrangements. As such, physician-owned practice settings may be adversely impacted if the viability of the GPO business model is compromised. Whatever the flaws in their funding structure, the Council finds that GPOs serve a function in enabling cost savings and efficiencies in procurement to facilitate patient care.

Accordingly, the Council believes that adopting a policy to oppose the GPO safe harbor may not only hurt the AMA's credibility but also will not accomplish the objectives set forth by proponents of repeal because limited economic studies show no impact on repeal, entities involved may continue to operate the same practices under a different safe harbor, and repeal would potentially cause a disruption of care and the supply chain.

Instead, the Council believes that the AMA should promote greater transparency and accountability efforts regarding the actions covered by the GPO and PBM anti-kickback safe harbor. In 2014, GAO recommended that CMS should determine whether hospitals are appropriately reporting administrative fee revenues on their Medicare cost reports and take steps to address any underreporting that may be found. In response, CMS issued a Technical Direction Letter to the Medicare Administrative Contractors (MACs) in 2015 adding steps to the desk review program. Specifically, CMS directed MACs to verify that GPO revenues have been offset where appropriate in order to mitigate any risk to the Medicare program. However, nothing has been publicly released based off of these desk reviews. Moreover, HHS has the capability to request records from GPOs the amount received from each vendor with respect to purchases made by or on behalf of the GPOs customers. Yet, the Council is unaware of any requests or public reports based off any requests since the GAO report. Given the push for greater price and cost transparency and the lack of recent data related to GPOs and PBMs, the Council recommends that the federal government renew efforts to support greater public transparency and accountability efforts involving the contracting mechanisms and funding structures subject to the GPO and PBM anti-kickback safe harbor.

Additionally, the Council believes that the AMA should focus efforts on modernizing the fraud and abuse laws to address the changing realities of the health care delivery and payment system. The Anti-Kickback Statute was passed in 1972, Stark (physician self-referral law) in 1989. Significant changes in health care payment and delivery have occurred since the enactment of these laws. For example, PBMs did not exist, or were at least not as pervasive, when these laws were created. Numerous initiatives are attempting to align payment and coordinate care to improve the

quality and value of care delivered. The delivery of care is going through a digital transformation with innovative technology. However, the fraud and abuse laws have not commensurably changed.

The fraud and abuse laws were enacted during a time when fee-for-service, which pays for services on a piecemeal basis, was blamed for rising costs. The policy reasoning behind the fraud and abuse laws is to act as a deterrent against overutilization, inappropriate patient steering, and compromised medical judgment with heavy civil and criminal penalties, such as treble damages, exclusion from participation in federal health care programs, and potential jail time.

The health care system has evolved since the creation of these laws, and the Council believes that they need to be updated to reflect changing business practices and technologies in the health care industry.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 252-A-18, and the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-125.986 supporting efforts to ensure that reimbursement policies established by pharmaceutical benefit managers (PBMs) are based on medical need; these policies include, but are not limited to, prior authorization, formularies, and tiers for compounded medications.
2. That our AMA reaffirm Policy H-110.992 stating 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.
3. That our AMA reaffirm Policy H-100.956 calling for collaboration with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
4. That our AMA renew efforts urging the federal government to support greater public transparency and accountability efforts involving the contracting mechanisms and funding structures subject to the Group Purchasing Organization and PBMs anti-kickback safe harbor, including the potential impact on drug pricing and drug shortages.
5. That our AMA support efforts to update and modernize the fraud and abuse laws and regulations to address changes in the health care delivery and payment systems including the potential impact on drug pricing and drug shortages.
6. That the AMA, via a letter, immediately ask the Secretary of HHS and other appropriate stakeholders to request the HHS OIG to examine the supply chain of pharmaceuticals, pharmacy benefit managers, Safe Harbor laws and regulations, and expeditiously make recommendations to make prescription drugs more accessible and affordable to patients with an emphasis on examining the governing contracts for drugs in short supply and/or that are exceedingly expensive to ensure compliance with all the safe harbor provisions.

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8. H.R. Rep. No. 99-727, at 73 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3607, 3663.

9. 56 Fed. Reg. 35952, 35982 (July 29, 1991).
10. Social Security Act § 1128B(b)(3)(A).
11. H.R. Report No. 95-393(II), at 53, reprinted in 1977 U.S.C.C.A.N. 3039, 3056. (“In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.”).
12. 42 CFR §1001.952(h).
13. Medicare rules generally require providers to offset purchase discounts, allowances, and refunds against expenses on their Medicare cost reports. In 2005, OIG reviewed 21 GPO members, and found that they did not fully account for net revenue distributions on their Medicare cost reports. There was considerable variation among the GPOs, with members of one GPO offsetting 92 percent of the distributions, members of another offsetting only 54 percent. In total, 22 percent of net revenue distributions were not offset. OIG, Health Care Fraud and Abuse Control Program Annual Report for FY 2005, (Aug. 2006), <https://oig.hhs.gov/publications/docs/hcfac/hcfacreport2005.pdf>.
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## **9. HEALTH PLAN PAYMENT OF PATIENT COST-SHARING (RESOLUTION 707-A-18)**

*Reference committee hearing: see report of Reference Committee G.*

### **HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 707-A-18 REMAINDER OF REPORT FILED**

*See Policies H-165.828, H-165.838, H-165.849, H-165.985, D-180.979 and D-190.974*

At the 2018 Annual Meeting, the House of Delegates referred Resolution 707, which was introduced by the California Delegation and assigned to the Council on Medical Service for study. Resolution 707-A-18 asked:

That our American Medical Association (AMA) urge health plans and insurers to bear the responsibility of ensuring physicians promptly receive full payment for patient copayments, coinsurance and deductibles.

This report provides an overview of patient cost-sharing obligations including the rise of high-deductible health plans, highlights patient collection management practices by insurers, summarizes relevant AMA policy, provides a summary of relevant AMA advocacy activities, and recommends policy.

### **BACKGROUND**

Despite coverage gains in recent years, the health care system continues to struggle with decreasing the number of uninsured patients and, even for the insured population, utilizing health care services is often unaffordable. For the insured, the trend of rising health insurance deductibles has been altering health insurance from more comprehensive coverage to insurance with higher out-of-pocket costs.<sup>1</sup> Deductibles have gradually risen for decades and contribute to the changing nature of health insurance. One rationale behind high deductible health plans (HDHPs) is that they moderate the cost of health care and health insurance by shifting the rising cost of health care from insurers and employers to patients. Health plans with higher levels of cost-sharing generally have lower premiums and put a financial obligation of higher out-of-pocket costs on patients when services are used.<sup>2</sup>

The prevalence of HDHPs is not limited to the Affordable Care Act (ACA) Exchanges but also widespread in employer-sponsored coverage. Notably, the growth in HDHP enrollment has been fastest among those with employer-based coverage. About 40 percent of companies that offer health insurance make HDHPs the only choice for their employees.<sup>3</sup> About half of people with employer coverage have a deductible of at least \$1,000.<sup>4</sup> Moreover, the shift to plans with rising deductibles began before the ACA was passed.<sup>5</sup> The average general annual deductible for employees has increased 49 percent over the last five years.<sup>6</sup> Overall, in 2018, 29 percent of workers with employer-based coverage were enrolled in a HDHP. Although the Council believes that health insurance should balance patient responsibility and patient choice; increasingly employees do not have a choice of coverage options.<sup>7</sup>

The impact of cost-sharing imposed by HDHPs is an ongoing concern for patients and physicians. HDHPs with tax-preferred savings accounts may not be a good fit for some patients, particularly low-income patients who may struggle to fund their health savings accounts (HSAs).<sup>8</sup> For example, there is evidence that exposing patients to increased cost-sharing has unintended and negative consequences. Overall, HDHPs can be a good option for people who are in relatively good health, but they may expose people who have more modest incomes to out-of-pocket costs that can be a barrier to care and a risk to their financial security. HDHPs also make beneficiaries increasingly vulnerable to sharp increases in drug prices. Cost-sharing, even when tied with available information on the price of services, generally does not induce patients to shop for lower-priced services. Instead, patients more often reduce their use of health services, potentially delaying needed care and exacerbating health issues. The burden of higher cost-sharing has a disproportionate impact on patients with lower incomes whose deductible may exceed available liquid assets.

The shift in financial responsibility toward patients may contribute to physicians' concerns about collecting cost-sharing from patients. However, if physicians do not collect these cost-sharing amounts, they sustain bad debt that adversely affects the financial sustainability of their practices.<sup>9</sup>

Bad debt typically is the difference between what providers billed patients and the amount those patients ultimately paid, and the phenomenon of bad debt has become an industry-wide issue for health care practitioners. Patient



payments are an increasing share of expected revenues.<sup>10</sup> According to the American Hospital Association, this uncompensated care reached \$38.3 billion in 2016. Bad debt may affect the financial viability of practices, and collecting on bad debt takes practice time and resources, and the additional time physician offices spend on collection of bad debt is not reflected in the cost of providing care. Moreover, the significant time used to collect on such debt may cause disruptions to the patient-physician relationship.

#### EXAMPLE OF INSURER PROGRAM COLLECTING COST-SHARING

To mitigate bad debt, major national health plans, including UnitedHealthcare and Anthem, have patient payment programs through InstaMed, which allow insurers to manage patient collections for the physician practice; however, there are caveats to this model. First, practices do not have a choice of if they want to receive patient payments in this manner. Therefore, if a patient signs up for InstaMed, the practice will get paid through InstaMed. Moreover, these programs typically only issue electronic payments to the practice. If the practice does not sign up for the program and receive standard electronic fund transfers, the practice will be issued a virtual credit card for the patient's payment. Importantly, such credit cards are associated with fees that tend to be 2-5 percent of the overall payment. Furthermore, practices may have reasons for wishing to manage patient payments themselves. For instance, the practice may have worked out a payment plan with the patient or there may be secondary or tertiary payers. The solution sought by Resolution 707-A-18 may negatively impact such business autonomy by precluding such arrangements. Advocating for patient payment programs may appear as an endorsement of such programs, which may be problematic for physicians and provider representatives of plans impacted by these patient collection methods. Accordingly, such action may adversely affect physician payment levels and processes, and could have unintended consequences within some physician practices.

#### AMA POLICY

Long-standing AMA policy and advocacy efforts acknowledge and support the business freedom of physician practices (Policies H-165.985 and H-165.838). Some physicians prefer the flexibility afforded to payment operations and do not want to cede patient collections to health plans. Physicians currently have the ability to offer discounts or payment plans to patients to facilitate goodwill, which is an arrangement supported by long-standing Policy H-165.849. Moreover, Policy H-165.849 states that our AMA will engage in a dialogue with health plan representatives (e.g., America's Health Insurance Plans and Blue Cross and Blue Shield Association) about the increasing difficulty faced by physician practices in collecting co-payments and deductibles from patients enrolled in HDHPs.

Policy D-190.974 demonstrates the AMA's commitment to administrative simplification. Among numerous actions, it directs the AMA to continue its strong leadership role in automating, standardizing, and simplifying all administrative revenue cycle transactions between physicians in all specialties and modes of practice and all their trading partners, including, but not limited to, public and private payers, vendors, and clearinghouses. Moreover, it directs the AMA to prioritize efforts to automate, standardize, and simplify the process for physicians to estimate patient and payer financial responsibility before the service is provided, and determine patient and payer financial responsibility at the point of care.

The AMA remains committed to health insurance affordability. Policy H-165.828 specifically 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 an HSA partially funded by an amount determined to be equivalent to the cost-sharing subsidy. Moreover, Policy H-165.828 supports additional education regarding deductibles and cost-sharing at the time of health plan enrollment, including the use of online prompts and the provision of examples of patient cost-sharing responsibilities for common procedures and services.

#### AMA ACTIVITY

The AMA has developed a comprehensive point-of-care pricing toolkit to help practices with patient collections (<https://www.ama-assn.org/practice-management/claims-processing/managing-patient-payments>). The toolkit recognizes concerns about uncollected patient financial responsibility that can result in physician practices taking on debt and contains varied resources to help mitigate the problem. This toolkit addresses point-of-care and post-visit collections and includes:

- Step-by-step guidance toward providing point-of-care pricing and collecting from patients at the time of service;
- Guidance on calculating the price of treatment at the point-of-care;
- Sample scripts to help practices collect patient payment;
- Letter templates to ask health insurers and other payers about terms and conditions of insurance contracts regarding physicians' rights to provide point-of-care pricing and collect payments at the time of care;
- Webinars designed for practices to help patients understand their financial responsibility;
- Resource providing information on how practices can implement an effective strategy for collection of payment after a patient has left the office; and
- Guidance on the steps to take when a patient fails to pay for treatment in full.

In addition to the AMA's point-of-care pricing toolkit, the AMA has repeatedly voiced its concern about virtual credit card payments and the fact that it may cause physicians to lose a significant amount of contractual payments to high interchange fees charged by the credit card companies. The AMA continuously advocates for transparency in virtual credit card payments including advanced disclosure of transaction fees and any rebates or incentives awarded to payers for using this payment method.

Furthermore, pursuant to Policy H-165.849, the AMA continues to engage in ongoing dialogue with health insurers and health insurance representatives about the increasing difficulty of practices in collecting co-payments and deductibles. The AMA continues to hold such meetings with insurers to address this issue as well as other issues relating to physician burden and practice sustainability.

## DISCUSSION

Bad debt can affect the financial viability of practices, and collecting on this debt takes practice time and expense. Nonetheless, the Council is concerned about the unintended consequences of adopting Resolution 707-A-18. In particular, if insurance companies collect patient co-payments and deductibles, they would likely charge administrative fees to practices or lower physician payment levels. Nonetheless, the Council believes that the issues raised by Resolution 707-A-18 are compelling and warrant action, particularly for small physician practices that may be most impacted by an increase in bad debt brought about by some patients not fulfilling their cost-sharing obligations.

First, the Council recommends reaffirming long-standing policy illustrating the AMA's commitment to the business freedom of physician practices (Policies H-165.985 and H-165.838). Additionally, because the evidence suggests that it is not the HDHP itself that is necessarily problematic but rather the inability to meaningfully fund a corresponding HSA, the Council recommends reaffirming Policy H-165.828 encouraging the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to an HSA partially funded by an amount determined to be equivalent to the cost-sharing subsidy. Due to the trend of increasing use of HDHPs, the Council also recommends encouraging states and other stakeholders to monitor the growth of HDHPs and other forms of cost-sharing in health plans to assess the impact of such plans on access to care, health outcomes, medical debt, and provider practice sustainability.

The Council believes that a factor contributing to uncompensated care is the lack of patient education on their health plans. Importantly, Policy H-165.828 also supports education regarding deductibles and cost-sharing at the time of health plan enrollment, including the use of online prompts and the provision of examples of patient cost-sharing responsibilities for common procedures and services. Although the Council remains steadfast in its belief that patient education will help solve the problem of uncompensated care, it notes that the Emergency Medicine Treatment and Labor Act forbids emergency care providers from discussing with the patient any potential costs of care or details of their insurance coverage until the patient is screened and stabilized. The Council agrees with and respects this prohibition. Therefore, while the Council strongly supports patient education of costs not only at the time of enrollment but also at the time of care, the Council recognizes that this discussion is precluded at the point-of-care in the case of emergencies.

To further patient education efforts, the Council recommends amending Policy D-190.974 by updating part four by addition such that our AMA will prioritize efforts to automate, standardize, and simplify the process for physicians to estimate patient and payer financial responsibility before the service is provided, and determine patient and payer financial responsibility at the point of care, especially for patients in HDHPs. Following from this, the Council also believes that more sophisticated IT systems are critical to help enable physicians and empower patients to better

understand financial obligations. Additionally, the Council recommends taking this opportunity to amend part six of Policy D-190.974 to reflect the ending of the Heal the Claims campaign and instead recommends calling attention to the AMA's continued efforts to ensure that physicians are aware of automating their claims cycle.

As previously noted, the prevalence of HDHPs is not isolated to the ACA Exchanges, but is also widespread in employer-sponsored coverage. The Council believes that health insurance should balance patient responsibility and patient choice; however, increasingly patients do not have a choice of coverage options. Therefore, the Council recommends reaffirming Policy H-165.849 urging the AMA to continue to engage in ongoing dialogue with health insurers and health insurance representatives about the increasingly difficulty of practices in collecting co-payments and deductibles and the underlying issue of affordability.

The Council firmly believes that there are no easy solutions to the problem of patient collections and remains unconvinced that giving insurers additional control over the process is the best solution. Instead, the Council believes that the AMA should remain committed to addressing the concerns of its members and seeking solutions to the major issue underlying Resolution 707-A-18, which is greater affordability of health insurance premiums and cost-sharing responsibilities. Accordingly, the Council suggests a set of recommendations intended to address the root of the problem.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 707-A-18 and the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policies H-165.985 and H-165.838 illustrating the AMA's commitment to the business freedom of physician practices.
2. That our AMA reaffirm Policy H-165.849 stating that the AMA will continue to engage in ongoing dialogue with health insurers and health insurance representatives about the increasing difficulty of practices in collecting co-payments and deductibles.
3. That our AMA reaffirm Policy H-165.828 encouraging the development of demonstration projects to allow individuals who forego cost-sharing subsidies by enrolling in a bronze plan to have access to a partially-funded health savings account and supporting additional education regarding deductibles and cost-sharing at the time of health plan enrollment.
4. That our AMA amend Policy D-190.974 by addition and deletion as follows:

### Administrative Simplification in the Physician Practice

1. Our AMA strongly encourages vendors to increase the functionality of their practice management systems to allow physicians to send and receive electronic standard transactions directly to payers and completely automate their claims management revenue cycle and will continue to strongly encourage payers and their vendors to work with the AMA and the Federation to streamline the prior authorization process.
  2. Our AMA will continue its strong leadership role in automating, standardizing and simplifying all administrative actions required for transactions between payers and providers.
  3. Our AMA will continue its strong leadership role in automating, standardizing, and simplifying the claims revenue cycle for physicians in all specialties and modes of practice with all their trading partners, including, but not limited to, public and private payers, vendors, and clearinghouses.
  4. Our AMA will prioritize efforts to automate, standardize and simplify the process for physicians to estimate patient and payer financial responsibility before the service is provided, and determine patient and payer financial responsibility at the point of care, especially for patients in high-deductible health plans.
  5. Our AMA will continue to use its strong leadership role to support state and specialty society initiatives to simplify administrative functions.
  6. Our AMA will continue its efforts ~~expand its Heal the Claims process(TM) campaign as necessary~~ to ensure that physicians are aware of the value of automating their claims cycle.
5. That our AMA support the development of sophisticated information technology systems to help enable physicians and patients to better understand financial obligations.

6. That our AMA encourage states and other stakeholders to monitor the growth of high deductible health plans and other forms of cost-sharing in health plans to assess the impact of such plans on access to care, health outcomes, medical debt, and provider practice sustainability.
7. That our AMA advocate for the inclusion of health insurance contract provisions that permit network physicians to collect patient cost-sharing financial obligations (eg, deductibles, co-payments, and co-insurance) at the time of service.
8. That our AMA monitor programs wherein health plans and insurers bear the responsibility of collecting patient co-payments and deductibles.

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### 10. ALTERNATIVE PAYMENT MODELS AND VULNERABLE POPULATIONS (RESOLUTION 712-A-18)

*Reference committee hearing: see report of Reference Committee G.*

#### **HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 712-A-18 REMAINDER OF REPORT FILED**

*See Policies H-160.896, H-280.945, H-350.974, H-385.908, H-385.913, H-440.828  
H-450.924, D-35.985, D-350.995 and D-385.952*

At the 2018 Annual Meeting, the House of Delegates referred Resolution 712, which was introduced by the New England Delegation and assigned to the Council on Medical Service for study. Resolution 712-A-18 asked:

That our American Medical Association (AMA): (1) study the impact of current advanced Alternative Payment Models (APMs) and risk adjustment on providers caring for vulnerable populations; and (2) advocate legislatively that advanced APMs examine the evaluation of quality performance (for bonus or incentive payment) of providers caring for vulnerable populations in reference to peer group (similarities in SES status, disability, percentage of dual eligible population).

This report provides an overview of vulnerable populations and the emergence of APMs, highlights numerous APMs and value-based care initiatives incorporating social determinants of health into their models, summarizes relevant AMA policy, provides a summary of AMA advocacy activities, and recommends policy to encourage the development of APMs that serve vulnerable populations while protecting physicians from being financially penalized.

## BACKGROUND

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) ended the Sustainable Growth Rate (SGR) formula and created new ways for the Medicare program to pay physicians for the care they provide to Medicare beneficiaries. Specifically, MACRA's physician payment program is the Quality Payment Program (QPP). The QPP has two tracks of participation: APMs and the Merit-based Incentive Payment System (MIPS). As part of the QPP's drive to value-based care, it creates incentives for physicians to participate in APMs, which aim to provide greater flexibility to manage the health of patient populations by aligning provider incentives with cost and quality goals. MACRA specifically encourages the development of Physician-Focused Payment Models (PFPs), which are APMs wherein Medicare is the payer, physician group practices or individual physicians are APM participants, and the focus is on the quality and cost of physician services. MACRA established the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to review and assess PFP proposals submitted by stakeholders to the committee based on certain criteria defined in regulations. The PTAC is an 11-member independent federal advisory committee. Since its inception, the PTAC has received 31 proposals for consideration, a few of which have not been reviewed yet by PTAC. Of those proposals, PTAC has recommended 15 proposals to the Secretary of Health and Human Services (HHS) to test in various ways.

As the national push toward value-based payment and care delivery continues, many studies have demonstrated substantial evidence linking social circumstances to health and health outcomes.<sup>1</sup> It is now understood that non-medical factors, such as social determinants of health (SDH), account for about 60 percent of a person's health outcomes.<sup>2</sup> Together, the drive toward value and recognition of SDH impacts on health are fueling interest in the ways in which addressing SDH may be incorporated into new payment and delivery models like APMs. Within an APM, physicians often are financially rewarded for keeping patients healthy and out of the hospital and emergency departments. To achieve this goal, APMs often have the flexibility to support services that can significantly improve health outcomes. Therefore, physicians can respond to APM incentives by improving care coordination and integration, which may be particularly beneficial for vulnerable populations.

However, APMs may inadvertently create incentives for physicians to avoid caring for vulnerable patients who are at increased risk for high costs and poor outcomes that are beyond the physician's control.<sup>3</sup> In order to increase health equity and to fully realize the benefits of APMs, APMs must contemplate and account for vulnerable populations.

### *Impact of Vulnerable Population Status on Patient Outcomes*

Vulnerable populations in health care include the economically disadvantaged, racial and ethnic minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ) groups; uninsured individuals; rural individuals who may have trouble accessing care; and those with stigmatized chronic conditions such as severe mental illness or human immunodeficiency virus (HIV).<sup>4</sup> These populations may be more likely to suffer from hunger and access to healthy food options, lack social and economic support, have lower education levels, live in unsafe neighborhoods devoid of parks and playgrounds, and often are subjected to discrimination.<sup>5</sup>

Vulnerable populations are less likely to have health coverage, struggle with health care access, and often have little interaction or trust in the health care system. They are less likely to receive preventive services and are more likely to go to the emergency department or hospital for a condition that might have been treated in a lower cost facility.<sup>6</sup> As a result, their medical interventions generally come much later and at significantly higher cost than for other populations. Moreover, lower income populations are twice as likely as those with higher incomes to have behavioral health problems, three times as likely to be socially isolated, and 10 times more likely to experience food insecurity.<sup>7</sup> Additionally, there is considerable overlap in vulnerable populations. For example, Black and Hispanic American minorities are significantly more likely than Whites to be uninsured, live below the poverty line, and have higher rates of HIV or AIDS diagnosis and death rates.<sup>8</sup>

Though access to health care is essential for well-being, it is not the greatest health determinant.<sup>9</sup> Zip Code™ now is understood to be a stronger predictor of quality of health than even genetic code. Research suggests that health-related behaviors such as smoking, diet, and exercise, are more important determinants of early death than health care itself. Furthermore, there is a growing consensus that non-medical factors shape an individual's ability to engage in health behaviors. For example, children born to parents who have not completed high school are more likely to live in an environment that poses barriers to health such as lack of safety, exposed garbage, and substandard housing.<sup>10</sup> Such environmental factors may have multi-generational impacts.

Generally, the current health care system is not built around the poorest and most vulnerable. Exacerbating the ability to effectively care for these populations is the fact that many physicians are not able to identify high-risk patients. Some of the current risk algorithms used by payers were originally developed without access to electronic medical record (EMR) data, so many current predictive risk tools have limited utility. The link between non-medical factors and poor health outcomes is well-documented, but few traditional payment and delivery models are equipped to address these non-medical factors that drive high health care costs and poor outcomes.

### *Addressing the Unique Needs of Vulnerable Populations in Payment and Delivery*

There are a growing number of initiatives to address SDHs and challenges unique to vulnerable populations within and outside of the health care system. These include multi-payer federal and state initiatives, Medicaid initiatives led by states or health plans, and physician-level activities focused on identifying and addressing the social needs of their patients. APMs can provide opportunities to cover services that can help provide care and support that vulnerable or high-risk populations need but that are generally not available under traditional payment models. Examples of such initiatives are highlighted below and include: Accountable Health Communities, the Chinese Community Accountable Care Organization (ACO), the Acute Unscheduled Care Model, and the Patient-Centered Opioid Addiction Treatment (P-COAT) APM.

#### Accountable Health Communities

In 2016, the Center for Medicare and Medicaid Innovation (CMMI), which was established by the Affordable Care Act, announced the Accountable Health Communities model, which is focused on connecting Medicare and Medicaid beneficiaries with community services to address health-related social needs.<sup>11</sup> The model provides funding to examine whether systematically identifying and addressing social needs of beneficiaries through screening, referral, and community navigation services affects health costs and reduces health care utilization. In 2017, CMMI awarded grants to organizations to participate in the model over a five-year period.<sup>12</sup>

Twenty awardees will encourage partner alignment to ensure that community services are available and open to the needs of beneficiaries. To implement the alignment approach, bridge organizations will serve as “hubs” in their communities that will identify and partner with clinical delivery sites to conduct systematic screenings of beneficiary health-related social needs and make referrals to community services that may be able to address the recognized social needs; coordinate and connect beneficiaries to community service providers through community service navigation; and align model partners to optimize community capacity to address these social needs.

#### The Chinese Community ACO

The Chinese Community ACO (CCACO) is a community-based physician-owned ACO that serves about 12,000 Medicare fee-for-service (FFS) beneficiaries in the Chinese communities in New York City.<sup>13</sup> The aim of the model is to reduce overall health care costs and disparities by identifying high-risk individuals and undertaking proactive disease management. The CCACO establishes a network of organizations by partnering with hospitals, nursing homes, home health agencies, senior centers, and others to facilitate coordinated care. The model anticipates that, due to care coordination efforts, it will prevent emergency room visits and hospital readmissions in this population.

#### Acute Unscheduled Care Model (AUCM) Enhancing Appropriate Admissions from the American College of Emergency Physicians (ACEP)

The AUCM was developed by the ACEP. The particular payment model was submitted to the PTAC, and the PTAC subsequently recommended to the Secretary of HHS that the model be implemented. It centers on incentivizing improved quality and decreased costs associated with the discharge decisions made by emergency department (ED) physicians.<sup>14</sup> The model proposes that it may reduce Medicare spending and improve quality care by reducing avoidable hospital inpatient admissions and observation days by giving ED physicians the ability to coordinate and manage post-discharge home services. The model is a bundled payment, and the episode of care begins with a qualifying ED visit and ends after 30 days or with the patient’s death.<sup>15</sup> All of the Medicare services received within that 30-day window are included in the bundle. To assist in care transformation efforts, the model also uses several waivers in order to allow ED physicians to offer telehealth services, bill for transitional management codes, and permit clinical staff to offer home visits.

### Patient-Centered Opioid Addiction Treatment (P-COAT) APM

The P-COAT model is a payment model created jointly by the American Society of Addiction Medicine (ASAM) and the AMA. The model proposes to manage opioid use disorder, a highly stigmatized condition, by increasing utilization of and access to medications for the treatment of opioid use disorder by providing the appropriate financial support to successfully treat patients and broaden the coordinated delivery of medical, psychological, and social supports.<sup>16</sup> The current payment system offers little support for the coordination of behavioral and social supports that patients being treated for opioid use disorder need. Therefore, under P-COAT, treatment teams are eligible to receive two new types of payments that would be expected to provide the necessary financial support to enable providers to deliver the appropriate opioid addiction treatment.<sup>17</sup>

### AMA POLICY

The AMA has a wealth of policy on both APMs and SDH. Regarding APMs, Policy H-385.913 promulgates goals for physician-focused APMs, develops guidelines for medical societies and physicians to begin identifying and developing APMs, encourages the Centers for Medicare & Medicaid Services (CMS) and private payers to support assistance to physician practices working to implement APMs, and states that APMs should account for the patient populations, including non-clinical factors. Policy H-385.908 states that the AMA will continue to urge CMS to limit financial risk requirements to costs that physicians participating in an APM have the ability to control or influence, will work with stakeholders to design risk adjustment systems that identify new data sources to enable adequate analyses of clinical and non-clinical factors that contribute to a patient's health and success of treatment, such as disease stage, access to health care services, and socio-demographic factors.

Moreover, 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-390.953 directs the AMA to advocate with CMS and Congress for alternative payment models developed in concert with specialty and state medical organizations. Policy H-390.844 emphasizes the importance of physician leadership and accountability to deliver high quality and value to patients and directs the AMA to advocate for providing opportunities for physicians to determine payment models that work best for their patients, their practices, and their regions. Policy H-450.961 states that incentives should be intended to promote health care quality and patient safety and not primarily be intended to contain costs, provide program flexibility that allows physicians to accommodate the varying needs of individual patients, adjust performance measures by risk and case-mix to avoid discouraging the treatment of high-risk individuals and populations, and support access to care for all people and avoid selectively treating healthier patients. Additionally, Policy D-35.935 supports physician-led, team-based care delivery recognizing that the interdisciplinary care team is well equipped to provide a whole-person health care experience.

The AMA has myriad policies on health disparities, health inequities, and diversity, and the AMA continues to exercise leadership aimed at addressing disparities (Policies H-350.974, D-350.991, D-350.995, D-420.993, H-65.973, H-60.917, H-440.869, D-65.995, H-150.944, H-185.943, H-450.924, H-350.953, H-350.957, D-350.996, H-350.959). Policy H-350.974 affirms that the AMA maintains a zero-tolerance policy toward racially or culturally based disparities in care and states that the elimination of racial and ethnic disparities in health care are an issue of highest priority for the organization. The policy encourages the development of evidence-based performance measures that adequately identify socioeconomic and racial/ethnic disparities in quality. Furthermore, Policy H-350.974 supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons. Moreover, the policy actively supports the development and implementation of training regarding implicit bias and cultural competency. Policy H-280.945 calls for better integration of health care and social services and supports while Policy H-160.896 calls to expand payment reform proposals that incentivize screening for social determinants of health and referral to community support systems. Additionally, Policy D-350.995 promotes diversity within the health care workforce, which can help expand access to care for vulnerable and underserved populations.

Recognizing that current risk adjustment and performance measure systems may disincentivize caring for the most vulnerable, Policy H-450.924 supports that hospital program assessments should account for social risk factors so that they do not have the unintended effect of financially penalizing hospitals, including safety net hospitals, and physicians that may exacerbate health care disparities.

## AMA ACTIVITY

The AMA continues to work to aid physicians in the implementation of MACRA and by encouraging and enabling physician participation in APMs. The AMA has been active in educational activities including webinars and regional conferences for physicians and staff and will be continuing these activities. Recent AMA advocacy activity has called for improvements in the methodologies behind APMs. Such areas for improvement in methodology include performance targets, risk adjustment, and attribution. The AMA recognizes that proper methodologies enable more physicians to participate in APMs and promotes design of APMs in such a way that prioritizes the patient's need.

The AMA continues to strive to ensure that all communities of Americans receive equal access to quality health care. The AMA is committed to working toward the goal of all Americans having access to affordable and meaningful health care. It is addressing this issue systemically by striving for health equity by mitigating disparity factors. For example, the AMA has developed numerous resources including a Health Disparities Toolkit that helps connect physicians and care teams to chronic disease prevention programs in the community. The AMA STEPSForward™ module entitled Addressing Social Determinants of Health describes how a practice can select and define a plan to address SDH issues. Additionally, steps toward health equality are being taken in the AMA's effort toward creating the medical school of the future. Within the AMA's Accelerating Change in Medical Education (ACE) initiative, some medical schools are incorporating education on disparities within their curricula while others are addressing diversity in the health care workforce by changing admissions and pipeline programs to ensure that our nation has the diverse workforce that it needs.

Additionally, the AMA is integrating SDH into its Integrated Health Model Initiative (IHMI), a collaborative effort that supports a continuous learning environment to enable interoperative technology solutions and care models that evolve with real world use and feedback. IHMI's collaborative platform is discussing SDH with the goal of identifying those factors that should be incorporated into the IHMI data model. Moreover, the IHMI team has delivered a module that incorporates two of the widely accepted SDH: the nine-digit Zip Code™ where one lives and those who are dually-eligible for Medicaid and Medicare.

Importantly, the AMA recognizes that health quality can only happen in concert with efforts to improve physician satisfaction and wellbeing. Therefore, the AMA is helping create an engaged workforce and mitigating burnout. To that end, the AMA has developed STEPSForward™ resources and Burnout Assessment Tools to allow physicians to assess their practices and find ways to leverage their entire care team to improve physician and patient experience and care. The AMA knows that advocating for physicians and patients is critical to achieve health equity. Patients and the public are partners in the quest for equitable access to quality health and health care.

Moreover, the AMA is establishing a new Health Equity Center with the goal of enabling optimal health for all with an eye on social justice. The Center will serve as a demonstration of the AMA's long-term and enduring commitment to health equity.

## DISCUSSION

Health care disparities often occur in the context of wider inequality. It has been shown that if patients' basic needs are not met, they are not likely to stay healthy regardless of the quality of health care received. Because APMs are typically designed to be flexible to compensate for care that is not traditionally reimbursed, they present an opportunity to better care for and serve vulnerable populations. However, several studies have demonstrated that value-based payment programs disproportionately penalize physicians serving the poorest and most vulnerable populations, possibly disincentivizing physicians from caring for them. Therefore, the Council offers a set of recommendations that it hopes mitigates these negative outcomes, penalties, and events. In doing so, the Council recommends ways in which the health care system can do more to address non-medical factors that often go undetected and untreated among vulnerable populations within the context of a changing payment and delivery system.

The Council's recommendations build upon the AMA's current policy on value-based payment programs and social determinants of health. The Council notes that reaffirming existing AMA policies helps to highlight the need for health equity across populations and the corresponding need for APMs and risk adjustment methodologies to protect against financially penalizing the physicians who care for and serve populations who are overwhelmingly sicker and poorer. The Council is sensitive to concerns that APMs may have the impact of not only financially penalizing physicians caring for at-risk populations, but also causing adverse selection in patient treatment. The Council believes that it is



critical that social determinants of health be meaningfully incorporated into APM quality measures to encourage and support physicians to care for these patients. The current health care system was not built for vulnerable populations, and they remain woefully underserved. Therefore, the Council recommends that APMs be designed with the flexibility needed to address the unique challenges of vulnerable populations and believes that PFPs provide an excellent opportunity to transform care delivery to better meet the needs of underserved populations.

The Council understands and agrees with the sponsor's concern that APMs may have adverse effects on vulnerable populations because current risk adjustment methodologies are not accurate enough to distinguish between suboptimal care and high-quality care provided to high-risk individuals. Accordingly, the Council believes that it is critical that the AMA continue to advocate for appropriate risk adjustment of performance results based on clinical and social determinants of health. The Council is steadfast in its belief that the structure and quality reporting of APMs must protect against penalizing physicians whose performance and aggregated data are impacted by factors outside of the physician's control. Furthermore, because of the Council's commitment to this principle, the Council believes that the topic of risk adjustment warrants revisiting and notes that at the 2019 Interim Meeting, it will present a report specifically addressing ways in which risk adjustment methodology and implementation can be improved.

## RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 712-A-18 and the remainder of the report be filed:

1. That our American Medical Association (AMA) support alternative payment models (APMs) that link quality measures and payments to outcomes specific to vulnerable and high-risk populations and reductions in health care disparities.
2. That our AMA continue to encourage the development and implementation of physician-focused APMs that provide services to improve the health of vulnerable and high-risk populations.
3. That our AMA continue to advocate for appropriate risk adjustment of performance results based on clinical and social determinants of health to avoid penalizing physicians whose performance and aggregated data are impacted by factors outside of the physician's control.
4. That our AMA reaffirm Policy H-385.913 stating that APMs should limit physician accountability to aspects of spending and quality that they can reasonably influence; APMs should understand their patient populations, including non-clinical factors; and support new data sources that enable adequate analyses of clinical and non-clinical factors that contribute to a patient's health and success of treatment.
5. That our AMA reaffirm Policy H-385.908 stating that the AMA should continue advocating for APMs limiting the financial risk requirements to costs that physicians participating in an APM have the ability to control or influence and work with stakeholders to design risk adjustment systems that identify new data sources to enable adequate analyses of clinical and non-clinical factors that contribute to a patient's health and success of treatment, such as severity of illness, access to health care services, and socio-demographic factors. Moreover, Policy H-385.908 recognizes that technology should enable the care team and states that the AMA should work with stakeholders to develop information technology (IT) systems that support and streamline clinical participation and enable IT systems to support bi-directional data exchange.
6. That our AMA reaffirm Policy H-350.974 recognizing that racial and ethnic health disparities is a major public health problem, stating that the elimination of racial and ethnic disparities in health care is an issue of highest priority for the AMA, and supporting education and training on implicit bias, diversity, and inclusion.
7. That our AMA reaffirm Policy D-35.985 supporting physician-led, team-based care recognizing that interdisciplinary physician-led care teams are well equipped to provide a whole-person health care experience.
8. That our AMA reaffirm Policy D-350.995 promoting diversity within the workforce as one means to reduce disparities in health care.

9. That our AMA reaffirm Policy H-440.828 on community health workers (CHWs) recognizing that they play a critical role as bridgebuilders between underserved communities and the health care system and calling for sustainable funding mechanisms to financial CHW services.
10. That our AMA reaffirm Policy H-450.924 supporting that hospital program assessments should account for social risk factors so that they do not have the unintended effect of financially penalizing safety net hospitals and physicians that exacerbate health care disparities.
11. That our AMA reaffirm Policy H-280.945 supporting better integration of health care and social services and supports.
12. That our AMA reaffirm Policy H-160.896 calling to expand payment reform proposals that incentivize screening for social determinants of health and referral to community support systems.

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## 11. CORPORATE INVESTORS

*Reference committee hearing: see report of Reference Committee G.*

### **HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED**

*See Policies H-160.891, H-160.960, H-215.981, H-225.950 and H-285.951*

At the 2018 Annual Meeting, the House of Delegates adopted Policy D-383.979, “Corporate Investors.” This policy states that our American Medical Association (AMA) will study, with report back at the 2019 Annual Meeting, the effects on the health care marketplace of corporate investors (e.g., public companies, venture capital/private equity firms, insurance companies and health systems) acquiring a majority and/or controlling interest in entities that manage physician practices, such as the degree of corporate investor penetration and investment in the health care marketplace; the impact on physician practice and independence; patient access; resultant trends in the use of non-physician extenders; long term financial viability of practices; effects of ownership turnovers and bankruptcies on patients and practice patterns; effectiveness of methodologies employed by unpurchased private independent, small group and large group practices to compete for insurance contracts in consolidated marketplaces; and the relative impact corporate investor transactions have on the paths and durations of junior, mid-career and senior physicians.

This report describes physician practice consolidation with corporate investors, including private equity investment in physician practices; discusses the corporate practice of medicine; summarizes relevant AMA policy; and makes policy recommendations.

### **BACKGROUND**

Consolidation among health care entities, including consolidation involving physician practices, is closely monitored by the AMA. An array of factors—including changes in payment and delivery models, physician payment challenges, high costs of new technology and equipment, and increased administrative and regulatory burdens—have driven some physicians to be employed by, merge with or join hospitals, health systems and insurers. Increasingly, private equity partnerships/firms, which pool funds to invest in companies with the goal of running them more efficiently and selling them at a profit, have also acquired majority and/or controlling interests in entities that manage physician practices.

While the extent of corporate investment in health care is not precisely known, increasing numbers of physicians are employed by corporations, including hospitals, health systems and health insurers.<sup>1</sup> Data from the 2018 Health Care Services Acquisition Report demonstrates corporate investor interest in physician practices. The report documented that 2017 saw the highest annual number of transactions (166 deals) involving physician medical groups since 1998 (264 deals). Of the 10 largest physician medical group transactions completed between 2013 and 2017, two were acquisitions of large physician groups by UnitedHealth’s Optum unit, and another two involved private equity firms. Many of the largest transactions involved public companies.<sup>2</sup>

The long-term trend away from physicians being practice owners and toward physicians being employees has been documented via the AMA’s Physician Practice Benchmark Surveys, which yield nationally representative samples of non-federal physicians providing at least 20 hours of patient care. These surveys, conducted biennially, have found that physician ownership dropped by seven percentage points (from 53.2 percent to 45.9 percent) between 2012 and 2018.<sup>3</sup> Notably, the year 2018 was the first time that the percentage of physician owners was less than the percentage of physician employees (47.4 percent).<sup>4</sup>

### *Private Equity Investment in Physician Practices*

Private equity firms, which acquire equity in businesses with funds from private investors, vary in terms of size, structure, business model and investment thesis. Venture capital is typically used to invest in emerging or early stage businesses such as start-ups. Buyout or leveraged buyout firms typically invest in mature or later-stage businesses, often taking a controlling interest.

Private equity investment in dermatology, radiology, anesthesiology, urology, gastroenterology, cardiology, orthopedic, radiology and ophthalmology practices, among other specialties, has garnered substantial publicity and attention from the physician community. Growth in the demand for health care services, coupled with an aging

population and the development of innovative treatments, have made the health care sector attractive to private equity investors. Globally, total disclosed value of deals in the sector exceeded \$63 billion in 2018, the most since 2006, with much of this activity concentrated in North America and the US in particular.<sup>5</sup> Providers and related services, including physician practice management, accounted for the most deals in 2018, with increased activity observed in anesthesia, radiology and behavioral health.<sup>6</sup> A reported 84 private equity deals involving providers (including but not limited to physician practices) were consummated in 2018, totaling \$23 billion.<sup>7</sup> Private equity firms have also invested in hospitals, ambulatory surgical centers, retail health, health information technology (IT), home care and hospice, among many other services.<sup>8</sup>

Hospitals, health systems, academic medical centers, large multispecialty groups, and corporate buyers frequently compete with private equity firms for the same physician practice targets. Corporate buyers may also partner with private equity investors or form consortia of buyers to acquire highly sought-after practices. Increased competition for physician groups in some specialties has led price valuations of these practices to rise.

Because many private equity transactions are not disclosed (nondisclosure agreements are commonly used during negotiations),<sup>9</sup> the degree of investment in physician practices, while believed to be relatively small overall, cannot be precisely determined. Incomplete data on corporate transactions involving physician practices is in fact a significant impediment to determining the impact of corporate investors on physicians, patients, and the health care marketplace. That said, there is evidence that physician practices are being acquired, not only by private equity firms but also by hospitals, health systems, academic medical centers, insurers, and large physician groups. Transactions involving private equity investors are occurring with some regularity. Consequently, affected physician specialties are attempting to understand these practice shifts as well as the risks and benefits of this practice model.

Dermatology is one such specialty, having experienced a surge in private equity deals involving dermatology-related practices in the last three to five years. Fifteen percent of recent private equity/physician practice transactions have been “dermatology-related,” although dermatologists make up only one percent of US physicians.<sup>10</sup> As noted in a recent commentary in *JAMA Dermatology*:

Consolidation of practices fueled by private equity investments has begun to transform dermatology ... Existing dermatologists are encouraged to stay after the sale through equity stakes or deferred payouts, but in some cases, the investors may accept departures because the buyout recipients can sometimes be replaced by younger dermatologists or physician assistants who are paid at a lower level.<sup>11</sup>

Private equity firms have also shown interest in ophthalmology practices, as described in *Review of Ophthalmology*:

The basic premise is that a private equity firm offers to form a partnership with an ophthalmology practice that it believes has the potential to grow. It provides funding to the practice owners, including an upfront payment in cash and/or stock, in exchange for a percentage of future profits. Ultimately, the goal is to increase the value of the practice by investing in its growth—often partly by consolidating it with other practices—so that in a few years it can be resold to another private equity firm for a significant profit.<sup>12</sup>

Noted researcher Lawrence Casalino, MD, et al. described the phenomenon as follows:

These investors anticipate average annual returns of 20 percent or more. To achieve such returns, private equity firms focus on acquiring “platform practices” that are large, well managed, and reputable in their community. The firms sell these practices after augmenting their value by recruiting additional physicians, acquiring smaller practices to merge with the larger practice, increasing revenue (for example, by bringing pathology services into a dermatology practice), and decreasing costs (for example, by substituting physician assistants for physicians). Growth makes it possible to spread fixed costs, exploit synergies across merged practices, expand ancillary revenues, and increase negotiating leverage with health insurers.<sup>13</sup>

A recent *JAMA Viewpoint* concluded:

Even though consolidation may create economies of scale and layoffs and other cost-cutting measures may reduce operating costs, increased market power over price negotiations with insurers and boosting volume for ancillary revenue streams may increase spending. Empirical analysis is needed to understand the net consequences and to compare spending among private equity-owned, hospital-owned, and independent practices.<sup>14</sup>

### *Risks and Benefits of Partnering with Corporate Investors*

There is little peer-reviewed evidence regarding the impact of corporate investors on physicians, physician autonomy, patients or health care prices. Anecdotal information suggests an increase in the use of non-physician extenders by some private equity firms and other challenges facing physicians working for practices affiliated with private equity firms. The experiences of practices entering employment arrangements with hospitals, health systems, academic medical centers and insurers may differ from private equity investors because these entities function in the health care marketplace and frequently have existing physician leadership in place. Additionally, in contrast to private-equity backed practices, hospitals, health systems and academic medical centers may use some of their revenues to provide uncompensated care and/or contribute to medical education and training.<sup>15</sup>

There are risks and benefits of partnering with any corporate investor, including a private equity firm. Risks include loss of control over the physician practice and its future and future revenues; loss of some autonomy in decision-making; an emphasis on profit or meeting financial goals; potential conflicts of interest; and potential uncertainties for non-owner early and mid-career physicians. Benefits include financially lucrative deals for physicians looking to exit ownership of their practices; access to capital for practice expenses or expansions, which may relieve physicians' financial pressures; potentially fewer administrative and regulatory burdens on physicians; and centralized resources for certain functions such as IT, marketing or human resources. Concerns regarding these partnerships have primarily centered on the potential for subsequent increases in prices, service volume, and internal referrals, as well as the use of unsupervised non-physician providers.<sup>16</sup> Importantly, corporate investors are obviously not all the same and may differ significantly in terms of their business models and culture. Some are centralized and physician-led, while others are centralized but not physician-led; the degree of physician autonomy in decision making also varies.

### AMA ACTIVITY

In monitoring mergers and acquisitions, the AMA's position is that each health care entity consolidation must be examined individually, taking into account case-specific variables related to market power and patient needs. AMA policy strongly supports and encourages competition in all health care markets to provide patients with more choices while improving care and lowering the costs of that care. Markets should be sufficiently competitive to allow physicians to have adequate practice options. The AMA also recognizes that employment preferences vary greatly among physicians, and that employment by large systems can be an attractive practice option for some physicians. A 2013 AMA-RAND study on professional satisfaction found that physicians in physician-owned practices were more satisfied than physicians in other ownership models (e.g., hospital or corporate ownership), but that work controls and opportunities to participate in strategic decisions mediate the effect of practice ownership on overall professional satisfaction.<sup>17</sup>

The AMA promotes physician leadership in integrated structures and has developed policies and resources intended to help safeguard physicians employed by large systems. The AMA has also developed several [resources](#) intended to help physicians understand employment contracts. These include the Annotated Model Co-Management Service Line Agreement, Annotated Model Physician-Group Practice Employment Agreement, and the Annotated Model Physician-Hospital Employment Agreement as well as a Making the Rounds podcast on contracts. For physicians considering a practice setting change or looking for an alignment strategy with an integrated health system, the AMA developed the guide [Joining or Aligning with a Physician-led Integrated Health System](#). The AMA has also made available a set of resources called "Unwinding Existing Arrangements" that guides employed physicians on how to "unwind" from their organization, factoring in operational, financial, and strategic considerations.

At the time that this report was written, the AMA was planning to release, mid-year in 2019, resources related to venture capital and private equity investments that highlight the main issues physicians may encounter when engaging with such firms, including modifications to compensation, investment in infrastructure, how to evaluate contractual agreements, and hands-on management. A related checklist was also planned that will offer specific considerations such as terms-of-sale for the practice, standardization techniques and economies of scale, and unwinding terms.

### *Corporate Practice of Medicine*

The term "corporate practice of medicine" encompasses complex legal issues that may mean different things to different people and vary widely by state. The corporate practice of medicine can, for example, prohibit a lay corporation from practicing medicine or employing physicians, or prohibit non-physicians or lay organizations from

having an ownership interest in a physician practice. The doctrine is based on concerns that: (1) allowing corporations to practice medicine or employ physicians will result in the commercialization of the practice of medicine; (2) a corporation's obligation to its shareholders may not align with a physician's obligations to his or her patients; and (3) employment of a physician by a corporation may interfere with the physician's independent medical judgement.<sup>18</sup>

As delivery systems and physician employment arrangements have evolved over the years, so too has the corporate practice of medicine doctrine. The health care environment is shifting toward increased integration of care, with growth in both the number of employed physicians and acquisitions of physician practices. These trends have led to formalized employment relationships between physicians and non-physician entities, arrangements that in certain states may run afoul of corporate practice of medicine policies. Council on Medical Service Report 6-I-13 addressed the corporate practice of medicine.

#### RELEVANT AMA POLICY

Policy H-215.981 opposes federal legislation preempting state laws prohibiting the corporate practice of medicine; states that the AMA will continue monitoring the corporate practice of medicine and its effect on the patient-physician relationship, financial conflicts of interest, and patient-centered care; and directs the AMA to provide guidance, consultation and model legislation regarding the corporate practice of medicine, at the request of state medical associations, to ensure the autonomy of hospital medical staffs, employed physicians in non-hospital settings, and physicians contracting with corporately-owned management service organizations. Under Policy D-225.977, the AMA continues to assess the needs of employed physicians, ensuring physician clinical autonomy and self-governance. Policy H-285.951 states that physicians should have the right to enter into whatever contractual arrangements they deem desirable and necessary but should be aware of potential conflicts of interest due to the use of financial incentives in the management of care. Policy H-215.968 supports and encourages competition between and among health facilities as a means of promoting the delivery of high-quality, cost-effective care. Antitrust relief is a top AMA priority under Policy H-380.987.

AMA Principles for Physician Employment are outlined in Policy H-225.950. Policy H-225.997 addresses physician-hospital relationships, and Policy H-225.942 outlines physician and medical staff rights and responsibilities. Policy H-225.947 encourages physicians who seek employment as their mode of practice to strive for employment arrangements consistent with a series of principles, including that: (a) physician clinical autonomy is preserved; (b) physicians are included and actively involved in integrated leadership opportunities; (c) physicians are encouraged and guaranteed the ability to organize under a formal self-governance and management structure; (d) physicians are encouraged and expected to work with others to deliver effective, efficient and appropriate care; (e) a mechanism is provided for the open and transparent sharing of clinical and business information by all parties to improve care; and (f) a clinical information system infrastructure exists that allows capture and reporting of key clinical quality and efficiency performance data for all participants and accountability across the system to those measures. Policy H-160.960 states that when a private medical practice is purchased by corporate entities, patients shall be informed of the ownership arrangement by the corporate entities and/or the physician. Truth in advertising is addressed by Policies H-410.951 and H-405.969.

AMA policy does not prohibit the application of restrictive covenants in the physician employment context generally, although Policy H-225.950, "Principles for Physician Employment," discourage physicians from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment. AMA Code of Medical Ethics Opinion 11.2.3.1 states that covenants-not-to-compete restrict competition, can disrupt continuity of care, and may limit access to care. Accordingly, physicians should not enter into covenants that: (a) unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship; and (b) do not make reasonable accommodation for patients' choice of physician. This opinion also states that physicians in training should not be asked to sign covenants not to compete as a condition of entry into any residency or fellowship program.

Policy H-140.984 opposes an across-the-board ban on self-referrals because of benefits to patients including increased access to competition, and includes standards to ensure ethical and acceptable financial arrangements. This policy states that the opportunity to invest in the medical or health care facility established by a health care services financial arrangement should be open to all individuals who are financially able and interested in an investment.

## DISCUSSION

The Council's study of corporate investors acquiring majority and/or controlling interest in entities that manage physician practices was hindered by the lack of empirical evidence regarding the impact of these practice models on physicians, patients, medical practice, and the costs and quality of care. Although anecdotal information is available from affected specialties, there is not sufficient data to draw meaningful or actionable conclusions. Nonetheless, the Council underscores the paramount importance to this discussion of safeguarding patient-centered care, clinical governance and physician autonomy in all physician practice arrangements, including those involving corporate investors.

The Council also believes it is worth noting that physician opinions vary regarding corporate investor involvement in physician practices. Although there has been a great deal of angst among many physicians regarding private equity investments in practices, other physicians and physician groups have readily partnered with these firms. Long-standing policy states that physicians are free to choose their mode of practice and enter into contractual arrangements as they see fit, and it is essential that the AMA maintain a leadership role that is uniting and supportive of all physicians and care delivery models.

The Council recommends, therefore, reaffirmation of four existing AMA policies—on the corporate practice of medicine, financial incentives, physician employment, and corporate ownership of private medical practices—that are relevant to corporate investor relationships with physician practices. Because physicians appear to be looking for guidance and solutions, the Council also recommends a series of guidelines that it believes should be considered by physicians who are contemplating corporate investor partnerships.

As previously noted, nondisclosure agreements are commonly used in private equity and corporate investor transactions, and the Council believes that more information is needed regarding the degree of corporate investment in physician practices and what this means for health care prices. The lack of complete and accurate information may prevent health care markets from operating efficiently and preclude patients from making informed decisions regarding low-cost, high-value care. Accordingly, the Council recommends supporting improved transparency regarding corporate investment in physician practices and subsequent changes in health care prices.

The Council recognizes that further study is needed on the impact of corporate investors, and recommends encouraging national medical specialty societies to research and develop tools and resources on the impact of corporate investor partnerships on patients and physicians.

Finally, the Council recommends rescinding Policy D-383.979, which led to the development of this report.

## RECOMMENDATIONS

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

1. That our American Medical Association (AMA) reaffirm Policy H-215.981, which opposes federal legislation preempting state laws prohibiting the corporate practice of medicine; states that the AMA will continue monitoring the corporate practice of medicine and its effect on the patient-physician relationship, financial conflicts of interest, and patient-centered care; and directs the AMA to provide guidance, consultation and model legislation regarding the corporate practice of medicine, at the request of state medical associations, to ensure the autonomy of hospital medical staffs, employed physicians in non-hospital settings, and physicians contracting with corporately-owned management service organizations.
2. That our AMA reaffirm Policy H-225.950, which affirms that a physician's paramount responsibility is to his or her patients, and which outlines principles related to conflicts of interest and contracting.
3. That our AMA reaffirm Policy H-285.951, which states that physicians should have the right to enter into whatever contractual arrangements they deem desirable and necessary but should be aware of potential conflicts of interest due to the use of financial incentives in the management of medical care.

4. That our AMA reaffirm Policy H-160.960, which states that when a private medical practice is purchased by corporate entities, patients shall be informed of the ownership arrangement by the corporate entities and/or the physician.
5. That our AMA encourage physicians who are contemplating corporate investor partnerships to consider the following guidelines:
  - a. Physicians should consider how the practice's current mission, vision, and long-term goals align with those of the corporate investor.
  - b. Due diligence should be conducted that includes, at minimum, review of the corporate investor's business model, strategic plan, leadership and governance, and culture.
  - c. External legal, accounting and/or business counsels should be obtained to advise during the exploration and negotiation of corporate investor transactions.
  - d. Retaining negotiators to advocate for best interests of the practice and its employees should be considered.
  - e. Physicians should consider whether and how corporate investor partnerships may require physicians to cede varying degrees of control over practice decision-making and day-to-day management.
  - f. Physicians should consider the potential impact of corporate investor partnerships on physician and practice employee satisfaction and future physician recruitment.
  - g. Physicians should have a clear understanding of compensation agreements, mechanisms for conflict resolution, processes for exiting corporate investor partnerships, and application of restrictive covenants.
  - h. Physicians should consider corporate investor processes for medical staff representation on the board of directors and medical staff leadership selection.
  - i. Physicians should retain responsibility for clinical governance, patient welfare and outcomes, physician clinical autonomy, and physician due process under corporate investor partnerships.
6. That our AMA support improved transparency regarding corporate investment in physician practices and subsequent changes in health care prices.
7. That our AMA encourage national medical specialty societies to research and develop tools and resources on the impact of corporate investor partnerships on patients and the physicians in practicing in that specialty.
8. That our AMA support consideration of options for gathering information on the impact of private equity and corporate investors on the practice of medicine.
9. That our AMA rescind Policy D-383.979, which requested this report.

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## APPENDIX

### Corporate Practice of Medicine H-215.981

1. Our AMA vigorously opposes any effort to pass federal legislation preempting state laws prohibiting the corporate practice of medicine. 2. At the request of state medical associations, our AMA will provide guidance, consultation, and model legislation regarding the corporate practice of medicine, to ensure the autonomy of hospital medical staffs, employed physicians in non-hospital settings, and physicians contracting with corporately-owned management service organizations. 3. Our AMA will continue to monitor the evolving corporate practice of medicine with respect to its effect on the patient-physician relationship, financial conflicts of interest, patient-centered care and other relevant issues.

### AMA Principles for Physician Employment H-225.950

#### 1. Addressing Conflicts of Interest

a) A physician's paramount responsibility is to his or her patients. Additionally, given that an employed physician occupies a position of significant trust, he or she owes a duty of loyalty to his or her employer. This divided loyalty can create conflicts of interest, such as financial incentives to over- or under-treat patients, which employed physicians should strive to recognize and address. b) Employed physicians should be free to exercise their personal and professional judgment in voting, speaking, and advocating on any matter regarding patient care interests, the profession, health care in the community, and the independent exercise of medical judgment. Employed physicians should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests. c) In any situation where the economic or other interests of the employer are in conflict with patient welfare, patient welfare must take priority. d) Physicians should always make treatment and referral decisions based on the best interests of their patients. Employers and the physicians they employ must assure that agreements or understandings (explicit or implicit) restricting, discouraging, or encouraging particular treatment or referral options are disclosed to patients. (i) No physician should be required or coerced to perform or assist in any non-emergent procedure that would be contrary to his/her religious beliefs or moral convictions; and (ii) No physician should be discriminated against in employment, promotion, or the extension of staff or other privileges because he/she either performed or assisted in a lawful, non-emergent procedure, or refused to do so on the grounds that it violates his/her religious beliefs or moral convictions. e) Assuming a title or position that may remove a physician from direct patient-physician relationships--such as medical director, vice president for medical affairs, etc.--does not override professional ethical obligations. Physicians whose actions serve to override the individual patient care decisions of other physicians are themselves engaged in the practice of medicine and are subject to professional ethical obligations and may be legally responsible for such decisions. Physicians who hold administrative leadership positions should use whatever administrative and governance mechanisms exist within the organization to foster policies that enhance the quality of patient care and the patient care experience.

Refer to the AMA Code of Medical Ethics for further guidance on conflicts of interest.

#### 2. Advocacy for Patients and the Profession

a) Patient advocacy is a fundamental element of the patient-physician relationship that should not be altered by the health care system or setting in which physicians practice, or the methods by which they are compensated. b) Employed physicians should be free to engage in volunteer work outside of, and which does not interfere with, their duties as employees.

#### 3. Contracting

a) Physicians should be free to enter into mutually satisfactory contractual arrangements, including employment, with hospitals, health care systems, medical groups, insurance plans, and other entities as permitted by law and in accordance with the ethical principles of the medical profession. b) Physicians should never be coerced into employment with hospitals, health care systems, medical groups, insurance plans, or any other entities. Employment agreements between physicians and their employers should be negotiated in good faith. Both parties are urged to obtain the advice of legal counsel experienced in physician employment matters when negotiating employment contracts. c) When a physician's compensation is related to the revenue he or she generates, or to similar factors, the employer should make clear to the physician the factors upon which compensation is based. d) Termination of an employment or contractual relationship between a physician and an entity employing that physician does not necessarily end the patient-physician relationship between the employed physician and persons under his/her care. When a physician's employment status is unilaterally terminated by an employer, the physician and his or her employer should notify the physician's patients that the physician will no longer be working with the employer and should provide them with the physician's new contact information. Patients should be given the choice to continue to be seen by the physician in his or her new practice setting or to be treated by another physician still working with the employer. Records for the physician's patients should be retained for as long as they are necessary for the care of the patients or for addressing legal issues faced by the physician; records should not be destroyed without notice to the former employee. Where physician possession of all medical records of his or her patients is not already required by state law, the employment agreement should specify that the physician is entitled to copies of patient charts and records upon a

specific request in writing from any patient, or when such records are necessary for the physician's defense in malpractice actions, administrative investigations, or other proceedings against the physician. (e) Physician employment agreements should contain provisions to protect a physician's right to due process before termination for cause. When such cause relates to quality, patient safety, or any other matter that could trigger the initiation of disciplinary action by the medical staff, the physician should be afforded full due process under the medical staff bylaws, and the agreement should not be terminated before the governing body has acted on the recommendation of the medical staff. Physician employment agreements should specify whether or not termination of employment is grounds for automatic termination of hospital medical staff membership or clinical privileges. When such cause is non-clinical or not otherwise a concern of the medical staff, the physician should be afforded whatever due process is outlined in the employer's human resources policies and procedures. (f) Physicians are encouraged to carefully consider the potential benefits and harms of entering into employment agreements containing without cause termination provisions. Employers should never terminate agreements without cause when the underlying reason for the termination relates to quality, patient safety, or any other matter that could trigger the initiation of disciplinary action by the medical staff. (g) Physicians are discouraged from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment. (h) Physician employment agreements should contain dispute resolution provisions. If the parties desire an alternative to going to court, such as arbitration, the contract should specify the manner in which disputes will be resolved. Refer to the AMA Annotated Model Physician-Hospital Employment Agreement and the AMA Annotated Model Physician-Group Practice Employment Agreement for further guidance on physician employment contracts.

#### 4. Hospital Medical Staff Relations

a) Employed physicians should be members of the organized medical staffs of the hospitals or health systems with which they have contractual or financial arrangements, should be subject to the bylaws of those medical staffs, and should conduct their professional activities according to the bylaws, standards, rules, and regulations and policies adopted by those medical staffs. b) Regardless of the employment status of its individual members, the organized medical staff remains responsible for the provision of quality care and must work collectively to improve patient care and outcomes. c) Employed physicians who are members of the organized medical staff should be free to exercise their personal and professional judgment in voting, speaking, and advocating on any matter regarding medical staff matters and should not be deemed in breach of their employment agreements, nor be retaliated against by their employers, for asserting these interests. d) Employers should seek the input of the medical staff prior to the initiation, renewal, or termination of exclusive employment contracts.

Refer to the AMA Conflict of Interest Guidelines for the Organized Medical Staff for further guidance on the relationship between employed physicians and the medical staff organization.

#### 5. Peer Review and Performance Evaluations

a) All physicians should promote and be subject to an effective program of peer review to monitor and evaluate the quality, appropriateness, medical necessity, and efficiency of the patient care services provided within their practice settings. b) Peer review should follow established procedures that are identical for all physicians practicing within a given health care organization, regardless of their employment status. c) Peer review of employed physicians should be conducted independently of and without interference from any human resources activities of the employer. Physicians--not lay administrators--should be ultimately responsible for all peer review of medical services provided by employed physicians. d) Employed physicians should be accorded due process protections, including a fair and objective hearing, in all peer review proceedings. The fundamental aspects of a fair hearing are a listing of specific charges, adequate notice of the right to a hearing, the opportunity to be present and to rebut evidence, and the opportunity to present a defense. Due process protections should extend to any disciplinary action sought by the employer that relates to the employed physician's independent exercise of medical judgment. e) Employers should provide employed physicians with regular performance evaluations, which should be presented in writing and accompanied by an oral discussion with the employed physician. Physicians should be informed before the beginning of the evaluation period of the general criteria to be considered in their performance evaluations, for example: quality of medical services provided, nature and frequency of patient complaints, employee productivity, employee contribution to the administrative/operational activities of the employer, etc. (f) Upon termination of employment with or without cause, an employed physician generally should not be required to resign his or her hospital medical staff membership or any of the clinical privileges held during the term of employment, unless an independent action of the medical staff calls for such action, and the physician has been afforded full due process under the medical staff bylaws. Automatic rescission of medical staff membership and/or clinical privileges following termination of an employment agreement is tolerable only if each of the following conditions is met: i. The agreement is for the provision of services on an exclusive basis; and ii. Prior to the termination of the exclusive contract, the medical staff holds a hearing, as defined by the medical staff and hospital, to permit interested parties to express their views on the matter, with the medical staff subsequently making a recommendation to the governing body as to whether the contract should be terminated, as outlined in AMA Policy H-225.985; and iii. The agreement explicitly states that medical staff membership and/or clinical privileges must be resigned upon termination of the agreement.

Refer to the AMA Principles for Incident-Based Peer Review and Disciplining at Health Care Organizations (AMA Policy H-375.965) for further guidance on peer review.

#### 6. Payment Agreements

a) Although they typically assign their billing privileges to their employers, employed physicians or their chosen representatives should be prospectively involved if the employer negotiates agreements for them for professional fees, capitation or global billing, or shared savings. Additionally, employed physicians should be informed about the actual payment amount allocated to the professional fee component of the total payment received by the contractual arrangement. b) Employed physicians have a responsibility to assure that bills issued for services they provide are accurate and should therefore retain the right to review billing claims as may be necessary to verify that such bills are correct. Employers should indemnify and defend, and save harmless,

employed physicians with respect to any violation of law or regulation or breach of contract in connection with the employer's billing for physician services, which violation is not the fault of the employee.

#### Financial Incentives Utilized in the Management of Medical Care H-285.951

Our AMA believes that the use of financial incentives in the management of medical care should be guided by the following principles: (1) Patient advocacy is a fundamental element of the physician-patient relationship that should not be altered by the health care system or setting in which physicians practice, or the methods by which they are compensated. (2) Physicians should have the right to enter into whatever contractual arrangements with health care systems, plans, groups or hospital departments they deem desirable and necessary, but they should be aware of the potential for some types of systems, plans, group and hospital departments to create conflicts of interest, due to the use of financial incentives in the management of medical care. (3) Financial incentives should enhance the provision of high quality, cost-effective medical care. (4) Financial incentives should not result in the withholding of appropriate medical services or in the denial of patient access to such services. (5) Any financial incentives that may induce a limitation of the medical services offered to patients, as well as treatment or referral options, should be fully disclosed by health plans to enrollees and prospective enrollees, and by health care groups, systems or closed hospital departments to patients and prospective patients. (6) Physicians should disclose any financial incentives that may induce a limitation of the diagnostic and therapeutic alternatives that are offered to patients, or restrict treatment or referral options. Physicians may satisfy their disclosure obligations by assuring that the health plans with which they contract provide such disclosure to enrollees and prospective enrollees. Physicians may also satisfy their disclosure obligations by assuring that the health care group, system or hospital department with which they are affiliated provide such disclosure to patients seeking treatment. (7) Financial incentives should not be based on the performance of physicians over short periods of time, nor should they be linked with individual treatment decisions over periods of time insufficient to identify patterns of care. (8) Financial incentives generally should be based on the performance of groups of physicians rather than individual physicians. However, within a physician group, individual physician financial incentives may be related to quality of care, productivity, utilization of services, and overall performance of the physician group. (9) The appropriateness and structure of a specific financial incentive should take into account a variety of factors such as the use and level of "stop-loss" insurance, and the adequacy of the base payments (not at-risk payments) to physicians and physician groups. The purpose of assessing the appropriateness of financial incentives is to avoid placing a physician or physician group at excessive risk which may induce the rationing of care. (10) Physicians should consult with legal counsel prior to agreeing to any health plan contract or agreeing to join a group, delivery system or hospital department that uses financial incentives in a manner that could inappropriately influence their clinical judgment. (11) Physicians agreeing to health plan contracts that contain financial incentives should seek the inclusion of provisions allowing for an independent annual audit to assure that the distribution of incentive payments is in keeping with the terms of the contract. (12) Physicians should consider obtaining their own accountants when financial incentives are included in health plan contracts, to assure proper auditing and distribution of incentive payments. (13) Physicians, other health care professionals, third party payers and health care delivery settings through their payment policies, should continue to encourage use of the most cost-effective care setting in which medical services can be provided safely with no detriment to quality.

#### Corporate Ownership of Established Private Medical Practices H-160.960

When a private medical practice is purchased by corporate entities, patients going to that practice shall be informed of this ownership arrangement by the corporate entities and/or by the physician.