REPORTS OF THE COUNCIL ON MEDICAL SERVICE

The following reports were presented by Stephen Epstein, MD, MPP, Chair:

1. COUNCIL ON MEDICAL SERVICE SUNSET REVIEW OF 2015 HOUSE POLICIES

Reference committee hearing: see report of Reference Committee G.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED

Policy G-600.110, "Sunset Mechanism for AMA Policy," calls for the decennial review of American Medical Association (AMA) policies to ensure that our AMA's policy database is current, coherent, and relevant. Policy G-600.010 reads as follows, laying out the parameters for review and specifying the procedures to follow:

1. As the House of Delegates adopts policies, a maximum 10-year time horizon shall exist. A policy will typically sunset after 10 years unless action is taken by the House of Delegates to retain it. Any action of our AMA House that reaffirms or amends an existing policy position shall reset the sunset "clock," making the reaffirmed or amended policy viable for another 10 years.

2. In the implementation and ongoing operation of our AMA policy sunset mechanism, the following procedures shall be followed: (a) Each year, the Speakers shall provide a list of policies that are subject to review under the policy sunset mechanism; (b) Such policies shall be assigned to the appropriate AMA councils for review; (c) Each AMA council that has been asked to review policies shall develop and submit a report to the House of Delegates identifying policies that are scheduled to sunset; (d) For each policy under review, the reviewing council can recommend one of the following actions: (i) retain the policy; (ii) sunset the policy; (iii) retain part of the policy; or (iv) reconcile the policy with more recent and like policy; (e) For each recommendation that it makes to retain a policy in any fashion, the reviewing council shall provide a succinct, but cogent justification (f) The Speakers shall determine the best way for the House of Delegates to handle the sunset reports.

3. Nothing in this policy shall prohibit a report to the HOD or resolution to sunset a policy earlier than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or has been accomplished.

4. The AMA councils and the House of Delegates should conform to the following guidelines for sunset: (a) when a policy is no longer relevant or necessary; (b) when a policy or directive has been accomplished; or (c) when the policy or directive is part of an established AMA practice that is transparent to the House and codified elsewhere such as the AMA Bylaws or the AMA House of Delegates Reference Manual: Procedures, Policies and Practices.

5. The most recent policy shall be deemed to supersede contradictory past AMA policies.

6. Sunset policies will be retained in the AMA historical archives.

RECOMMENDATION

The Council on Medical Service recommends that the House of Delegates policies that are listed in the appendix to this report be acted upon in the manner indicated and the remainder of this report be filed.

APPENDIX – Recommended Actions

POLICY #	Title	Text	Recommendation
D-120.977	Medicare Patient Access to Implantable Morphine Pumps	Our AMA, in collaboration with appropriate medical societies, will continue to work to address the need for appropriate treatment of patients requiring long-term pain management.	Rescind. Numerous AMA policies address pain management, including H-185.931, D-120.976, and H-120.960. **Workforce and Coverage for Pain Management H-185.931** 1. Our AMA supports efforts to improve the quality of care for patients with pain, ensuring access to multiple analgesic strategies, including non-opioid options and interventional approaches when appropriate, with a focus on achieving improvement in function and activities of daily living. 2. Our AMA supports guidance on pain management for different clinical indications developed by the specialties who manage those conditions and disseminated the same way other clinical guidelines are promoted, such as through medical journals, medical societies, and other appropriate outlets. 3. Our AMA will advocate for an increased focus on comprehensive, multidisciplinary pain management approaches that include the ability to assess co-occurring mental health or substance use conditions, are physician led, and recognize the interdependency of treatment methods in addressing chronic pain. 4. Our AMA supports health insurance coverage that gives patients access to the full range of evidence-based chronic pain management modalities, and that coverage for these services be equivalent to coverage provided for medical or surgical benefits. 5. Our AMA supports efforts to expand the capacity of practitioners and programs capable of providing physician-led interdisciplinary pain management services, as well as an expanded behavioral health workforce to improve the availability of services to address the psychological, behavioral, and social aspects of pain and pain management within multidisciplinary pain clinics. Patients and their caregivers should be involved in the decision-making process.

POLICY #	Title	Text	Recommendation
			6. Our AMA supports an expanded availability of comprehensive multidisciplinary pain medicine clinics for patients in both urban and rural areas, and an improvement in payment models for comprehensive multidisciplinary pain clinics services such that such services can become more financially viable. **Pain Management D-120.976** Our AMA will: (1) support more effective promotion and dissemination of educational materials for physicians on prescribing for pain management; (2) take a leadership role in resolving conflicting state and federal agencies' expectations in regard to physician responsibility in pain management; (3) coordinate its initiatives with those state medical associations and national medical specialty societies that already have already established pain management guidelines; and (4) disseminate Council on Science and Public Health Report 5 (A-06),"Neuropathic Pain," to physicians, patients, payers, legislators, and regulators to increase their understanding of issues surrounding the diagnosis and management of maldynia (neuropathic pain); and (5) disseminate Council on Science and Public Health Report 5 (A-10), "Maldynia: Pathophysiology and Nonpharmacologic Approaches," to physicians, patients, payers, legislators, and regulators to increase their understanding of issues surrounding the diagnosis and management of maldynia (neuropathic pain). **Protection for Physicians Who Prescribe Pain Medication H-120.960** Our AMA supports the following: (1) the position that physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain should not be subject to the burdens of excessive regulatory scrutiny, inappropriate disciplinary action, or criminal prosecution. It is the policy of the AMA that state medical societies and boards of medicine develop or adopt mutually acceptable guidelines

POLICY #	Title	Text	Recommendation
			protecting physicians who appropriately prescribe and/or administer controlled substances to relieve intractable pain before seeking the implementation of legislation to provide that protection; (2) education of medical students and physicians to recognize addictive disorders in patients, minimize diversion of opioid preparations, and appropriately treat or refer patients with such disorders; and (3) the prevention and treatment of pain disorders through aggressive and appropriate means, including the continued education of doctors in the use of opioid preparations. Our AMA opposes harassment of physicians by agents of the Drug Enforcement Administration in response to the appropriate prescribing of controlled substances for pain management.
D-160.933	Payment Mechanisms for Physician-Led Team-Based Health Care	Our AMA will develop educational programs to assist members wishing to develop and implement physician-led team based care payment methodologies at the individual team, practice, accountable care organization, hospital and health system levels.	Rescind. Accomplished by several *Advocacy Issue Briefs* and other resources on the AMA website: 1) Physician-Led Team-Based Care 2) AMA Advocacy Resource Center – Physician-Led Health Care Teams 3) Models of Physician-Led Team-Based Care 4) Summary of physician payment & delivery models 5) Ed Hub Module – Physician Payment Models Guide 6) Ed Hub Module – Physician-Led Models to Achieve the Quadruple Aim 7) AMA/AHIP/NAACOS Playbook of Voluntary Best Practices for VBC Payment Arrangements
D-165.954	Update on HSAs, HRAs, and Other Consumer-Driven Health Care Plans	Our AMA will: (1) educate physicians about health insurance plan practices that may impact physician billing and collection of payment from patients with health savings accounts (HSAs), health reimbursement arrangements (HRAs), and other forms of consumer-driven health care; and (2) monitor and support rigorous research on the impact of HSAs and HRAs on physician practices, and on levels and appropriateness of utilization, including preventive care, costs, and account savings.	Retain.

POLICY #	Title	Text	Recommendation
D-280.988	Observation Status and Medicare Part A Qualification	Our AMA will advocate for Medicare Part A coverage for a patient's direct admission to a skilled facility if directed by their physician and if the patient's condition meets skilled nursing criteria.	Rescind. Superseded by Policy H-280.947. **Three Day Stay Rule H-280.947** 1. Our American Medical Association will continue to advocate that Congress eliminate the three-day hospital inpatient requirement for Medicare coverage of post-hospital skilled nursing facility services, and educate Congress on the impact of this requirement on patients. 2. Our AMA will continue to advocate, as long as the three-day stay requirement remains in effect, that patient time spent in the hospital, observation care or in the emergency department count toward the three-day hospital inpatient requirement for Medicare coverage of post-hospital skilled nursing facility services. 3. Our AMA will actively work with the Centers for Medicare and Medicaid Services (CMS) to eliminate any regulations requiring inpatient hospitalization as a prerequisite before a Medicare beneficiary is eligible for skilled (SNF) or long-term care (LTC) placement. 4. Our AMA advocates that the Medicare three-day hospital inpatient requirement for skilled nursing facility admissions be immediately rescinded for uniformity and safety for all Medicare recipients.
D-290.987	Early and Periodic Screening, Diagnosis, and Treatment	Our AMA recognizes the importance of the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program and will advocate for EPSDT to remain intact as critical to the health and well-being of children.	Retain.
D-375.996	Peer Review Immunity	Our AMA: (1) recommends that medical staffs adopt bylaws that provide for a peer review process that is consistent with HCQIA criteria and AMA policy; (2) recommends medical staffs include bylaw provisions that provide an option or alternative for external and impartial review when there is an allegation by a reviewed physician; (3) recommends that if physicians believe that negligent or misdirected peer review is a	Rescind: Superseded by Policy D-375.997. **Peer Review Immunity D-375.997** 1. Our American Medical Association will recommend medical staffs adopt/implement staff by laws that are consistent with HCQIA and AMA policy by communicating the guidelines from AMA policy H-375.983 widely through appropriate media to the relevant organizations and institutions, including a direct mailing to

POLICY #	Title	Text	Recommendation
		problem, legislative action be considered at the state level to assure a fair due process proceeding for physicians subject to review; and (4) shall continue to monitor the legal and regulatory challenges to peer review immunity and non-discoverability of peer review records and proceedings, as well as consider legislative remedies, including the feasibility and impact of amending HCQIA to provide the option for external peer review for hospital medical staff physicians.	all medical staff presidents in the United States, indicating that compliance is required to conform to HCQIA and related court decisions. 2. Our AMA will monitor legal and regulatory challenges to peer review immunity and non discoverability of peer review records/proceedings and continue to advocate for adherence to AMA policy, reporting challenges to peer review protections to the House of Delegates and produce an additional report with recommendations that will protect patients and physicians in the event of misdirected or negligent peer review at the local level while retaining peer review immunity for the process. 3. Our AMA will continue to work to provide peer review protection under federal law.
D-450.958	Pain Medicine	Our AMA: (1) continues to advocate that the Centers for Medicare & Medicaid Services (CMS) remove the pain survey questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); (2) continues to advocate that CMS not incorporate items linked to pain scores as part of the CAHPS Clinician and Group Surveys (CG-CAHPS) scores in future surveys; and (3) encourages hospitals, clinics, health plans, health systems, and academic medical centers not to link physician compensation, employment retention or promotion, faculty retention or promotion, and provider network participation to patient satisfaction scores relating to the evaluation and management of pain.	Retain.
D-450.962	Pain Management and the Hospital Value-Based Purchasing Program	1. Our AMA urges the Centers for Medicare & Medicaid Services (CMS) to: (a) evaluate the relationship and apparent disparity between patient satisfaction, using the Hospital Consumer Assessment of Health Providers and Systems (HCAHPS) and Emergency Department Patient Experience of Care (ED-PEC) survey, and hospital performance on clinical process and outcome measures used in the	Retain.

POLICY #	Title	Text	Recommendation
		hospital value based purchasing program; and (b) reexamine the validity of questions used on the HCAHPS and ED-PEC surveys related to pain management as reliable and accurate measures of the quality of care in this domain. 2. Our AMA urges CMS to suspend the use of HCAHPS and ED-PEC measures addressing pain management until their validity as reliable and accurate measures of quality of care in this domain has been determined.	
D-510.991	Requiring The Joint Commission to Conduct Root-Cause Analysis to Determine How its Surveys Allowed Veterans Administration Hospitals to Cause Delay in Treatment and Harm Veterans	Our AMA supports The Joint Commission making public its findings following its resurveying of Veterans Health Administration (VHA) facilities to ensure quality of care and patient safety.	Rescind: This has been completed.
D-70.945	ICD-10 Implementation	1. If a delay of ICD-10 implementation is not feasible, our American Medical Association will ask the Centers for Medicare & Medicaid Services (CMS) and other payers to allow a two-year grace period for ICD-10 transition, during which physicians will not be penalized for errors, mistakes, and/or malfunctions of the system. Physician payments will also not be withheld based on ICD-10 coding mistakes, providing for a true transition where physicians and their offices can work with ICD-10 over a period of time and not be penalized. 2. Our AMA will educate physicians of their contractual obligations under Medicare and insurance company contracts should they decide to not implement ICD-10 and opt to transition to cash-only practices which do not accept insurance.	Rescind: ICD-10-CM was implemented on 10/1/15.

POLICY #	Title	Text	Recommendation
		3, Our AMA will aggressively promote this new implementation compromise to Congress and CMS since it will allow implementation of ICD-10 as planned, and at the same time protect patients' access to care and physicians' practices. 4. Our AMA will provide the needed resources to accomplish this new compromise ICD-10 implementation and make it a priority. 5. Our AMA will seek data on how ICD-10 implementation has affected patients and changed physician practice patterns, such as physician retirement, leaving private practice for academic settings, and moving to all-cash practices and that, if appropriate, our will AMA release this information to the public.	
D-70.946	Physician Participation as the 5th Cooperating Party in the International Classification of Diseases System in the United States	1. Our American Medical Association will advocate for a group with strong physician participation to be the 5th Cooperating Party for ICD-9-CM and ICD-10-CM with equal power of the current four Cooperating Parties in the planning, interpretation and deployment of ICD-9-CM, ICD-10-CM and future ICD systems. 2. Our AMA will seek to be invited by the United States Department of Health and Human Services to submit nominee[s] for physician group[s] or a group with strong physician participation to be designated as the 5th Cooperating Party for ICD-9-CM, ICD-10-CM and future ICD systems.	Retain; still relevant, as it references "future ICD systems" (e.g., ICD-11).
D-70.947	Uncoupling of CPT from ICD-10	Our American Medical Association recommends that the Comptroller General of the Government Accountability Office not address uncoupling the ICD diagnosis code from the CPT procedure code at the present time but this may be reconsidered in the future if new mechanisms are developed for payment of physician services.	Retain; still relevant, as it outlines reconsideration "if new mechanisms are developed for payment of physician services."

POLICY #	Title	Text	Recommendation
D-70.948	ICD-10 Transparency and Conversion	1. The provisions of the Protecting Access to Medicare Act of 2014 delaying the compliance date for the ICD-10 transition are consistent with and supported by existing AMA policy. 2. During the delay in implementation of the ICD-10 transition our AMA will seek and support efforts to ensure that any health plan (commercial, Medicare, Medicaid, or other) operating in the United States, shall provide to their provider network sufficient and timely information apprising providers of all planned changes, including coverage, guidelines, authorization, certifications, claims adjudications, pricing, payment, reporting, incentives and other rules, as well as resources such as crosswalks or maps, based on the conversion from ICD-9 to ICD-10.	Rescind: ICD-10-CM was implemented on 10/1/15.
D-70.949	Stop the Implementation of ICD-10	1. Our AMA will continue to work diligently and actively with Congress to permanently remove the unnecessary administrative burden on physicians of ICD-10 implementation. 2. Our AMA will advocate that Congress ask the Comptroller General of the United States, in consultation with stakeholders in the medical community, to conduct a study to identify steps that can be taken to mitigate the disruption on health care providers resulting from a replacement of ICD-9 in the future; and that the Comptroller General shall submit to each House of Congress a report on such study no later than May 1, 2015 and such report shall include appropriate recommendations. 3. The Comptroller General's report should at least address these issues: 1) decreasing the massive number of codes down to a reasonable number such as Canada did; 2) putting the replacement of ICD-9 on hold until physicians fully implement the new Electronic	Rescind: ICD-10-CM was implemented on 10/1/15.

POLICY #	Title	Text	Recommendation
		Medical Record systems, the new government regulations and the Affordable Care Act regulations; and 3) consider adopting a policy for Medicare that provides a two year implementation period during which Medicare will not be allowed to deny payment based on the specificity of the ICD-10 code.	
D-70.951	Alleviating the Financial Burdens Associated with ICD-10 Implementation	1. Our AMA will seek federal legislative and regulatory reform to require funding assistance be provided to physician practices to alleviate the financial burdens associated with the implementation costs, upgrades and staff training necessitated as part of the transition to ICD-10. 2. Our AMA will work toward the goal of having insurance companies and governmental entities reimburse physicians for the extra cost of increasingly complex and mandatory changes in coding.	Rescind: ICD-10-CM was implemented on 10/1/15.
D-70.952	Stop the Implementation of ICD-10	1. Our AMA will: (A) vigorously work to stop the implementation of ICD-10 and to reduce its unnecessary and significant burdens on the practice of medicine; (B) do everything possible to let the physicians of America know that our AMA is fighting to repeal the onerous ICD-10 requirements on their behalf; (C) work with other national and state medical and informatics associations to assess an appropriate replacement for ICD-9; and (D) evaluate the feasibility of moving from ICD-9 to ICD-11 as an alternative to ICD-10 and report back to the House of Delegates. 2. In order to alleviate the increasing bureaucratic and financial burden on physicians, our AMA will vigorously advocate that the Centers for Medicare & Medicaid Services eliminate the implementation of ICD-10. 3. Our AMA will immediately reiterate to the Centers for Medicare & Medicaid Services that the burdens imposed by ICD-10 will force many physicians in small	Rescind: ICD-10-CM was implemented on 10/1/15.

POLICY #	Title	Text	Recommendation
		practices out of business. This communication will be sent to all in Congress and displayed prominently on our AMA website. 4. Our AMA: (A) will educate US physicians on the burdens of ICD-10 and how our AMA is fighting to repeal the onerous ICD-10 requirements on their behalf; (B) supports federal legislation to stop the implementation of ICD-10 and remain with ICD-9 until ICD-11 can be properly evaluated; and (C) supports federal legislation to mandate a two-year "implementation" period by all payers, including CMS, if ICD-10 or ICD-11 is implemented. During this time, payers will not be allowed to deny payment based on specificity of ICD-10/11 diagnosis. However, they will be required to provide feedback for incorrect diagnosis. In addition, no payer will be allowed to ask for "takebacks" due to lack of ICD-10/11 diagnosis code specificity for the aforementioned two-year implementation period.	
D-70.960	Implementation of ICD-10-CM	Our AMA will work for delayed implementation of a simplified, modified ICD-10-CM coding system which is less burdensome on practicing physicians, hospitals, and the health insurance industry.	Rescind: ICD-10-CM was implemented on 10/1/15.
D-90.994	Threats Against Physicians Based on Americans With Disabilities Act	Our American Medical Association encourages AMA members who are threatened with non-meritorious lawsuits, supposedly founded on the Americans with Disabilities Act, to contact the AMA's Private Sector Advocacy Group for assistance. The AMA will post a notice on its web site, informing physicians how to report such incidents.	Retain-in-part: Our American Medical Association encourages AMA members who are threatened with non-meritorious lawsuits, supposedly founded on the Americans with Disabilities Act, to contact the AMA. ~~'s Private Sector Advocacy Group for assistance. The AMA will post a notice on its web site, informing physicians how to report such incidents.~~
H-120.933	Emergency Prescription Drug Refills	Our AMA will advocate the following principles to guide the dispensing of emergency refills of prescription drugs: 1. Emergency refills should only be authorized if, in the pharmacist's professional judgment, failure to refill the prescription might result in an important interruption of a	Retain.

POLICY #	Title	Text	Recommendation
		therapeutic regimen that could cause patient harm. 2. Emergency refills should only be dispensed if the pharmacy is unable to readily obtain refill authorization from the prescriber; prior authorization cannot be obtained in a timely manner from the patient's health plan; or when an emergency order or a proclamation of a state of emergency is declared by a state's governor. 3. Schedule II controlled substances can be dispensed on an emergency basis as allowed under Drug Enforcement Administration protocol. 4. In general, the pharmacist may dispense a sufficient supply of the medication to maintain the prescribed treatment until prescriber authorization can be achieved. 5. If an emergency order or proclamation of a state of emergency is issued by a state's governor, an executive order may allow pharmacists to dispense up to a 30-day supply of a prescription drug, or other amount as provided for under existing state law. 6. The dispensing pharmacist should notify the prescriber of the emergency refill within 72 hours of dispensing. 7. Emergency refills should not be a regular occurrence. 8. The pharmacist should inform the patient or the patient's agent at the time of dispensing that the refill is being provided without the prescriber's authorization and that authorization of the prescriber is required for a future refill. 9. The pharmacist should notify the patient or the patient's agent of any cost-sharing responsibilities prior to dispensing. 10. A prescriber should not be subject to liability for any damages resulting from an emergency refill of a prescription drug by a pharmacist.	
H-120.935	Medication Administration	Our AMA supports medication administration by appropriately trained facility staff for residents of	Retain.

POLICY #	Title	Text	Recommendation
	in Assisted Living Facilities	assisted living and dementia care facilities who require assistance in taking their medications.	
H-155.956	Make Simplicity the Foremost Criteria for Any CMS Program	Our American Medical Association will: (1) continue to advocate for simplicity in any current or future programs initiated by the Centers for Medicare & Medicaid Services (CMS) that impact physicians; and (2) continue to advocate by all means necessary that any current or future programs initiated by the Centers for Medicare and Medicaid Services be summarized into an executive summary format or other format that is easily comprehensible to physicians, medical staff and administration in a medical office.	Retain.
H-155.965	Health Care Rationing	The AMA defines "health care rationing" as follows: "a process of allocating health care resources that results in limitations or denials of medical services."	Retain.
H-155.980	Patient and Public Education about Cost of Care	The AMA, as a part of its program to strengthen the US health care system, supports intensifying its efforts to better understand patient concerns regarding fees and other costs of health care in all settings, including the cost of medication, and supports attempts to relieve these concerns.	Retain.
H-155.994	Sharing of Diagnostic Findings	The AMA (1) urges all physicians, when admitting patients to hospitals, to send pertinent abstracts of the patients' medical records, including histories and diagnostic procedures, so that the hospital physicians sharing in the care of those patients can practice more cost-effective and better medical care; (2) urges the hospital to return all information on in-hospital care to the attending physician upon patient discharge; and (3) encourages providers, working at the local level, to develop mechanisms for the sharing of diagnostic findings for a given patient in order to avoid duplication of expensive diagnostic tests and procedures.	Retain.
H-160.922	Physician and Health Plan Provision of	The AMA: (1) continues to urge physicians to share in the provision	Retain.

POLICY #	Title	Text	Recommendation
	Uncompensated Care	of uncompensated care to the uninsured indigent. (2) opposes any health plan-originated prohibition or discouragement of the provision of any uncompensated care by the plan's employed or participating physicians, in the absence of any external legislative or regulatory prohibition of such pro bono activities. (3) supports legislation prohibiting health plan-originated attempts to prohibit the provision of any uncompensated care by the plan's employed or participating physicians. (4) encourages physicians to contract wherever possible only with those health care delivery or financing plans that contribute in some way to care of the uninsured indigent and/or other community health needs, and that allow individual participating physicians to provide uncompensated care. (5) encourages all health care delivery or financing plans that control the source of covered services and the amount of payment for such services, including plans owned or sponsored by physicians, to contribute to the care of the uninsured indigent or to other community health needs through such means as: (a) Offering direct plan enrollment to individuals and families lacking group coverage and/or offering special coverages or premium subsidies for older, lower-income, and/or less healthy populations; (b) Provision of preventive or basic care services to disadvantaged populations at reduced or no charge; (c) Health education programs for the community at large; and (d) Provision of professional staff services, training, equipment and/or other assistance to public health clinics, community health centers or other care resources serving the disadvantaged. (6) encourages organizations and entities that accredit or develop and	

POLICY #	Title	Text	Recommendation
		apply performance measures for health plans to consider inclusion of recognition for such contributions in their evaluation criteria. (7) urges state medical societies to collect information on, recognize, and publicize the pro bono activities of health plans. (8) encourages state medical societies to support development of state assistance with malpractice premiums, caps on liability, or immunity from liability for services provided to uninsured indigent patients. (9) continues to support state legislation requiring diversion of assets to charitable causes by non-profit health plans converting to for-profit status.	
H-160.945	Subacute Care Standards for Physicians	AMA guidelines for physicians' responsibilities in subacute care include: (1) Physicians are responsible to their patients for delivery of care in all subacute care settings, 24 hours a day, 7 days a week. (2) Patients who might benefit from subacute care should be admitted to and discharged under the orders of the physician who is responsible for the continuous medical management needed to meet the patient's needs and safety and maintaining quality of care. (3) Physicians are responsible for coordinating care for their patients with other physicians including medical directors, primary care physicians, and appropriate specialists, to optimize the quality of care in subacute settings. (4) Physicians are responsible for supervision and coordination of the medical care for their patients and providing leadership for all other health care providers in subacute care. (5) Physicians should guide procedures for their patients performed within integrated practices and direct other health care providers, consistent with federal and state regulations.	Retain.

POLICY #	Title	Text	Recommendation
		(6) Physicians are responsible for: (a) Fulfilling their roles and identifying the medical skills needed to deliver care in subacute facilities and for creating and developing continuing medical education to meet the special needs of patients in subacute care. (b) Identifying and appropriately utilizing subacute care facilities in their communities. (c) Oversight of physician credentialing in subacute settings (d) Promoting medical staff organization and by-laws that may be needed to support peer evaluations. (e) Planning care of their patients with acute and chronic conditions in subacute care, as well as pursuing efforts to restore and maintain functions for quality of life. (7) Subacute units and/or programs need physician medical directors to assure quality of medical care, provide peer group liaisons, and coordinate and supervise patients and families input and needs. (8) Physicians provide a plan of care for medically necessary visits after completing an initial assessment within 24 hours of admission that identifies the medical services expected during subacute care. (9) Attending physicians should: (a) make an on-site visit to review the interdisciplinary care plan within seventy two hours of admission. (b) Determine the number of medically necessary follow up visits; these may occur daily but never less often than weekly. (c) Document active involvement of physicians in interdisciplinary care and all major components of the patient care plan including completing a progress note for each patient visit. (10) Physicians should implement these guidelines through organized medical staff by-laws in subacute settings to assure quality patient care.	
H-160.971	Uncompensated Care	Our AMA supports (1) communicating to the public the problem of uncompensated care and	Retain.

POLICY #	Title	Text	Recommendation
		the ever increasing regulations involving such care as well as the detrimental effect that uncompensated care has on the availability of necessary health care services to many citizens; and (2) publicizing the programs currently instituted to address uncompensated care and pursuing additional solutions for dealing with the problem of uncompensated care.	
H-165.854	Health Reimbursement Arrangements	It is the policy of the AMA: (1) to support Health Reimbursement Arrangements (HRAs) as one mechanism for empowering patients to have greater control over their health care decision-making; and (2) that employers offering HRAs be encouraged to consider: (a) making HRAs into real (rather than notional) accounts; (b) allowing rollover of all unspent HRA balances annually; and (c) making unspent HRA balances available to employees upon their retirement or departure from the company.	Retain.
H-165.863	Flexible Spending Accounts (FSAs)	1. Along with other efforts to liberalize the Health Savings Account rules, our AMA places a top priority on allowing employees to roll-over any unexpended funds in a Flexible Spending Account into a Health Savings Account. 2. Our AMA will advocate for a reasonable increase in Section 125 Flex Spending accounts.	Retain.
H-170.991	Information on Products and Services	The AMA strongly urges firms advising purchasers to seek medical advice regarding use of any product or service to include the name, address and telephone number of a responsible contact from whom information can be readily accessible to physicians on request (e.g., toll-free access or prompt delivery of printed matter about the product or service).	Retain.
H-180.956	Physician Privileges Application - Timely Review by Managed Care	Our AMA policy is that: (1) final acceptance of residents who otherwise are approved by a health plan should be contingent upon the receipt of a letter from their program director stating that their training has been satisfactorily	Retain.

POLICY #	Title	Text	Recommendation
		completed; (2) health plans which require board certification should allow the completing resident to be included in their plan after showing evidence of having completed the required training and of working towards fulfilling the requirements in the time frame established by their respective Board for completion of certification; and (3) Medicare, Medicaid, and managed care organizations should (a) make final physician credentialing determinations within 45 calendar days of receipt of a completed application; (b) grant provisional credentialing pending a final credentialing decision if the credentialing process exceeds 45 calendar days; and (c) retroactively compensate physicians for services rendered from the date of their credentialing.	
H-185.928	Burdensome Paperwork for Breast Pumps	Our AMA will vigorously oppose unnecessary and burdensome paperwork which presents barriers to lactation support, such as prescriptions to support physiologic functions; and further, to ensure that The Joint Commission and Healthy People 2020 breastfeeding goals are met.	Retain-in-part: Our AMA will vigorously oppose unnecessary and burdensome paperwork which presents barriers to lactation support, such as prescriptions to support physiologic functions.~~; and further, to ensure that The Joint Commission and Healthy People 2020 breastfeeding goals are met.~~
H-185.930	Notification to Physicians Regarding COBRA Grace Period	Our American Medical Association will advocate for notification to physicians where patients are within the 45-day or 30-day COBRA grace periods in a manner similar to the ACA-required insurance marketplace 90-day notifications to physicians and, if possible, require such information to be provided in real-time.	Retain.
H-185.944	Subscriber Identification Cards	Our AMA: (1) urges any pertinent official or governmental agency to require health insurance plans to issue identification cards to its subscribers which prominently identify the full legal name of the insured; name of the policy holder; identification numbers needed for claim submission; and the primary insurance company name with its appropriate mailing address; and (2) will advocate for legislative and regulatory sanctions against	Retain.

POLICY #	Title	Text	Recommendation
		insurance companies which present obstacles to the timely filing of claims which result in the denial of benefits.	
H-185.952	Elimination of Lifetime Maximums of Health Insurance Benefits	It is the policy of our AMA that employers and health insurers should eliminate the lifetime maximums of health insurance benefits.	Retain.
H-185.953	Health Insurance Coverage of Specialty Pharmaceuticals	Our AMA supports complete transparency of health care coverage policies related to specialty pharmaceuticals, including co-payment or co-insurance levels and how these levels are determined.	Retain.
H-185.955	Pap Smears as a Clinical Laboratory Test	The AMA: (1) advocates that it is imperative that Pap smear screening have sufficient payment levels to support the technology and personnel costs required to provide the service, and (2) seeks legislative and regulatory change in the Medicare payment policy for Pap smears so that payment for the technical component of the service is adequate to cover the cost of providing the service, and that pathologists are reimbursed for interpretation of abnormal Pap smears based on the RBRVS.	Retain.
H-185.956	Health Plan Coverage for Over-the-Counter Drugs	Our AMA: (1) opposes mandated health plan coverage for over-the-counter (OTC) pharmaceuticals, including those that had previously been available only with a prescription; (2) encourages health insurers and health plans to cover medically necessary OTC drugs for which no prescription alternative exists; and (3) continues to support efforts to study the effects of converting medically necessary drugs from prescription to over-the-counter status on the costs and access to such medications.	Retain.
H-185.957	Coverage for Strabismus Surgery	Our American Medical Association supports legislation that requires all third party payers that cover surgical benefits to cover all strabismus surgery where medically indicated.	Retain.
H-185.958	Equity in Health Care for	Our AMA: (1) encourages the development of domestic partner health care benefits in the public	Retain; Policy H-140.901 is identically titled; recommend amending title by addition as follows: "Equity in Health

POLICY #	Title	Text	Recommendation
	Domestic Partnerships	and private sector; and (2) supports equity of pre-tax health care benefits for domestic partnerships.	Care Benefits for Domestic Partnerships."
H-185.959	Health Care Benefit Discrepancies for Small Employers Under COBRA	Our AMA supports the principle that small employers who provide their employees with a group health insurance benefit, and who can afford to do so, should be encouraged to provide continuation coverage for their former employees, ideally consistent with the 18 months of coverage under COBRA.	Retain.
H-210.978	Improving Home Health Care	Our American Medical Association: (1) supports the appropriate training of home health aides to ensure the quality of services they provide, guided by the standards of the Medicare Conditions of Participation, accreditation entities and the Institute of Medicine; (2) supports regulatory oversight of home health agencies that employ home health aides; and (3) will work with interested state medical associations to support state legislation that requires home health aides to obtain appropriate training before caring for patients.	Retain.
H-215.967	For-Profit Conversions of Health Care Organizations	The AMA adopts as policy the following principles regarding the for-profit conversion of not-for-profit health care organizations: (1) Representatives of state government (e.g. state attorney general, state insurance commissioner) should oversee all for-profit conversions of health care organizations; (2) Public notice and subsequent public hearings should be required prior to the approval of a for profit-conversion; (3) The health care organization converting to for-profit status should be required to obtain an independent appraisal of its assets prior to the conversion. This appraisal should be made available to the representatives of state government (e.g., state attorney general, state insurance commissioner) overseeing the for-profit conversion; (4) For-profit conversions should be structured to prohibit private	Retain.

POLICY #	Title	Text	Recommendation
		inurement from officers, directors and key employees of the converting health care organization, as well as private benefit from other individuals; (5) If the establishment of a charitable foundation is required as part of the for-profit conversion, the mission of the foundation, as well as its proposed program agenda, should be determined and offered for public comment prior to the completion of the conversion; (6) The mission of a charitable foundation resulting from a for-profit conversion should closely reflect the original mission of the not-for-profit health care organization; (7) A designated proportion of the members serving on the board of directors of a charitable foundation should be new, independent members not previously affiliated with the converting organization, who are selected based on their experience relative to the mission of the foundation; (8) The level of compensation received by members serving on the board of directors of a charitable foundation should be consistent with that received by board members of similar types and sizes of foundations; (9) Representatives of state government (e.g., state attorney general, state insurance commissioner) should approve the mission and governance of any charitable foundation established as a result of for-profit conversions; (10) Once a charitable foundation has been established as a result of a for-profit conversion, ongoing community liaison with the foundation should occur on a regular basis (e.g., community advisory committees, periodic public reports); and (11) There should be meaningful physician presence on the board of directors of a charitable foundation formed as a result of the conversion of a not-for-profit health care	

POLICY #	Title	Text	Recommendation
		organization to a for-profit organization	
H-215.992	Hospital Security	Our AMA supports efforts by physicians and other hospital staff to encourage all hospitals to institute and/or maintain appropriate and adequate security measures, such as general identification, patrols, visual monitoring systems and metal detectors, in order to protect staff and patients.	Retain.
H-215.993	Medical Society-Governing Body (Trustee) Liaison Program	Our AMA (1) encourages state medical associations to maintain this activity to assure ongoing communication with hospital governing bodies; and (2) encourages state medical associations to draw upon all sources, including national level activities, to enhance their own direct communication with hospital governing bodies.	Retain.
H-220.980	Credentialing Procedure	The AMA encourages The Joint Commission to continue to monitor medical staff credentialing procedures to include clearly delineated authority to an elected physician of the medical staff for access, review and judgment over contents, to ensure that the individual medical staff member's credentials file contains only well documented and appropriate data and does not include information that is immaterial, misleading or of questionable value.	Retain.
H-220.989	Physician Credentialing	The AMA encourages The Joint Commission to develop standards that permit hospital medical staffs to establish educational needs as one of the criteria for medical staff privileges in teaching hospitals, to assure an appropriate number and variety of patients for educational purposes	Retain.
H-220.990	Principles for Revision of the Medical Staff Section of The Joint Commission "Accreditation Manual for Hospitals"	The AMA supports adherence to the following principles as the basis for any revision of the Medical Staff Section of the "Accreditation Manual for Hospitals": (1) continued use of the term "Medical Staff" in the title of the chapter and throughout the Manual; (2) deletion of any specific reference to limited licensed practitioners without	Retain.

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		precluding such practitioners from having hospital privileges consonant with their training, experience and current competence, if approved by the normal credentialing process; (3) consideration of qualified limited licensed practitioners in accordance with state law, and when approved by the executive committee of the medical staff, by the governing board, and when their services are appropriate to the goals and missions of that hospital, taking into account the training, experience and current clinical competence of the practitioners; (4) provision that the executive committee of the medical staff is composed of members selected by the medical staff, or appointed in accordance with the hospital bylaws. All members of the active medical staff, as defined in the Medical Staff Bylaws, are eligible for membership on the executive committee, and a majority of the executive committee members must be fully licensed physician members (Doctors of Medicine or Doctors of Osteopathy) of the active medical staff in the hospital; (5) assurance that the medical care of all patients remains under the supervision and direction of qualified, fully licensed physicians (Doctors of Medicine or Doctors of Osteopathy); and (6) assurance that the continued high quality of care, credentialing of physicians and other licensed practitioners, and effective quality assurance programs remain under the supervision and direction of fully licensed physicians.	
H-225.945	Temporary Medical Staff Privileges	Our AMA: (1) supports the use of temporary privileges in the following situations: (a) to fulfill an important patient care, treatment, or service need, or (b) when an applicant for new privileges with a 'clean' application is awaiting review and approval by the medical staff executive committee and the governing body; and (2) will work with other stakeholders to preserve	Retain.

POLICY #	Title	Text	Recommendation
		the use of temporary privileges in the following situations: (a) to fulfill an important patient care, treatment, or service need, or (b) when an applicant for new privileges with a 'clean' application is awaiting review and approval by the medical staff executive committee and the governing body.	
H-225.987	Reporting of Incidents	The AMA believes that (1) all hospital reports mandated by state agencies or outside authorities involving individual physician care of patients should be reviewed by an appropriate medical staff committee prior to reporting; (2) hospital medical staffs should be given a reasonable period of time to evaluate any reports pertaining to a physician's care of patients; and (3) the organized medical staff should seek the assurance of the state agency or outside authority that the report will remain strictly confidential.	Retain.
H-225.988	Hospital-Medical Staff Joint Ventures	The AMA believes it is vital for physicians to appraise responsibly the benefits and risks of specific hospital medical staff joint venture activities in light of their individual circumstances and the advice of knowledgeable and independent financial advisors and legal counsel.	Retain.
H-225.993	Medical Staff Policy Determination	The AMA believes that only fully licensed physicians on the medical staff should establish overall medical staff standards and policy for quality medical care, where consistent with local, state and federal laws.	Retain.
H-230.955	Clarification of Medical Staff Rights in Granting Clinical Staff Privileges	Our AMA: (1) policy is that medical staffs may establish any method of granting clinical privileges that complies with The Joint Commission standard MS.06.01.05; and (2) requests that its Commissioners to The Joint Commission ask The Joint Commission to notify all hospitals and medical staffs that there can be multiple ways to comply with The Joint Commission standards.	Retain.
H-230.957	Access to Hospital Records	Our AMA will support legislation guaranteeing that physicians engaged in staff privileges disputes	Retain.

POLICY #	Title	Text	Recommendation
		have free and full access to all medical records related to those disputes so they can adequately defend themselves.	
H-230.958	Economic Loyalty Criteria for Medical Staff Privileges	Our AMA strongly opposes the implementation of economic loyalty criteria for medical staff privileges.	Retain.
H-230.971	Economic Credentialing	Our AMA will work with The Joint Commission to assure, through the survey process, that any criteria used in the credentialing process are directly related to the quality of patient care.	Retain.
H-230.985	Medical Staff Privileges	The AMA believes that if, under the principle of self-governance, a medical staff determines that productivity, as it has a direct relationship to quality of care, is a reasonable criterion to use in its consideration of reappointment, it should be permitted to do so. However, the AMA does not believe that economic productivity should be a factor in medical staff reappointment.	Retain.
H-230.987	Hospital Decisions to Grant Exclusive Contracts	Our American Medical Association supports the concept that individual medical staff members who have been granted clinical privileges are entitled to full due process in any attempt to abridge those privileges by granting of exclusive contracts by the hospital governing body.	Retain.
H-230.988	Guidelines for Maintenance and Exchange of Credentialing Information	The AMA supports the development of guidelines for the maintenance and exchange of credentialing information and encourages all health care facilities, including the military, the Veterans Administration and the Public Health Service, to comply with such guidelines.	Retain.
H-230.993	Physician Credentialing	The AMA recommends that hospital medical staffs adopt bylaws which enable them to retain the prerogative and responsibility, as granted by the hospital governing body, for credentialing all physicians and other licensees who apply for clinical privileges, including those who seek to enter into contractual arrangements with hospitals.	Retain.

POLICY #	Title	Text	Recommendation
H-235.980	Hospital Medical Staff Self-Governance	1. Our AMA: supports essentials of self-governance for hospital medical staffs which, at a minimum include the right to: (a) initiation, development and adoption of medical staff bylaws, rules and regulations; (b) approval or disapproval of amendments to the medical staff bylaws, rules and regulations; (c) selection and removal of medical staff officers; (d) establishment and enforcement of criteria and standards for medical staff membership; (e) establishment and maintenance of patient care standards; (f) accessibility to and use of independent legal counsel; (g) credentialing and delineation of clinical privileges; (h) medical staff control of its funds; and (i) successor-in-interest rights. 2. Our AMA opposes any attempts to reengineer or otherwise amend medical staff bylaws or split the bylaws into a variety of separate and unincorporated manuals or policies, thereby eliminating the control and approval rights of the medical staff as required by the principles of medical staff self-governance. 3. Our AMA will ask its Commissioners to the Joint Commission on Accreditation of Healthcare Organizations to require that JCAHO medical staff standards require the following components to be an integral part of the medical staff bylaws, and not separate "governance documents," requiring approval by the entire medical staff. The medical staff is responsible for the following: (a) Application, reapplication, credentialing and privileging standards; (b) Fair hearing and appeal process; (c) Selection, election and removal of medical staff officers; (d) Clinical criteria and standards which manage quality assurance, utilization review;	Retain.

POLICY #	Title	Text	Recommendation
		(e) Structure of the medical staff organization; (f) Rules and regulations that affect the entire medical staff. 4. Our AMA recognizes that hospital non-compliance with JCAHO Standard MS 1.20 will be treated in the same way as hospital non-compliance with any other standard.	
H-235.983	AMA Response to Hospital Governing Bodies in Challenging Medical Staff Self-Governance	The AMA (1) reaffirms its policy in support of medical staff self-governance, including the process of electing and seating officers of the staff in accordance with medical staff bylaws, and its policy in opposition to improper interference by the governing body in that process; and (2) supports working with state hospital medical staff sections, state medical societies, and individual medical staffs to support medical staff self-governance in appropriate situations.	Retain.
H-235.993	Representation of the Medical Staff on All Committees of the Governing Board and Administration of American Hospitals	The AMA supports (1) medical staff representation on all committees of the governing board and administration of American hospitals; and (2) hospital administration representation on administrative committees of the medical staff.	Retain.
H-235.996	Bylaws and Rules and Regulations - No Incorporation by Reference	The AMA encourages medical staffs to develop their own bylaws, rules and regulations and not to incorporate other documents by reference.	Retain.
H-240.979	Intrusion by Hospitals into the Private Practice of Medicine	The AMA urges private third party payers to implement coverage policies that do not unfairly discriminate between hospital-owned and independently-owned outpatient facilities with respect to payment of "facility" costs.	Retain.
H-240.995	Diagnostic Related Groups	The AMA (1) supports input by hospital medical staffs into the DRG process to insure that quality of care is not compromised; and (2) supports the concept that the individual hospital medical staff's responsibility is to ensure appropriate quality of care for patients.	Retain.

POLICY #	Title	Text	Recommendation
H-245.970	Early Hearing Detection and Intervention	Our AMA: 1) supports early hearing detection and intervention to ensure that every infant receives proper hearing screening, diagnostic evaluation, intervention, and follow-up in a timely manner; and 2) supports federal legislation that provides for the development and monitoring of statewide programs and systems for hearing screening of newborns and infants, prompt evaluation and diagnosis of children referred from screening programs, and appropriate medical, educational, and audiological interventions and follow-up for children identified with hearing loss.	Retain.
H-280.974	Medically Necessary Nursing Facility Visits	Our AMA (1) defines a "medically necessary" visit to a Medicare/Medicaid resident in a nursing facility as any physician visit necessary to complete comprehensive nursing facility assessments and other assessments that are required as a condition of Medicare or state statute, as well as those visits that respond to a patient's development of a significant complication or a significant new problem which requires the creation of a new medical plan of care or visits that respond to the reported possibility of a change in patient condition; (2) supports the concepts embodied in the CPT Evaluation and Management codes for Nursing Facility services, including the concept that counseling and/or coordination of care that are provided consistent with the patient and/or family's needs be recognized as medically appropriate and necessary; (3) will monitor the use of the CPT codes for Nursing Facility Services and Medicare's determination of medical necessity to determine if revisions to the definitions of medical necessity are necessary;	Retain.

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		(4) supports eliminating the Medicare established arbitrary visit frequency parameters (inclusive of multiple same day visits where quality of care and severity of condition necessitates such encounters); (5) supports eliminating required documentation for obtaining such payments which place a significant burden on physician endeavors to provide quality care; (6) urges carrier refrainment from references to bona fide multiple patient visits on the same day as "gang visits," which unjustly impugn the quality of medical care provided; (7) supports establishment of a moratorium by CMS on any carrier collection of past "overpayments" for such multiple visits, and (8) will use whatever means necessary to achieve these objectives.	
H-280.995	Medicare Coverage of "Skilled Nursing Care"	The AMA encourages CMS to (1) clarify the Medicare definitions of "skilled nursing care" and "custodial care"; (2) identify and implement appropriate measures to assure greater consistency in the administrative interpretation of rules governing coverage of nursing home care; and (3) better explain to beneficiaries the exclusion for custodial care services.	Rescind: Accomplished by Centers for Medicare & Medicaid Services document that explains the definitions of "skilled nursing care" and "custodial care."
H-285.906	Protecting Against Forced Network Exclusivity of Specialist Physicians	Our AMA supports allowing specialty physicians to have primary contract status in more than one network.	Retain.
H-285.907	Out of Network Restrictions of Physicians	Our American Medical Association opposes the denial of payment for a medically necessary prescription of a drug or service covered by the policy based solely on the network participation of the duly licensed physician ordering it.	Retain.
H-285.969	Managed Care Education	The AMA will continue to emphasize professionalism, patient	Retain.

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		and physician autonomy, patient and physician rights, and practical assistance to physicians as key principles to guide AMA advocacy efforts related to managed care.	
H-285.970	Physician Office Review by Third Party Payers	The AMA supports development of standardized criteria to be used in managed care contracts for reviewing physicians' office and medical records in order to avoid multiple review.	Retain.
H-285.987	Guidelines for Qualifications of Managed Care Medical Directors	The AMA has adopted the following "Guidelines for Qualifications of Medical Directors of Managed Care Organizations": To the greatest extent possible, physicians who are employed as medical directors of managed care organizations shall: (1) hold an unlimited current license to practice medicine in one of the states served by the managed care organization, and where that Medical Director will be making clinical decisions or be involved in peer review that Medical Director should have a current license in each applicable state; (2) meet credentialing requirements equivalent to those met by plan providers; (3) be familiar with local medical practices and standards in the plan's service area; (4) be knowledgeable concerning the applicable accreditation or "program approval" standards for preferred provider organizations and health maintenance organizations; (5) possess good interpersonal and communications skills; (6) demonstrate knowledge of risk management standards; (7) be experienced in and capable of overseeing the commonly used processes and techniques of peer review, quality assurance, and utilization management; (8) demonstrate knowledge of due process procedures for resolving issues between the participating physicians and the health plan administration, including those	Retain.

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		related to medical decision-making and utilization review; (9) be able to establish fair and effective grievance resolution mechanisms for enrollees; (10) be able to review, advise, and take action on questionable hospital admissions, medically unnecessary days, and all other medical care cost issues; and (11) be willing to interact with physicians on denied authorizations. The AMA strongly encourages managed care organizations and payer groups to utilize these guidelines in their recruitment and retention of medical directors.	
H-285.989	AMA Opposition to All Products Clauses	Our AMA will seek legislative action to prohibit tying a physician's membership in an insurance product (e.g., a PPO) to that physician's participation in any other insurance product (e.g., an HMO, workers' compensation, automobile personal injury protection insurance, Medicare and Medicaid).	Retain.
H-290.974	Status Report on the Medicaid Program	1. It is the policy of our AMA 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 the Children's Health Insurance Program, with the goal of improving access to health care coverage to otherwise uninsured groups. 2. Our AMA advocates that any tax treatment applied to health insurance for the purpose of encouraging individual ownership also apply to long-term care insurance. 3. Our AMA urges Congress and the Administration to develop proposals and enact solutions to address the pending growth of long-term care needs of the American population.	Retain.
H-290.995	Case Management	The AMA has adopted the following policy: (1) That states be	Retain.

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	System for Outpatient Clinics	given the authority to establish primary care case management programs for populations whose medical care is provided through Medicaid or other public welfare funding: (a) on a voluntary basis with incentives provided toward a prudent choice of care source; and (b) on a mandatory basis only for those recipients in a given area who have been identified as overutilizers or misutilizers of services; and (2) that comparative analyses of these programs be undertaken to determine their relative effectiveness regarding patient access, quality of and satisfaction with care, and cost reduction.	
H-320.955	Conflict of Interest in Care Review	AMA policy is that utilization review organizations make every effort to avoid potential conflicts of interest for physician reviewers by not assigning cases to a physician reviewer who (1) is an associate or competitor of the physician under review, (2) actively practices in the same hospital as the physician under review when feasible, (3) participated in the development or execution of the patient's treatment plan, or (4) is a member of the patient's family.	Retain.
H-320.969	Concurrent Review Procedures of Inpatient Care by HMO Representatives	The AMA encourages state regulation of third party reviewers who are on site in hospitals evaluating inpatient management so that these representatives: (1) must accrue clinical data in the hospital only under the control of hospital-based utilization review/quality assurance (UR/QA) personnel; (2) must not be enabled to have any direct inpatient contact; (3) must both communicate such suggestions directly to the attending physician and document all actions in the hospital's utilization office if they wish to provide input regarding patient management; (4) it is the role of the utilization review program or managed care plan to credential/certify that its reviewers are appropriately licensed and have the required experience to perform review; (5) prior to the on-site	Retain.

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		review, the utilization review program or managed care plan should provide upon request the name(s), credentials and background of their reviewers to the medical staff credentials committee and/or quality assurance/utilization review committee; and (6) the medical staff should have: (a) established protocol for reviewers entry into the hospital and (b) a process for monitoring the reviewer's activities and the confidentiality of the records they review.	
H-320.993	Utilization Management	The AMA encourages physicians to take a leadership role in implementing and maintaining utilization management programs within their hospitals.	Retain.
H-330.881	Medicare Coverage for Evidence-Based Lymphedema Treatment	Our AMA supports Medicare coverage for appropriate and evidence-based treatment of lymphedema.	Retain.
H-330.882	Oppose Local Coverage Determination for Lower Limb Prostheses	Our AMA (1) opposes local coverage determinations on lower limb prostheses that undermine physician judgment and compromise patient access; and (2) will request that the Centers for Medicare and Medicaid Services expeditiously host a national meeting open to all interested parties to focus on appropriate standards for lower limb prostheses that optimize care for patients.	Retain.
H-330.883	Parity of Payment for Administering Biologic Medications	Our AMA supports and encourages interested national medical specialty societies and other stakeholders to submit a request to Medicare for a national coverage determination directing Medicare Administrative Contractors to consider all biologics as complex injections or infusions.	Retain.
H-373.994	Patient Navigation Programs	1. Our AMA recognizes the increasing use of patient navigator and patient advocacy services to help improve access to care and help patients manage complex aspects of the health care system. In order to ensure that patient navigator services enhance the delivery of high-quality patient care, our AMA supports the	Retain.

POLICY #	Title	Text	Recommendation
		following guidelines for patient navigator programs: a) The primary role of a patient navigator should be to foster patient empowerment, and to provide patients with information that enhances their ability to make appropriate health care choices and to receive medical care with an enhanced sense of confidence about risks, benefits, and responsibilities. b) Patient navigator programs should establish procedures to ensure direct communication between the navigator and the patient's medical team. c) Patient navigators should refrain from any activity that could be construed as clinical in nature, including interpreting test results or medical symptoms, offering second opinions, or making treatment recommendations. Patient navigators should provide a supportive role for patients and, when necessary, help them understand medical information provided by physicians and other members of their medical care team. d) Patient navigators should fully disclose relevant training, experience, and credentials, in order to help patients understand the scope of services the navigator is qualified to provide. e) Patient navigators should fully disclose potential conflicts of interest to those whom they serve, including employment arrangements. 2. Our AMA will work with the American College of Surgeons and other entities and organizations to ensure that patient navigators are free of bias, do not have any role in directing referrals, do not usurp the physician's role in and responsibility for patient education or treatment planning, and act under	

POLICY #	Title	Text	Recommendation
		the direction of the physician or physicians primarily responsible for each patient's care. 3. Policy provisions for patient navigators are also relevant for community health workers and other non-clinical public health workers.	
H-375.994	Peer Review in All Health Care Facilities	The AMA supports the provision of comparable peer review systems of medical services offered in public, private and governmental hospitals.	Retain.
H-385.915	Integrating Physical and Behavioral Health Care	Our American Medical Association: (1) encourages private health insurers to recognize CPT codes that allow primary care physicians to bill and receive payment for physical and behavioral health care services provided on the same day; (2) encourages all state Medicaid programs to pay for physical and behavioral health care services provided on the same day; (3) encourages state Medicaid programs to amend their state Medicaid plans as needed to include payment for behavioral health care services in school settings; (4) encourages practicing physicians to seek out continuing medical education opportunities on integrated physical and behavioral health care; and (5) promotes the development of sustainable payment models that would be used to fund the necessary services inherent in integrating behavioral health care services into primary care settings.	Retain.
H-385.955	Denial of Payment for Treatment of Immediate Family Members	The AMA calls upon CMS to amend its regulations denying payment for physician services and services incident to a physician's professional services for treatment of immediate family members by permitting an exception applicable to the services of any physician who is the single source of medical care in the community.	Retain.
H-385.989	Payment for Physicians Services	Our AMA: (1) supports a pluralistic approach to third party payment methodology under fee-for-service, and does not support a preference for "usual and customary or	Retain.

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		reasonable" (UCR) or any other specific payment methodology; (2) affirms the following four principles: (a) Physicians have the right to establish their fees at a level which they believe fairly reflects the costs of providing a service and the value of their professional judgment. (b) Physicians should continue to volunteer fee information to patients, to discuss fees in advance of service where feasible, to expand the practice of accepting any third-party allowances as payment in full in cases of financial hardship, and to communicate voluntarily to their patients their willingness to make appropriate arrangements in cases of financial need. (c) Physicians should have the right to choose the basic mechanism of payment for their services, and specifically to choose whether or not to participate in a particular insurance plan or method of payment, and to accept or decline a third-party allowance as payment in full for a service. (d) All methods of physician payment should incorporate mechanisms to foster increased cost-awareness by both providers and recipients of service; and (3) supports modification of current legal restrictions, so as to allow meaningful involvement by physician groups in: (a) negotiations on behalf of those physicians who do not choose to accept third party allowances as full payment, so that the amount of such allowances can be more equitably determined; (b) establishing additional limits on the amount or the rate of increase in charge-related payment levels when appropriate; and (c) professional fee review for the protection of the public.	
H-390.840	Update on Payment Mechanisms for Physician-Led Team-Based Health Care	1. Our AMA encourages public and private health insurers to develop and offer a variety of value-based contracting options so that physician practices can select payment models that best suit their delivery of care.	Retain.

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		2. Our AMA encourages the Centers for Medicare & Medicaid Services (CMS) to ensure that Medicare Alternative Payment Models (APMs) do not require physicians to assume responsibility for costs they cannot control because such a requirement could potentially create an ethical conflict of interest. 3. Our AMA will continue to actively advocate to CMS that physicians in all specialties and modes of practice must have at least one Medicare APM in which they can feasibly participate. 4. Our AMA will advocate to CMS that any review process of alternative payment models proposed by stakeholders be completed in a timely manner, include an administratively simple appeals process and access to an ombudsman.	
H-390.841	Value Based Modifier and Flawed Drug Cost Attribution	Our American Medical Association will work with the Centers for Medicare & Medicaid Services to modify Value Based Modifier cost attribution with regard to all drug costs, to ensure the cost calculation does not unfairly disadvantage certain providers.	Retain.
H-390.842	Include Physicians in CMS Rate Increases to Medicare Advantage Plans	Our American Medical Association (1) encourages Medicare Advantage plans to be transparent with respect to the allocation of their rate increases, and (2) encourages individual physicians to negotiate rate increases that parallel or improve upon the percentage increases received by the Medicare Advantage plans with which they contract.	Retain.
H-390.843	Physician-Led, Single and Multi-Specialty, Organized Group Practice Models	1. Our AMA recognizes that physician-led, single and multi-specialty group practices, integrated delivery systems, and other organized systems of care demonstrating the following attributes: (a) efficient provision of services, (b) organized system of care, (c) quality measurement and improvement activities, (d) care coordination, (e) use of IT and evidence-based medicine, (f)	Retain.

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		compensation practices that promote all aforementioned attributes, and (g) accountability, are credible models for providing coordinated, comprehensive, accountable, cost-effective, patient-centered care. 2. Our AMA will continue its involvement in activities that support physicians in all practice settings to implement solutions and strategies that can improve practice efficiency, helping them achieve improved quality at an affordable cost.	
H-390.872	Compensation for Physicians Who Accompany Seriously Ill or Injured Patients to Hospitals	The AMA: (1) urges CMS to allow payment for the services of physicians who accompany seriously ill or injured patients in the ambulance to hospitals and who report the appropriate level of evaluation and management service along with Prolonged Physician Service with Direct (Face-to-Face) Patient Contact (codes 99354 and 99355) or the Critical Care Services codes (99291 and 99292); and (2) urges CMS to expand its guidelines to carriers to allow payment for a physician's return trip from accompanying an ambulance-borne patient, consistent with above, using code 99082, Unusual travel (e.g., transportation and escort of patient).	Retain.
H-390.880	Interest Rates Charged and Paid by CMS	1. (A) Our AMA will (1) determine if the recent interest rate changes implemented by CMS comply with current Medicare laws; (2) seek to ensure that CMS's interest charges do not exceed legal limits; and (3) work with CMS to ensure parity in interest rates assessed against physicians by CMS and interest rates paid to physicians by CMS. (B) If an agreement cannot be reached with CMS, the AMA will seek legislation to correct this situation. 2. Our AMA supports amending federal Medicare law to require that interest on both overpayments and underpayments to providers attaches upon notice of the error to	Retain.

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		the appropriate party in either instance.	
H-390.921	Uniformity of Operations of Medicare Administrative Contractors	It is the policy of the AMA (1) to use its influence and resources to bring about uniformity of business policies and procedures among the Medicare Administrative Contractors, and (2) to investigate and monitor the differing policies and procedures among the Medicare Administrative Contractors with respect to physician reimbursement.	Retain.
H-390.991	CMS Reimbursement Policy for Physicians in Solo Practice "Covering" Medicare Patients for Each Other	The AMA supports permitting physicians in solo practice, and those in different groups, to "cover" Medicare patients for each other, and making it possible for the personal physicians of Medicare patients to bill and to receive reimbursement for professional services rendered by their colleagues who "cover" for them.	Retain.
H-400.955	Establishing Capitation Rates	1. Our AMA believes Geographic variations in capitation rates from public programs (e.g., Medicare or Medicaid) should reflect only demonstrable variations in practice costs and correctly validated variations in utilization that reflect legitimate and demonstrable differences in health care need. In particular, areas that have relatively low utilization rates due to cost containment efforts should not be penalized with unrealistically low reimbursement rates. In addition, these payments should be adjusted at the individual level with improved risk adjustors that include demographic factors, health status, and other useful and cost-effective predictors of health care use. 2. Our AMA will work to assure that any current or proposed Medicare or Medicaid (including waivers) capitated payments should be set at levels that would establish and maintain access to quality care. 3. Our AMA seeks modifications as appropriate to the regulations and/or statues affecting Medicare HMOs and other Medicare managed care arrangements to incorporate the	Retain.

POLICY #	Title	Text	Recommendation
		revised Patient Protection Act and to ensure equal access to Medicare managed care contracts for physician-sponsored managed care organizations. 4. Our AMA supports development of a Medicare risk payment methodology that would set payment levels that are fair and equitable across geographic regions; in particular, such methodology should allow for equitable payment rates in those localities with relatively low utilization rates due to cost containment efforts.	
H-400.956	RBRVS Development	(1) That the AMA strongly advocate CMS adoption and implementation of all the RUC's recommendations for the five-year review; (2) That the AMA closely monitor all phases in the development of resource-based practice expense relative values to ensure that studies are methodologically sound and produce valid data, that practicing physicians and organized medicine have meaningful opportunities to participate, and that any implementation plans are consistent with AMA policies; (3) That the AMA work to ensure that the integrity of the physician work relative values is not compromised by annual budget neutrality or other adjustments that are unrelated to physician work; (4) That the AMA encourage payers using the relative work values of the Medicare RBRVS to also incorporate the key assumptions underlying these values, such as the Medicare global periods; and (5) That the AMA continue to pursue a favorable advisory opinion from the Federal Trade Commission regarding AMA provision of a valid RBRVS as developed by the RUC process to private payers and physicians.	Retain.
H-405.956	Transparency of Health Care Provider Profiles in Commercial	1. Our AMA encourages accurate and transparent listings of professional degree(s), post-graduate specialty education, and	Retain.

POLICY #	Title	Text	Recommendation
	and Federal Physician Comparison Databases	naming of the certifying agency with board certification data released to the public for comparison of healthcare providers or other healthcare services, in accordance with existing AMA policy. 2. Our AMA urges commercial entities and federal programs providing healthcare provider ratings, comparisons, referrals, direct appointments, telehealth, or other services to revise the search and reporting methodology used for profiling of all healthcare providers so as to increase transparency requirements, including the description of professional degree(s), post graduate specialty education, and naming of the certifying board(s), in accordance with existing AMA policy.	
H-405.995	Administration and Supervision of Rehabilitation Units	The AMA believes that (1) third party coverage for the administration and supervision of patient rehabilitation in the office, hospital, and free-standing units should continue to be determined by physician competence based on training and experience, and should not be denied on the basis of specialty certification; and (2) the determination of criteria for qualification in the administration and supervision of rehabilitation units should be based on competence gained by training and experience, and should not be arbitrarily restricted by specialty designation.	Retain.
H-406.993	Development and Use of Physician Profiles	The AMA: (1) urges state medical associations, national medical specialty societies, hospital medical staff, and individual physicians to seek active involvement in the development, implementation, and evaluation of physician profiling initiatives; (2) encourages research to develop improved data sources, methods, and feedback approaches to physician profiling initiatives; (3) opposes the use of profiling procedures that do not meet AMA principles for the credentialing or termination of physicians by	Retain.

POLICY #	Title	Text	Recommendation
		managed care plans; (4) opposes physician profiling data being used for economic credentialing purposes; (5) believes that any disclosure or release of physician profiles shall follow strict conformance to AMA policy on the use and release of physician-specific health care data (Policy 406.996); and (6) will monitor the use of profiling procedures related to physician profiling.	
H-406.994	Principles of Physician Profiling	Our AMA advocates that managed care organizations, third party payers, government entities, and others that develop physician profiles adhere to the following principles: (1) The active involvement of physician organizations and practicing physicians in all aspects of physician profiling shall be essential. (2) The methods for collecting and analyzing data and developing physician profiles shall be disclosed to relevant physician organizations and physicians under review. (3) Valid data collection and profiling methodologies, including establishment of a statistically significant sample size, shall be developed. (4) The limitations of the data sources used to develop physician profiles shall be clearly identified and acknowledged. (5) Physician profiles shall be based on valid, accurate, and objective data and used primarily for educational purposes. (6) To the greatest extent possible, physician profiling initiatives shall use standards-based norms derived from widely accepted, physician-developed practice parameters. (7) Physician profiles and any other information that have been compiled related to physician	Retain.

POLICY #	Title	Text	Recommendation
		performance shall be shared with physicians under review. (8) Comparisons among physician profiles shall adjust for patient case-mix, control for physician specialty, and distinguish between the ordering or referring physician and the physician providing the service or procedure. (9) Effective safeguards to protect against the unauthorized use or disclosure of physician profiles shall be developed. (10) The quality and accuracy of physician profiles, data sources, and methodologies shall be evaluated regularly.	
H-406.997	Collection and Analysis of Physician-Specific Health Care Data	1. Our AMA advocates that third party payers, government entities, and others that collect and analyze physician-specific health care data adhere to the following principles: (a) The methods for collecting and analyzing physician-specific health care data shall be disclosed to physicians under review and the public. (b) Physician-specific health care data shall be valid, accurate, objective and used primarily for the education of both consumers and physicians. (c) Data elements used in the collection of physician-specific health care data, including severity adjustment factors, shall be determined by advisory committees which include actively practicing, and where relevant, specialty-specific, physicians from the region where the data are being collected. (d) Statistically valid data collection, analysis, and reporting methodologies, including establishment of a statistically significant minimum number of cases, shall be developed and appropriately implemented prior to the release of physician-specific health care data. (e) The quality and accuracy of the physician-specific health care data shall be evaluated by conducting periodic medical record audits.	Retain.

POLICY #	Title	Text	Recommendation
		2. Our AMA believes that health care coalitions which include physicians as full voting members are an appropriate forum for undertaking health care data collection and analysis activities; in consideration of the potential for misinterpretation, violation of privacy rights, and antitrust concerns, it is recommended that charge or utilization data provided to such entities by government, third party payers, and self-insureds companies be in the form of ranges or averages and not be physician-specific.	
H-406.998	Role of Physicians and Physician Organizations in Efforts to Collect Physician-Specific Health Care Data	Our AMA: (1) believes that physicians, as patient advocates and possessing unique qualifications in the review and analysis of health care data, must take the initiative in developing data collection systems at the local level which maintain high standards of confidentiality, accuracy and fairness; (2) urges state medical societies, national medical specialty societies, hospital medical staffs and individual physicians to: (a) participate in health care data collection programs designed to improve the quality of care; (b) be aware of the limitations of health care data; (c) encourage active involvement of physician organizations and practicing physicians in all aspects of health care data collection and interpretation; and (d) develop strategies to assist state agencies and others in improving the collection and interpretation of health data; (3) urges health data commissions and other entities that collect, evaluate, and disseminate health care data to: (a) facilitate active involvement of physician organizations and practicing physicians in all aspects of the efforts to collect health care data; (b) provide adequate opportunity for	Retain.

POLICY #	Title	Text	Recommendation
		physician organizations and practicing physicians to review and respond to proposed data interpretations and disclosures; (c) ensure accuracy of information in the data base; and (d) assure valid interpretation and use of health care data; (4) encourages relevant physician organizations to develop effective mechanisms to assist physicians in evaluating, using, and responding to physician-specific health care data; (5) encourages medical societies to use this information for educational purposes and for addressing such areas as utilization variation, quality assessment and appropriate cost containment activities; (6) encourages medical societies to play an active role in appropriate data collection and dissemination activities at the local level; and (7) urges state medical societies, hospital medical staffs and physicians to propose, monitor, and seek to influence quality of care and cost containment legislation to comply with AMA principles.	
H-435.955	Administrative and Liability Surcharges	Our AMA supports the ability of physicians to institute an "administrative surcharge" and/or a "liability surcharge."	Retain.
H-450.936	Physician Quality Reporting Initiative Payment	Our AMA will continue to advocate for improvements in the Physician Quality Reporting Initiative (PQRI) including early education and outreach to physicians by the Centers for Medicare and Medicaid Services (CMS), the provision of confidential interim and final feedback reports from CMS to physicians on potential problems in their PQRI reporting, easier access to feedback reports, development of meaningful dispute resolution processes, and the provision to our AMA of the 2007 PQRI data set file.	Rescind: The Physician Quality Reporting Initiative was replaced by the Merit-based Incentive Payment System (MIPS) in 2017.
H-465.986	Rural Health	1. The AMA urges CMS to disseminate widely information on	Retain; Policy H-465.989 is identically titled; recommend amending title by

POLICY #	Title	Text	Recommendation
		the Rural Health Clinics Program, not only to states and health facilities but to state medical associations as well. 2. The AMA encourages state medical associations to evaluate the potential benefits and drawbacks to rural practices of seeking certification as rural health clinics, and transmit the result of such evaluation to their members. 3. The AMA encourages state medical associations to carefully evaluate the relevant practice acts in their jurisdictions to identify any modifications needed to allow the most effective use of mid-level practitioners in improving access to care, while assuring appropriate physician direction and supervision of such practitioners.	addition as follows: "Rural Health Clinics."
H-465.989	Rural Health	It is the policy of the AMA that: (1) the AMA closely monitor the impact of balance billing restrictions mandated by the Budget Reconciliation legislation on reimbursement levels and access to care in rural areas, and take action as needed to moderate that impact; (2) the AMA closely monitor implementation of the legislation establishing essential access community hospitals and rural primary care hospitals, to ensure that this program is implemented in a manner conducive to high quality of patient care and consistent with Association policy concerning the functions and supervision of physician assistants and nurse practitioners; (3) state medical associations be encouraged to monitor similarly and to influence any legislation or regulations governing the development and operation of such limited service rural hospital facilities in their own jurisdictions; and (4) the AMA establish liaison with the American Hospital Association, Congress and the Centers for Medicare & Medicaid Services regarding any further development of essential	Retain.

POLICY #	Title	Text	Recommendation
		access community hospitals and rural primary care hospitals grants.	
H-70.916	Delay or Canceling of ICD-10	Our AMA supports delaying or canceling the implementation of ICD-10.	Rescind: ICD-10-CM was implemented on 10/1/15.

2. RECONSIDERING THE AFFORDABLE CARE ACT (ACA) ELIGIBILITY FIREWALL

Reference committee hearing: see report of Reference Committee A.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policies H-165.828 and H-165.843

At the June 2023 Annual Meeting, the House of Delegates referred Resolution 103, which was sponsored by the Medical Student Section and asked the American Medical Association (AMA) to: (1) recognize the inefficiencies and complexity of the employer-sponsored health insurance system and the existence of alternative models that better align incentives to facilitate access to high quality health care; (2) support movement toward a health care system that does not rely on employer-sponsored health insurance and enables universal access to high quality health care; (3) amend Policy H-165.828[1], "Health Insurance Affordability," by addition and deletion to read as follows:

Health Insurance Affordability H-165.828[1]
~~1. Our AMA supports modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered employer-sponsored coverage by lowering the threshold that determines whether an employee's premium contribution is affordable to that which applies to the exemption from the individual mandate of the Affordable Care Act (ACA).~~Our AMA advocates for the elimination of the employer-sponsored insurance firewall such that no individual would be ineligible for premium tax credits and cost-sharing assistance for marketplace coverage solely on the basis of having access to employer-sponsored health insurance.

and (4) amend Policy H-165.823[2] by deletion to read as follows:
Options to Maximize Coverage Under the AMA Proposal for Reform H-165.823[2]
2. Our AMA will advocate that any public option to expand health insurance coverage must meet the following standards:
a. The primary goals of establishing a public option are to maximize patient choice of health plan and maximize health plan marketplace competition.
~~b. Eligibility for premium tax credit and cost-sharing assistance to purchase the public option is restricted to individuals without access to affordable employer-sponsored coverage that meets standards for minimum value of benefits.~~
b~~e~~. Physician payments under the public option are established through meaningful negotiations and contracts. Physician payments under the public option must be higher than prevailing Medicare rates and at rates sufficient to sustain the costs of medical practice.
c~~d~~. Physicians have the freedom to choose whether to participate in the public option. Public option proposals should not require provider participation and/or tie participation in Medicare, Medicaid and/or any commercial product to participation in the public option.
d~~e~~. The public option is financially self-sustaining and has uniform solvency requirements.
e~~f~~. The public option does not receive advantageous government subsidies in comparison to those provided to other health plans.
f~~g~~. The public option shall be made available to uninsured individuals who fall into the "coverage gap" in states that do not expand Medicaid—having incomes above Medicaid eligibility limits but below the federal poverty level, which is the lower limit for premium tax credits—at no or nominal cost.

Council on Medical Service Report 2-A-24 was referred back to the Council to ensure that the recommendations maximize patient access to care while protecting physician practice revenue and sustainability. This report discusses employer-sponsored insurance (ESI) affordability, explains the ACA affordability threshold (known as the "firewall"), summarizes relevant AMA policy, and makes policy recommendations.

BACKGROUND

Almost a decade and a half after enactment of the ACA, employer-sponsored insurance ESI continues to be the dominant source of health coverage for Americans under 65 years of age. In 2023, 164.7 million people under age 65, or 60 percent of the non-elderly population, had health insurance coverage through an employer.[1] Although ESI is the most common type of health insurance, coverage varies significantly by income as well as race and ethnicity. While 84 percent of individuals with incomes at or above 400 percent of the federal poverty level (FPL) had ESI, it covered fewer than one-quarter of individuals with incomes below 200 percent FPL. Additionally, larger percentages of white and Asian people have ESI while individuals who are African American and Latino are less likely to have employer-based coverage.[2,3]

Overall, most Americans appear satisfied with employment-based coverage. According to KFF's survey of consumer experiences with health insurance, in 2023, 80 percent of adults with ESI and 73 percent of those with ACA marketplace coverage rated their health coverage as "excellent" or "good" although people in poorer health gave more negative ratings across all plan types. Regardless of health status, enrollees in marketplace plans were most likely to rate their experiences with health insurance as fair or poor.[4] Ninety-three percent of workers responding to a 2022 poll sponsored by the U.S. Chamber of Commerce expressed high rates of satisfaction with ESI, with a large majority (89 percent) expressing a preference for ESI over other types of coverage.[5] Eighty percent of respondents to this survey ranked health insurance as the most important workplace benefit provided to them, and a majority cited "affordability" and "high quality" as ESI's most critical features.[6]

Although ESI is popular, it has become increasingly costly for employers and employees, especially small firms and lower-income workers. According to 2024 data from the KFF Employer Health Benefits Survey:

- Fifty-four percent of all firms offered health benefits, including almost all (98 percent) large employers (those with 200 or more workers) and just over half (53 percent) of smaller firms (those with three to 199 workers). Eight percent of firms with at least 50 employees that offer health benefits offer a plan that has a narrow provider network.[7]
- Seventy-five percent of eligible employees took up coverage when it was offered to them, a slight decrease from 2013 (80 percent) and a more sizeable decrease from 2003 (84 percent). Across both firms that offer health benefits and those that do not, more than half (54 percent) of workers have employer coverage.[8]
- Annual health insurance premiums averaged $8,951 for individual coverage and $25,572 for family coverage, six and seven percent more than last year, respectively. In comparison, the Bureau of Labor Statistics found that wages increased 4.5 percent while inflation grew by 3.2 percent. Notably, premiums for family coverage have increased 24 percent over the last five years while, during the same time period, inflation has risen 23 percent and wages have increased 28 percent. Workers pay, on average, $1,368 annually for individual coverage and $6,296 toward the cost of family premiums.
- Seventy-six percent of firms offering coverage offered only one type of plan. Large firms were significantly more likely to offer more than one plan type than small firms.
- Almost half (48 percent) of covered employees are enrolled in preferred provider organizations (PPOs), the most common plan type offered. Twenty-seven percent of covered workers are enrolled in a high-deductible health plan (HDHP) with savings option.[9]

ESI Affordability

To manage costs, many employer-based plans include substantial deductibles and other out-of-pocket cost-sharing that, together with premium contributions, increase employee health costs and impact affordability.[10] The comparability of ESI and ACA marketplace plan affordability is complicated by differences among enrollees across plans; differences in plan design and regulatory requirements; and enrollee tax savings. In a 2024 report, the U.S. Government Accountability Office (GAO) found that average premiums for employer plans in 2022 were lower than average premiums for marketplace plans. However, after accounting for employer contributions to workers' premiums and federal premium tax credits for marketplace plans, average worker premium contributions to ESI plans were

higher than average enrollee premium contributions to marketplace plans.[11] A report from The Commonwealth Fund and Urban Institute found that, prior to the American Rescue Plan Act of 2021 (ARPA) enhancements to marketplace premium tax credits, adults with nongroup coverage reported higher average premiums and health care costs than ESI enrollees and were more likely to report foregoing health care and having problems affording care.[12]

According to KFF's 2024 Employer Health Benefits Survey, the average annual deductible for employees with single coverage was $1,787, a figure that has held relatively steady over the last five years but is 47 percent higher than the average deductible amount 10 years ago.[13] Overall, nearly a third of employees (32 percent) had plan deductibles of $2,000 or more, including half of workers at small firms, whose average annual deductible was $2,575 compared to $1,538 for employees of larger firms.[14]

High-Deductible Health Plans: Not only are deductible amounts rising, but more workers are now covered by high-deductible health plans (HDHPs), which typically have higher deductibles and lower premiums when compared to traditional plans. Such plans generally require patients to pay the full cost of health services and medications until deductibles are met. Although an HDHP's lower premium may be attractive to some people, the responsibility for out-of-pocket expenses becomes problematic when deductibles are too high for enrollees to afford and patients are unable to cover their costs. Not surprisingly, studies have found that reductions in health spending achieved through HDHPs are primarily due to patients simply receiving less medical care as they become more cost-conscious when seeking services.[15] As previously highlighted by the Council on Medical Service (Council on Medical Service Report 2-Nov-20, Mitigating the Negative Effects of High-Deductible Health Plans), the imposition of greater consumer cost-sharing is frequently used to ensure that those receiving health care services "have skin in the game," and as a lever to minimize premium growth.

Over the years, HDHPs have become a more common ESI offering. Among workers with HDHPs, 52 percent had plans with Health Savings Accounts (HSAs) while eight percent participated in plans with Health Reimbursement Arrangements (HRAs), figures that varied considerably between high and low wage employees. Among workers in the lowest 25 percent wage category, 32 percent had plans with HSAs and 12 percent had HRAs. Among workers in the highest 25 percent wage category, 66 percent had plans with HSAs and seven percent had HRAs.[16] Theoretically, lower premiums may result in higher wages that may help offset the risk associated with HDHPs.

Small Employer Coverage: Health coverage is especially challenging for small business, whose employees frequently pay more for health coverage. According to the Commonwealth Fund, these workers generally contribute a greater share of premium costs and have larger deductible amounts than large-firm employees.[17] KFF has also highlighted the lack of affordable family coverage options for workers at smaller firms employing fewer than 200 people. These employees pay on average $8,334 towards family coverage premiums each year with a quarter paying at least $12,000 annually, not including deductibles and other cost-sharing expenses.[18]

Lower-Income Employees and Affordability: Several analyses have pointed out that workers with lower incomes are disproportionately burdened by ESI costs and usually pay a greater share of income toward employer plan premiums and other out-of-pocket expenses.[19, 20, 21] A KFF analysis of data from its 2023 survey of consumer experiences with health insurance found that adults with incomes below 200 percent FPL who have ESI were significantly more likely than higher-income peers to report difficulties paying for medical care; treatment delays and declines in health due to insurance problems, such as prior authorization; dissatisfaction with the availability and quality of health providers in their plan's network; and more difficulty comparing plans and signing up for coverage.[22] Additional KFF research from 2022 found that, on average, families with incomes below 200 percent FPL pay approximately 10.4 percent of income toward health care premiums and out-of-pocket expenses (7.7 percent for premiums) while those with incomes at or above 400 percent FPL pay about 3.5 percent toward premiums and medical expenses (2.3 percent for premiums).[23] Though employers could utilize health benefit design strategies to address affordability issues facing lower-income workers, few seem to do so; in 2022, 10 percent of large firms reportedly had programs that lowered premium costs for lower-income employees while only five percent reported programs to lower their cost-sharing expenses.[24] COBRA coverage is often too costly an option for workers who are leaving a job.

Though many workers mistakenly think otherwise, they—not the firms they work for—pay the majority of ESI costs, both directly through contributions and indirectly through wage adjustments made to cover employers' health care costs.[25] Building on the literature linking growth in health insurance costs to stagnant wages, a 2023 *JAMA* analysis suggests a likely association between increased premium costs for workers with ESI family coverage and decreased earnings and increased income inequality.[26] Because workers earning lower wages contribute a greater share of income

toward ESI premiums, the analysis posits that making employer plans more affordable for lower-wage workers could help address earnings inequality. This study also identified large disparities in premium costs as a percentage of income by race (African American and Latino families paid higher percentages of earnings toward premium costs than white families), and found that over 30 years, families with ESI may have cumulatively lost, on average, more than $125,000 in earnings due to increases in premium costs.[27]

ACA Provisions on Affordability and Employer Shared Responsibility

Though not nearly as dominant as ESI, ACA marketplace plans have become a growing source of health coverage; in January 2025, more than 23 million people had enrolled in marketplace plans, up from 11 million in 2020.[28] Under the ACA, individuals are not eligible for marketplace premium tax credits if they are eligible for "minimum essential coverage," which is broadly defined to include Medicare, Medicaid, and other public programs as well as ESI. Accordingly, individuals with offers of coverage from an employer do not qualify for ACA marketplace subsidies unless their ESI offer is deemed either unaffordable or inadequate. In 2025, an employer plan was considered unaffordable if an employee's premium contribution exceeded 9.02 percent of that person's household income.[29] To be considered adequate, a plan must cover at least 60 percent of average costs (actuarial value); anything less is deemed inadequate.[30] The ACA provision making workers with affordable and adequate ESI offers ineligible to receive premium tax credits to purchase marketplace coverage is colloquially referred to as "the firewall." This affordability threshold was established to address multiple concerns with the landmark legislation; namely, to prevent disruption to the ESI market and prevent prohibitive increases in federal spending (for marketplace subsidies) while preserving ESI as the principal source of health coverage in this country. Notably, the affordability threshold changes from year to year based on a methodology that considers rates of premium growth and income growth.

As explained in a 2014 Council on Medical Service Report on the future of ESI, the ACA aimed to build upon the ESI framework and provide low-income, non-elderly individuals without access to ESI with either Medicaid coverage or subsidized private coverage offered through the nongroup marketplace. As such, provisions in the ACA statute included incentives and penalties intended to prevent disruption to the ESI market. For example, to incentivize employers to continue offering coverage, the ACA contained an "employer shared responsibility" provision, also called the "employer mandate," which requires employers with 50 or more full-time employees to either offer affordable minimum essential coverage to full-time employees and their dependents or pay a penalty to the Internal Revenue Service (IRS).[31] Under this provision, employers face two potential penalties:

- If an employer does not offer minimum essential coverage to at least 95 percent of its full-time employees and dependents, and at least one employee receives a premium tax credit for coverage offered through an ACA exchange, the employer faces a penalty that is based on all full-time employees (except 30), including those who have ESI or coverage from another source. In 2024, the penalty was $2,970 per employee.[32]
- If an employer offers coverage to at least 95 percent of its employees but at least one employee obtains a premium tax credit for ACA coverage due to the employer's coverage not being "affordable" or "adequate," the employer must pay a penalty for each employee who receives the premium tax credit. In 2024, the penalty is $4,460 per employee.[33]

AMA Policy on the ACA Affordability Threshold

In the early years of ACA implementation, a 2015 Council on Medical Service report on health insurance affordability recommended making changes to how affordable coverage is defined under the law in order to provide more workers and their families with access to marketplace plans when those plans are more affordable than employer plans. This report established Policy H-165.828, which included several provisions calling for the ACA's "family glitch" to be fixed and capping the tax exclusion for ESI as a funding stream to improve insurance affordability. Policy H-165.828[1] as originally written (prior to being amended in 2021) established AMA support for:

> … modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered ESI by lowering the threshold that determines whether an employee's premium contribution is affordable to that which applies to the exemption from the individual mandate of the ACA.

In 2015 when this policy was adopted, individuals were deemed exempt from the ACA's individual mandate—which was repealed in 2017—if the lowest-priced coverage available to them cost more than 8.05 percent of their household income. The same year, individuals with employer coverage offers were eligible for ACA marketplace plan premium

tax credits if their ESI premium contributions exceeded 9.56 percent of income. The aforementioned Policy H-165.828[1] was crafted to align the definitions of affordability with respect to being exempt from the individual mandate (>8.05 percent) and premium tax credit eligibility for individuals with ESI offers (>9.56 percent).

Policy H-165.828[1] was amended via adoption of the recommendations in a 2021 Council on Medical Service report to address new inconsistencies between the definition of affordability pertaining to premium tax credit eligibility and provisions in ARPA, which extended eligibility for premium subsidies to people with incomes greater than 400 percent FPL and capped premiums for those with the highest incomes at 8.5 percent of their income. ARPA increased the generosity of premium tax credits and lowered the cap on the percentage of income individuals are required to pay for premiums of the benchmark (second-lowest-cost silver) plan for everyone. At the time the report was written, in 2021, employer coverage with an employee share of the premium less than 9.83 percent of income was considered "affordable." To open the door to premium tax credit eligibility to individuals with ESI premiums that were above the maximum affordability threshold applied to subsidized marketplace plans, Policy H-165.828[1] was amended to establish AMA support for:

> … modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered ESI by lowering the threshold that determines whether an employee's premium contribution is affordable to the level at which premiums are capped for individuals with the highest incomes eligible for subsidized ACA coverage.

Federal Subsidies for ACA Premium Tax Credits and Cost-Sharing

In 2023, the federal government subsidized coverage obtained through the ACA marketplaces and the Basic Health Program (BHP) at a cost of $92 billion.[34] This figure includes ARPA federal subsidy enhancements for premium tax credits and cost-sharing reductions that were extended through 2025 by the Inflation Reduction Act (IRA), which decreased the maximum required contribution for previously eligible enrollees and extended eligibility to people with incomes exceeding 400 percent FPL, effectively reducing premium costs by 44 percent, on average. [35] Prior to ARPA, required premium contribution percentages ranged from about two percent of household income for people with poverty level income to nearly 10 percent of income for people with incomes between 300 to 400 percent FPL; people earning more than 400 percent FPL were not eligible for premium tax credits.[36] This year, as shown in Table 1, required premium contribution percentages range from zero for people with less than 150 percent FPL to 8.5 percent for those making around 400 percent FPL or more.

Table 1: Required Individual Contribution Percentage for 2025[37]

Household income percentage of Federal poverty line:	% at start of range	% at top of range
Less than 150%	0.00%	0.00%
At least 150% but less than 200%	0.00%	2.00%
At least 200% but less than 250%	2.00%	4.00%
At least 250% but less than 300%	4.00%	6.00%
At least 300% but less than 400%	6.00%	8.50%
At least 400% and higher	8.50%	8.50%

The more generous federal subsidies have made marketplace plan premiums much more affordable while targeting the largest premium tax credits to people most in need. Notably, more than 90 percent of the 21 million people enrolled in marketplace coverage in 2024 received subsidies that lowered their premium amounts. If the subsidies are not extended beyond 2025, many people will face substantial premium increases, making marketplace coverage less affordable and less attractive as an insurance option. According to the Congressional Budget Office (CBO), without a permanent extension of the premium tax credits, healthier people will leave the ACA marketplace and premiums will rise for remaining enrollees by an estimated 4.3 percent in 2026, 7.7 percent in 2027, and 7.9 percent, on average, over the 2026-2034 period. The CBO also estimates that the number of uninsured people will increase by 2.2 million in 2026, 3.7 million in 2027, and 3.8 million on average between 2026 and 2034.[38] The Urban Institute projects that expiration of the enhanced subsidies will cause four million people to lose health insurance, especially in states that have not adopted Medicaid expansion.[39] According to the Commonwealth Fund, the loss of enhanced subsidies after 2025 would also cause significant economic harm to states, including job losses to health providers and other economic sectors.[40]

Premium tax credits for ACA marketplace coverage are calculated by subtracting the required contribution from the actual cost of the "benchmark" (second-lowest-cost silver) plan, though the credit can be applied toward any marketplace plan except catastrophic coverage.[41] People with incomes below 250 percent FPL also receive subsidies for cost-sharing expenses that are based on income, so that people with incomes between 100 and 150 percent FPL receive the most generous subsidies.[42] These cost-sharing reductions are only available to those enrolled in silver plans. According to the CBO, in 2023 the average federal subsidy per ACA marketplace/BHP enrollee was $5,990,[43] although the range of subsidy amounts is considerable.

Federal Subsidies for ESI

For many decades, the U.S. tax code has provided a sizeable tax benefit to both employers and employees by excluding premium contributions towards ESI from federal income and payroll taxes. As ESI premiums have risen over the years, so has the tax benefit. The amount of an individual's subsidy depends on that person's marginal tax rate that would be owed if employer-paid premiums were taxed as wages. Accordingly, people with greater incomes and higher marginal tax rates receive larger federal ESI subsidies than people with lower-incomes and lower tax rates.[44] According to the CBO, the average federal subsidy per ESI enrollee in 2023 was $2,170.[45]

In part due to the enhanced subsidies for marketplace enrollees established by ARPA and extended by the IRA, several analysts have observed a growing disparity between federal subsidies that help defray ACA marketplace plan costs, and subsidies for ESI coverage. To illustrate this expanding gap, a 2024 American Enterprise Institute (AEI) paper calculated the value of subsidies that would be received by a family of four with $75,000 in income, depending on whether they purchased ESI or marketplace coverage. According to AEI, if the family enrolled in an employer-based plan, their tax subsidy would be around $4,100, compared to the more than $15,000 in federal premium subsidies the family would be eligible for if enrolled in a marketplace plan.[46] Other analyses have noted that workers with lower incomes may be contributing more for an employer-based plan than they would pay for coverage under a subsidized marketplace plan, and that it could be financially advantageous for these workers to move to the marketplace.[47] However, lower-income workers, including those with incomes at or below 200 percent of FPL ($30,120 for an individual; $62,400 for a family of four), cannot enroll in marketplace coverage if they have an offer of ESI. Without the firewall, and if current subsidy enhancements are extended, workers earning less than 150 percent of FPL would be eligible for zero premium silver plans in the ACA marketplace as well as generous cost-sharing reductions. Employees making 200 percent of FPL would also be eligible for cost-sharing reductions and their premium contributions would be capped at two percent of household income.[48] Thus, lower-income workers at or below 200 percent of FPL may find more affordable coverage on the marketplace, depending on how much they must pay for premiums, deductibles and copayments under their ESI plan.

Importantly, some lower-income employees who would be financially incentivized to enroll in a marketplace plan if the firewall is repealed might opt to retain ESI coverage if they are satisfied with their plan and able to see the physicians they want in a timely manner. The Centers for Medicare & Medicaid Services has previously acknowledged the proliferation of narrow networks among ACA exchange plans, and several studies have demonstrated varying degrees of challenges facing marketplace enrollees attempting to access in-network providers, most commonly mental health specialists. A 2020 *JAMA* study found that provider networks were broader in ESI plans and narrower in marketplace plans but that networks may also be limited in lower-quality employer plans.[49] The Council has previously observed that, while marketplace plans may be attractive to some people because their premium prices are lower, purchasers may not be aware that a plan's provider network could be narrower and that they may have trouble getting needed care from in-network physicians, hospitals, and other providers. Therefore, some workers with ESI coverage who would become newly eligible for marketplace subsidies if the firewall is repealed may decide to keep their employer plan to avoid possible care disruptions and to preserve relationships with their treating physicians. Depending on income and a range of other factors, this could be true for some employees who utilize more services and medications or who have a family member on their plan who has a health condition that requires timely access to specialty care.

POLICY OPTIONS ADDRESSING ESI AFFORDABILITY

During the development of this report, the Council reviewed papers from a broad spectrum of organizations and also met with subject matter experts who suggested a range of approaches to improving affordability in ESI and nongroup markets. Review of the literature uncovered a handful of data analyses and a range of conflicting opinions on the best way forward. The studies generally agreed that lifting the firewall would increase access to less expensive insurance

for people with low incomes. However, they differed in their assessment of the percent of the population that would move from ESI to the ACA marketplace, the impact of employer behavior, and their willingness to support increased federal health spending. These studies are summarized below in alphabetical order.

American Enterprise Institute (AEI): A 2020 paper published by AEI recognizes both the value of ESI to many Americans as well as its flaws, including rising costs for both employers and employees. AEI asserts that ESI is worth preserving and suggests tax reforms as the centerpiece of a framework for a more stable ESI system, including the provision of a tax benefit for employers that would be applied to employee premiums. According to AEI, such firm-level tax credits could be structured to provide greater support to lower-income employees but less support to those with higher incomes.[50]

Bipartisan Policy Center (BPC): A 2022 BPC report recognized that ESI is less affordable for lower-wage workers but suggests that fully eliminating the firewall would be quite costly for the federal government. Instead, BPC recommended that Congress adjust the affordability threshold to align with the percentage cap on premium contributions for marketplace plans.[51] As discussion of broad tax cut extensions (and the need to pay for them) intensified late last year, BPC suggested that the ESI tax exclusion be capped at the 80th percentile of premiums, or around $10,000 for single plans and $30,000 for family plans.[52]

Center on Budget and Policy Priorities (CBPP): A 2019 CBPP analysis acknowledged that eliminating the firewall would improve equity but concluded that a full repeal would be too costly to recommend. Instead, the CBPP suggested strengthening the standards for employer coverage offers, such as by raising the minimum value standard (from 60 to 70 percent) or establishing more robust benefit standards for ESI plans.[53]

Commonwealth Fund: A 2020 analysis found that, depending on marketplace subsidy amounts in place, between six and 13 percent of people with ESI would pay lower premium amounts if they were able to switch to marketplace plans. Importantly, the paper pointed out that people with the lowest incomes would benefit the most from lower marketplace premiums, as would African American, Latino, American Indian and Alaska Native individuals. According to the brief, much is unknown about potential employer responses to elimination of the firewall, including whether firms will incentivize sicker workers to move to exchange plans or stop offering coverage altogether.[54] A 2024 Commonwealth Fund paper on automatic enrollment in health insurance posits that 1.2 million people with incomes below 150 percent of FPL and 6.5 million people with income between 150 percent and 200 percent of FPL would become eligible for marketplace subsidies if the firewall were eliminated. The analysis states that "most" of these newly eligible individuals currently have ESI although some are paying full premiums for nongroup plans.[55]

Congressional Budget Office (CBO): In 2020, the CBO estimated that approximately 25 percent of workers with ESI would become eligible for marketplace subsidies if the firewall was repealed. For 20 percent of those newly eligible, post-subsidy premiums for marketplace plans would be lower than ESI premiums, thus making the nongroup market an attractive option. The CBO maintained that, although firms would respond differently to a lifting of the firewall, most of the savings incurred would likely be passed on to employees and adverse selection would be minimized.[56]

Urban Institute: Urban Institute data presented to the Council and published by The Commonwealth Fund estimated that eliminating the firewall would decrease ESI coverage by two percent or less, meaning approximately 1.8 million people would transition out of ESI, with most of these workers shifting to marketplace coverage. Urban Institute's modeling assumes that most workers would stay enrolled in ESI coverage because ESI tax benefits are substantial. In this scenario, federal spending on marketplace premium tax credits would increase by $17.8 billion, or 18 percent; state spending would increase by $460 million; employer spending on premium contributions would decrease $8.1 billion; and households would save $4.4 billion per year in health spending. This study also projected that 1.4 million fewer people would be uninsured if the firewall was eliminated, including 0.4 million people between 138 percent and 200 percent of the poverty line, 0.8 million people between 200 percent and 400 percent of the poverty line, and 0.1 million people above 400 percent of the poverty line. It is estimated that this would save an estimated $1.5 billion in uncompensated care costs. The study also noted additional benefits may occur from elimination of the ESI firewall due to elimination of red tape that will make it easier for individuals who already qualify for PTCs to actually receive those benefits.[57]

RELEVANT AMA POLICY

Policy H-165.829 encourages the development of state waivers to develop and test different models for transforming employer-provided health insurance coverage, including giving employees a choice between employer-sponsored coverage and individual coverage offered through health insurance exchanges, and allowing employers to purchase or subsidize coverage for their employees on the individual exchanges. Among its many provisions, Policy H-165.920 supports:

- A system where individually owned health insurance is the preferred option but employer- provided coverage is still available to the extent the market demands it;
- An individual's right to select his/her health insurance plan and to receive the same tax treatment for individually purchased coverage, for contributions toward employer-provided coverage, and for completely employer-provided coverage; and
- A replacement of the present federal income tax exclusion from employee's taxable income of employer-provided insurance coverage with tax credits for individuals and families.

Under Policy H-165.851, the AMA supports incremental steps toward financing individual tax credits for the purchase of health insurance, including but not limited to capping the tax exclusion for employment-based health insurance. Policy H-165.843 encourages employers to promote greater individual choice and ownership of plans; enhance employee education regarding how to choose health plans that meet their needs; and support increased fairness and uniformity in the health insurance market. Policy H-185.918 further encourages employers to: (a) provide robust education to help patients make good use of their benefits to obtain the care they need, (b) collaborate with employees to understand their health insurance preferences and needs, (c) tailor benefit designs to the health insurance preferences and needs of their employees, and (d) pursue strategies to help enrollees spread the costs associated with high out-of-pocket costs across the plan year. Policy H-165.881 advocates for equal-dollar contributions by employers irrespective of an employee's health plan choice. Policy H-165.854 supports Health Reimbursement Arrangements (HRAs)—account-based health plans that employers can offer to reimburse employees for their medical expenses—as one mechanism for empowering patients to have greater control over health care decision-making. Under Policy D-165.971, the AMA will work to ensure that any Association Health Plan Programs safeguard state and federal patient protection laws.

Policy H-165.824 supports improving affordability in health insurance exchanges by expanding eligibility for premium tax credits beyond 400 percent FPL; increasing the generosity of premium tax credits; expanding eligibility for cost-sharing reductions; and increasing the size of cost-sharing reductions. Policy H-165.828, which as previously noted addresses the affordability threshold (firewall), also supports capping the tax exclusion for employment-based health insurance as a funding stream to improve health insurance affordability. This policy further supports education regarding deductibles, cost-sharing, and Health Savings Accounts (HSAs).

Policy H-165.823 supports a pluralistic health care system and advocates that eligibility for premium tax credit and cost-sharing assistance to purchase a public option be restricted to individuals without access to affordable employer-sponsored coverage that meets standards for minimum value of benefits. This policy sets additional standards for supporting a public option and states that it shall be made available to uninsured individuals who fall into the "coverage gap" in states that do not expand Medicaid at no or nominal cost.

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. ESI continues to be the dominant source of health coverage for people under 65 years of age, and most people enrolled in employer coverage seem satisfied with it. Still, the Council acknowledges that because of shortcomings inherent to the ESI system—including equity and affordability concerns, and rising costs—it does not work well for everyone, especially workers with lower incomes and those employed by smaller firms.

As explained in this report, people with higher earnings receive larger federal ESI subsidies than their lower-income peers, and lower-income people pay a greater share of earnings towards ESI. The Council recognizes that federal tax benefits available to ESI subscribers facing the greatest affordability challenges are not nearly as generous as the enhanced subsidies currently available to lower-income individuals enrolled in ACA marketplace plans. However, the affordability "firewall" makes employees with "affordable" ESI offers ineligible for federal subsidies to purchase ACA plans. To illustrate, an employee of a big box retailer earning 200 percent of FPL or less could pay up to 9.02 percent of his income towards "affordable" ESI. However, if he was eligible to move to the ACA marketplace, his premium contributions would be capped at two percent of income and he would also be eligible for cost-sharing subsidies. Under Policy H-165.828[1]), the AMA supports lowering the affordability threshold (firewall) to the level at which premiums are capped for individuals with the highest incomes eligible for subsidized coverage (currently 8.5 percent).

During the development of this report, the Council reviewed the literature and heard from experts presenting an array of views regarding the potential impacts of fully eliminating the firewall, which is the policy change requested by referred Resolution 103-A-23. The Council found that estimates varied regarding how many workers would transition from ESI to exchange plans if the firewall was repealed. Therefore, we cannot predict with certainty how coverage patterns and payments to physicians would be affected. The Council's revised recommendations reflect, in part, our concerns regarding the harms that significant coverage transitions out of ESI and into ACA plans could have on physician payment and the sustainability of physician practices. Although payment rates in the nongroup market tend to vary, they are generally lower than rates paid by ESI plans. In fact, a study published in 2024 found that, in 2021, marketplace nongroup insurers paid health providers substantially less than employer small-group plans. Even though the study found that marketplace rates were generally higher than Medicare payments,[58] the Council is aware that in some states marketplace plan payments barely exceed, or are even lower than, Medicare rates. In the current environment of Medicare and Medicaid physician payment inadequacies, the Council recognizes that significant shifts from ESI to the ACA marketplace could have deleterious effects on physician practices, adding to their considerable burdens and threatening their viability.

The Council is also concerned about potential employer responses to a repeal of the firewall, which cannot be predicted and will likely vary, with some firms possibly shifting certain employees to the marketplace or ceasing to offer health coverage altogether, and without assurances that employer savings would be passed along to workers. Still, we understand that the firewall is problematic for lower-income workers who may be contributing more for an employer plan than they would pay for marketplace coverage and for people working for small employers whose ESI costs have become increasingly expensive. Given the enhanced subsidies for premium tax credits and cost-sharing reductions available under current law, it is likely that at least some employees with incomes at or below 200 percent of FPL—whose premium contributions for exchange plans would be capped at two percent of income—would find marketplace coverage significantly more affordable than their ESI plan. However, if the more generous premium tax credits are allowed to expire at the end of this year, the cost of marketplace coverage will rise, potentially making ACA plans less attractive. Even among employees who would benefit financially from transitioning to the marketplace, some may opt to retain ESI coverage if they are satisfied with that plan, concerned about the network breadth of exchange plans, or interested in preserving relationships with their treating physicians.

If the firewall was eliminated, the Council is also concerned about the potential costs that would be incurred by the federal government, which already spends upwards of $1.8 trillion on health insurance subsidies—across all coverage programs—each year.[59] Allowing potentially millions of ESI enrollees to access ACA marketplace subsidies could prove to be prohibitively expensive. We cannot estimate the exact costs of eliminating the firewall, which would depend on how many workers ultimately move to exchange plans, but expect it could total tens of billions of dollars or more per year. We believe that budgetary considerations may make the full repeal option unrealistic, financially, and also politically since it would be unpopular with ESI proponents, including employers (and employees) who value and want to preserve the ESI tax exclusion.

For all of these reasons, the Council decided to recommend an incremental approach to reducing the affordability threshold so that it first benefits workers most in need, after which the effects of this change on coverage patterns, federal and consumer health spending, and employer behavior could be monitored. At this time, we support a firewall policy change that targets employees with the lowest incomes who could benefit the most from ACA premium tax credit and cost-sharing subsidies not available under ESI. Accordingly, the Council recommends that the ACA eligibility firewall not apply to individuals offered employer-sponsored coverage whose household incomes are at or below 200 percent of the FPL, so they can receive federal premium tax credits and cost-sharing assistance if they opt

to enroll in a marketplace health plan. We believe this recommendation is an appropriate first step to addressing ESI affordability challenges among the lowest-wage workers while at the same time preserving physician practice sustainability, stability in the ESI market, and limits on federal spending increases. We recommend 200 percent of the FPL since it represents workers most in need and, as the studies cited in this report note, more data are available for individuals with incomes at this threshold. Furthermore, we believe that defining the affordability threshold by a percentage of FPL should make it easier for employees to determine whether they are eligible for ACA subsidies. To protect employees and their ability to choose a health plan that best meets their needs, the Council maintains that some level of employer shared responsibility requirements will need to continue so that employers do not push workers to the marketplace involuntarily or stop offering ESI to certain income groups.

Because ESI enrollees with lower incomes are more likely to report difficulties covering the costs of medical care and who may not know if they are firewalled, the Council recommends amending Policy H-165.843 to encourage employers to: 1) implement programs that improve affordability of ESI premiums and/or cost-sharing; 2) provide employees with user-friendly information regarding their eligibility for subsidized ACA marketplace plans based on their offer of ESI; and 3) provide employees with information regarding available health plan options, including the plans' cost, network breadth, and prior authorization requirements, which will help them choose a plan that meets their needs. The Council recognizes that employers are already required to provide employees with notice about the ACA marketplace and that, depending on income and ESI offer, they may be eligible for lower-cost coverage in the marketplace. However, it may be challenging for some employees to determine whether they are eligible for marketplace subsidies without tools to help them do so.

To address physician payment concerns, the Council also recommends advocating that physician payments by insurers participating in the ACA marketplace be sustainable, reflect the full cost of practice and the value of the care provided, include inflation-based updates, and pay no less than prevailing Medicare rates. This policy mirrors other AMA physician payment policies and is critical to ensuring physician practice sustainability.

RECOMMENDATIONS

The Council on Medical Service recommends that the following recommendations be adopted in lieu of Resolution 103-A-23, and that the remainder of the report be filed.

1. That it be the policy of our American Medical Association (AMA) that the Affordable Care Act (ACA) eligibility firewall not apply to individuals offered employer-sponsored coverage whose household incomes are at or below 200 percent of the federal poverty level, so they can receive federal premium tax credits and cost-sharing assistance if they opt to enroll in a marketplace health plan as an affordable alternative to their employer-based plan.

2. That our AMA amend Policy H-165.843 by addition and deletion to read:

   Our AMA encourages employers to:
   a) promote greater individual choice and ownership of plans;
   b) implement plans to improve affordability of premiums and/or cost-sharing, especially expenses for employees with lower incomes and those who may qualify for Affordable Care Act marketplace plans based on affordability criteria, while promoting meaningful coverage and the application of vital consumer and provider protections, such as prompt pay and network adequacy requirements.
   c) ~~help employees determine if their employer coverage offer makes them ineligible or eligible for federal marketplace subsidies~~ provide employees with user-friendly information regarding their eligibility for subsidized ACA marketplace plans based on their offer of employer-sponsored insurance;
   ~~b~~d) ~~enhance employee education regarding available health plan options and how to choose health plans that meet their needs~~ provide employees with information regarding available health plan options, including the plan's cost, network breadth, and prior authorization requirements, which will help them choose a plan that meets their needs;
   ~~e~~e) offer information and decision-making tools to assist employees in developing and managing their individual health care choices;
   ~~d~~f) support increased fairness and uniformity in the health insurance market; and
   ~~e~~g) promote mechanisms that encourage their employees to pre-fund future costs related to retiree health care and long-term care.

3. That our AMA advocate that physician payments by health insurers participating in the ACA marketplace be sustainable, reflect the full cost of practice and the value of the care provided, include inflation-based updates, and pay fair and equitable rates.

4. That our AMA support incrementally lifting the ESI firewall with continual monitoring and consideration of insurance marketplace stability, if and only if there is documentation that marketplace insurance pays sufficiently to ensure physician practice sustainability, and other relevant parameters, with the goal of maximizing the number of individuals able to freely choose the health insurance plan that is best for themselves and their families.

5. That our AMA support any incremental lifting of the firewall must be paired with a pause to review the relevant parameters, and the ability to pause permanently, or reverse if disruptive effects are detected.

Fiscal Note: Less than $500.

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3. REGULATION OF CORPORATE INVESTMENT IN THE HEALTH CARE SECTOR

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-215.981 and H-285.910

Policy D-215.982, "The Corporate Practice of Medicine, Revisited' and Policy D-160.904, "The Regulation of Private Equity in the Health Care Sector" were adopted at the 2024 Annual Meeting. The former asks our American Medical Association (AMA) to revisit the concept of restrictions on the corporate practice of medicine including, but not limited to, private equities, hedge funds, and similar entities, review existing state laws and study needed revisions and qualifications of such restrictions and/or allowances, in a new report that will study and report back by the 2025 Annual Meeting with recommendations on how to increase competition, increase transparency, support physicians and physician autonomy, protect patients, and control costs in already consolidated health care markets; and to inform

advocacy to protect the autonomy of physician-directed care, patient protections, medical staff employment and contract conflicts, and access of the public to quality health care, while containing health care costs. The latter asks our AMA to propose appropriate guidelines for the use of private equity in health care, ensuring that physician autonomy and operational authority in clinical care is preserved and protected.

Of note, the Council on Ethical and Judicial Affairs (CEJA) has prepared a related report, CEJA Report 5-A-25, "Protecting Physicians Who Engage in Contracts to Deliver Health Care Services" which offers specific ethics analysis and guidance for physicians impacted by private equity's involvement in medicine.

BACKGROUND

The corporate practice of medicine (CPOM) can take many forms. For example, private or public for-profit or non-profit companies can purchase ownership stakes in health care businesses, investment firms can partner with or acquire physician practices or hospitals, or health insurance companies can directly employ physicians. Private equity firms apply several types of investment strategies. Traditional private equity firms utilize funds from leveraged buyouts to take a controlling stake in mature companies, venture capital firms invest in fledgling businesses, and growth equity firms partner with promising later-stage businesses to help them expand.

As stated in Board of Trustees Report 9-I-24, it is important for AMA policy to distinguish between corporate investment, corporate ownership, and corporate control in physician practices:

> The Board of Trustees believes that decisions made by a corporate investor on matters often characterized as operational or administrative may in some cases intrude on clinical decision-making and physician autonomy, as well as affect quality of care and patient outcomes. This is not simply in cases where the difference may be blurred, even matters that may be typically characterized as operations (coding, billing and collections, administrative, and non-clinical management, risk management, etc.) may themselves be implemented in ways that interfere with clinical decision-making and physician autonomy and/or expose physicians to liability.

Private equity acquisitions of health care entities increased six-fold in a decade, growing from 75 deals in 2012 to 484 deals in 2021.[1] Since 2012, private equity firms have spent approximately $1 trillion on health care transactions and between 2018 and 2023, private equity firms spent $505 billion on health care acquisitions.[2,3] The shift toward private equity investment may have been exacerbated by the COVID-19 pandemic as a solution for practices struggling financially. According to the Private Equity Stakeholder Project, it is estimated that eight percent of all private hospitals in the United States and 22 percent of for-profit hospitals are owned by private equity firms.[4]

Private equity deals range from tens to hundreds of millions of dollars and are expected to deliver 20 to 30 percent returns to investors. Key tactics include increasing prices and volume.[5] Another common investment tactic for private equity firms following acquisition includes sale-leaseback arrangements, which sell acquired facilities' land and buildings to repay investors and then charge the facility rent on assets they once owned. On average, after a private equity firm acquires a hospital, the hospital's assets decrease by 24 percent relative to hospitals not purchased by private equity.[6] Private equity firms typically purchase an established practice and acquire smaller practices to create regional brands that can exercise greater bargaining power with insurers and medical supply companies. With these acquisitions, emphasis shifts to increasing profits, often by extracting higher contracted payment rates, lowering overhead, and increasing volume and ancillary revenue streams (i.e., imaging, procedures, over the counter products).[7]

The CPOM doctrine provides a legal basis for protecting the integrity of patient care in a health care environment complicated by corporate influence. Broadly, CPOM prohibitions forbid lay (i.e., non-physician) corporations from practicing medicine, owning physician practices, or otherwise employing physicians to provide medical services. While most states have CPOM restrictions in place, there is no single definition of what constitutes the CPOM, and exemptions – such as for-profit hospitals, nonprofits, or federally qualified health centers – vary broadly. Each state's CPOM doctrine has been shaped uniquely over the years by a combination of statutes, regulations, court decisions, attorney general opinions and actions by medical licensing boards. Consequently, it is difficult to succinctly summarize the CPOM doctrine of every individual state. However, CPOM restrictions generally aim to avoid the commercialization of medical practice that might result when corporations own practices, to address any lack of alignment between a corporation's obligation to its shareholders and a physician's obligation to their patients, and to

ensure that a physician's exercise of independent medical judgment is not threatened because they are employed by a corporate entity.

Types of corporate arrangements

There are several types of corporate structuring and financing of medical practices that can occur. One of the most common is investment by private equity firms. A private equity firm pools investments and uses leveraged buyouts to purchase an ownership stake in a physician practice or hospital. The private equity firm then cuts costs and drives up profit with the goal of selling the business for a profit in three to seven years.

In a 2024 Stanford Law Review analysis, Fuse Brown and Hall point out that private equity poses three risks:

> First, private equity investment spurs health care consolidation, which increases prices and potentially reduces quality and access. Second, the pressure from private equity investors to increase revenue can lead to exploitation of billing loopholes, overutilization, upcoding, aggressive risk-coding, harming patients through unnecessary care, excessive bills, and increasing overall health spending. Third, physicians acquired by private equity companies may be subject to onerous employment terms and lose autonomy over clinical decisions.[8]

While private equity investors are often viewed as exploitative, they may not be substantially different from other entities who invest in or acquire physician practices. Private equity investment is not inherently bad but likely includes both good and bad actors as does any other investor arrangement in the health care sector, or other markets more broadly. Professional risks are not unique to corporate investment alone. Notably, however, according to a study from the Private Equity Stakeholder Project, more than 20 percent of health care bankruptcies in 2023 were private equity-backed companies. Due to the nature of the leveraged buyout strategy employed by private equity firms, debt levels on these leveraged buyouts reached a 15 year high of 7.1 times earnings in 2022. Average debt to earnings before interest, taxes, depreciation, and amortization are around three times earnings.[9]

Hedge funds are also used to invest in and acquire health care entities. A hedge fund differs from private equity in that it is an investment strategy while private equity is a source of capital. Hedge funds pool money from wealthy entities to make investments in the stock market and use different market and trading strategies to insulate investments from market volatility. In another corporate arrangement seen in recent years, corporations such as Amazon (via One Medical) and Walmart have entered directly into the health care space. In addition, health insurers have entered the market by directly employing physicians. For example, Optum, a subsidiary of UnitedHealth Group, employs about 10,000 physicians and is affiliated with another approximately 80,000 physicians. In addition to physicians, Optum employs or is affiliated with approximately 40,000 non-physician practitioners (NPPs).[10,11]

Impact on Cost

Most studies done on the effects of private equity investment conclude that these transactions have led to higher prices for patients. Recently, private equity's role in contributing to the United States' medical debt crisis has been highlighted. According to the Private Equity Stakeholder Project, private equity firms are both "creating and profiting from medical debt" by expanding into billing services and collecting payments for the health care entities they acquire.[12] Private equity owned health care entities have been increasingly outsourcing financial work to the private equity firms themselves, who have consolidated debt collecting, claims processing, and billing into an "end-to-end" service. The result is higher costs for patients, either through upcoding, higher interest rates on outstanding balances, or more aggressive bill collection practices.[13]

Impact on Patients

Evidence on corporate investor impact on quality of care is mixed. According to a 2023 *JAMA* study, hospital-acquired adverse events increased by approximately 25 percent following private equity acquisition. The rise in adverse events was impacted by an increase in the number of falls and central line associated bloodstream infections, along with a larger, but less statistically precise increase in surgical site infections. Other studies have found that private equity acquisition may improve care quality, but only under certain market and regulatory conditions.[14,15] Greater transparency is needed over private equity investment in and ownership of physician practices to help patients make informed decisions about their care. While the onus should not be put on patients to know the ownership status of a

hospital or practice before receiving care, and in many cases patients may not have a choice on where they seek care, greater transparency would be beneficial for patients and communities if and when it allows for more informed decision-making.

Impact on Physicians

Physicians may value investment from corporate partners because : 1) it can offer a way for the practice to avoid selling to a health system; 2) the corporate partner can manage administrative, technical, and human resources aspects of the business; 3) the corporate partner can offer financially attractive deals for physician-owners wanting to retire or exit ownership; and 4) these investors can help with medical liability costs. Some risks of partnering with corporate investors include losing control of business decisions and/or clinical autonomy; drastic cost cutting measures, including replacing physicians with NPPs; non-compete agreements which can prevent physicians from easily moving to another job; and the possibility of debt or bankruptcy for the physician-owner after the corporate investor has extracted profits from the practice and exited the partnership.[16] The use of non-compete agreements, or restrictive covenants, by larger corporations has the potential to hamper physicians' ability to leave a practice in search of another position. This is especially true of corporations that have a large geographical footprint or those that are in concentrated markets. With more limited ability to leave for another opportunity, the physician's ability to advocate for better working conditions is undermined. In these scenarios, a physician's only choice may be to move to another geographic area entirely, often uprooting themselves and their families. For employed physicians, risks could also include loss of liability tail coverage or loss of pension or retirement funds if their facility comes under private equity ownership or ultimately goes bankrupt. Physicians may also be pressured to see more patients each day or meet lofty financial targets to maximize profitability. Financial targets could include sales goals, using lower cost supplies, or encouraging patients to seek optional or cosmetic procedures that are often lucrative, but not always necessary. Additionally, high levels of debt from leveraged buyouts or sale-leaseback arrangements can burden health care practices and increase the risk of failure.[17]

While private equity and corporate investment in health care is rightfully scrutinized, it cannot be ignored that many physicians willingly choose to partner with or sell their practices to corporate investors. Owning and managing a private practice has become increasingly challenging and corporate investment offers an alternative to being employed by a hospital or health system, or leaving the practice of medicine entirely. Additionally, when physicians sell a practice to a corporate entity, the money from the sale is taxed at capital gains rates which are more favorable than income tax rates, adding to the list of incentives for pursuing these transactions. Physician-owners choosing to enter these partnerships should be aware of risks and do their best to ensure that physician autonomy in clinical and operational decision-making is sustained.

In all types of medical practice, physician autonomy is of the utmost importance. Many physicians are rightfully concerned about the loss of professional control that could arise from partnering with a corporate entity. Almost 61 percent of physicians have a negative view of private equity and less than 11 percent have a positive view, according to a 2024 study.[18] There is also emerging evidence that trainees are less likely to join a practice backed by private equity and that these practices have higher staff turnover rates. In one specific case, dermatologists drawn to private equity backed practices by high salaries quit after being pressured to significantly cut costs and meet high financial targets.[19] A February 2025 *JAMA Health Forum* article found that physician turnover also increased when private equity companies sold the practice or facility they were invested in. Physicians employed by exiting private equity firms were 16.5 percentage points less likely to continue working in that practice two years after the private equity firm exited and 10.1 percentage points more likely to go on to be employed by a facility with more than 120 practicing physicians.[20]

According to the AMA's 2022 Physician Practice Benchmark survey, 49.7 percent of physicians were employees, 44 percent were owners, and 6.4 percent were independent contractors. Between 2012 and 2022, the share of physicians who worked in practices wholly owned by physicians – private practices – dropped by 13 percentage points from 60.1 percent to 46.7 percent. In 2022, 4.5 percent of physicians were participants in private equity ownership or investment arrangements.[21] Many physicians that have left private practice have become employed by a hospital or health system, where they feel as if they have less autonomy in clinical decision making. In 2023, 56 percent of employed physicians said what they like least about their job is decreasing autonomy, which was up from 48 percent the year prior. According to a survey from National Opinion Research Center at the University of Chicago, approximately 61 percent of employed physicians said they have moderate or no autonomy to make referrals outside of their practice or

ownership system, and 47 percent said they adjust patient treatments to reduce costs based on practice policies or incentives.[22]

Another concern is changing workplace composition and replacing physicians with NPPs who can often be hired at a lower salary than physicians, resulting in savings for the practice owner. A January 2023 study examined workforce composition changes in private equity acquired practices and found that in aggregate, the clinician replacement ratio was higher for private equity acquired practices compared to those not acquired by private equity. When compared to non-private equity acquired practices, those acquired by private equity had a significant yearly increase in the number of NPPs after acquisition. While the study claimed to be preliminary in nature, it supported the hypothesis that physicians may be more frequently replaced at private equity acquired practices versus those not acquired by private equity. However, the study also conceded that regardless of ownership, there was a statistically significant increase in NPPs at all practices examined, which could be in response to physician supply shortages, payment reforms, a shift to team-based care, or other factors.[23]

Impact on Consolidation and Market Concentration

A March 2024 *Health Affairs* study looked at private equity acquired practices and market penetration between 2012-2021. This study found that private equity acquired physician sites increased from 816 across 119 metropolitan statistical areas (MSA) in 2012 to 5,779 across 307 MSAs in 2021. The result was single private equity firms having a significant market share, exceeding 30 percent in 108 MSA specialty markets and exceeding 50 percent in 50 of those markets.[24] As can be seen in Appendices A and B of this report, gastroenterology, dermatology, urology, obstetrics and gynecology, ophthalmology, and radiology have seen the highest increases in private equity investment in recent years.

When private equity firms acquire multiple providers in the same specialty within a local or regional market (also known as a "roll-up"), those firms can gain significant market power, which can lead to higher prices or lower quality, or both, due to reduced competitive pressure.[25] An example of a roll-up is U.S. Anesthesia Partners, Inc. (USAP) in Texas. USAP, backed by private equity firm Welsh Carson, systematically bought up many large anesthesiology practices in Texas to create one dominant provider with the power to increase prices. USAP and Welsh Carson further drove up prices by entering into price-setting agreements with the remaining independent anesthesiology practices as well as paying a competing anesthesiology practice to stay out of USAP market territory. The Federal Trade Commission (FTC) sued USAP and Welsh Carson and, at the time this report was written, the case was still ongoing, although Welsh Carson has been dismissed from the case.[26]

Strengthening CPOM bans to protect the independent professional judgment of physicians

States are exploring legislation to protect the independent judgment of physicians by strengthening CPOM bans, in part by setting clearer requirements that lay entities (expressly including private equity firms) may not interfere with a physician's medical decision-making or independent judgment and defining what activities constitute medical decision-making. For example, legislation proposed in Washington State in 2025 would codify that the following be included in the "professional judgment or clinical decision-making" of a physician:

> "(a) The period of time a provider may spend with a patient, including the time permitted for a health care provider to triage patients in the emergency department or evaluate admitted patients; (b) The period of time within which a health care provider must discharge a patient; (c) The clinical status of the patient, including whether the patient should be admitted to inpatient status, whether the patient should be kept in observation status, whether the patient should receive palliative care, and whether and where the patient should be referred upon discharge; (d) The diagnoses, diagnostic terminology, or codes that are entered into the medical record by the health care provider; (e) The range of clinical orders available to a health care provider, including by configuring the medical record to prohibit or significantly limit the options available to the provider; or (f) Any other action specified by rule to constitute impermissible interference or control over the clinical judgment and decision making of a health care provider related to the diagnosis and treatment of a patient."[27]

Similar legislation has been introduced in California and Vermont this year, and in 2024, California's legislature considered CA AB 3129, which would have strengthened California's already-strong corporate practice ban through

similar provisions and by limiting private equity companies or hedge funds from controlling or directing a physician practice.[28,29]

Imposing limitations on the structure of Management Service Organizations (MSOs) to insulate corporate investors from clinical decisions

The structure of existing CPOM laws allow for broad workarounds that make room for corporate investors to influence the provision of health care. Every state allows for the creation of a special type of physician-owned legal entity, often known as a professional services corporation (PC), to provide medical services if the PC is entirely owned by physicians, with many states, such as Arizona, only requiring partial ownership of a PC by physicians.[30] When CPOM restrictions limiting practice ownership to physician-owned PCs ban corporate investors from employing physicians or practicing medicine, these lay entities may pursue ownership of a management services organization (MSO) to contract with the physician-owned PC. The MSO may operate the nonclinical aspects of a physician practice and conduct administrative functions, handle practice financials, or provide other clinical support services to the practice. Under these arrangements, the PC ostensibly maintains ownership.

However, existing state laws do not prevent corporate investors from exercising influence on patient care via "friendly PC" arrangements. Friendly PC or friendly physician models allow lay entities to invest in and control physician practices indirectly, generally through an MSO. Commonly, the corporate investor secures a physician(s) to work in the practice who is sympathetic ("friendly") to the investor, while the MSO is compensated to provide services necessary for practice operations. Often the "friendly physician(s)" will serve on the board of directors for or have an ownership stake in the PC, the MSO, or both. These types of arrangements may allow corporations to effectively assume control of physician practices. Major corporate investors in health care, including Oak Street Health and One Medical, leverage the friendly PC model.

Novel legislation first proposed in 2024 aims to address the friendly PC model and insulate corporate investors from clinical operations by imposing certain structural limitations on MSOs. These types of provisions, first seen in 2024 in Oregon (HB 4130), challenge the friendly PC model by prohibiting a physician from serving as a shareholder, director, officer, or employee of both a health care practice and an MSO with which the practice contracts. Essentially, they aim to prevent lay entities from circumventing CPOM bans and limit comingling between MSOs and PCs by ensuring that a physician associated with the MSO cannot also direct or own shares in the PC.[31] This year, legislation imposing structural requirements on MSOs has once again been proposed in Oregon and is being considered as a matter of first impression in both Washington and Vermont.[32] Notably, these provisions are controversial among physicians, in part because they could disrupt existing arrangements that are ostensibly working well, and also because they might prevent physicians who have equity in an MSO from benefitting financially in the event of a sale (i.e., from receiving "roll-over equity").

Improving transparency and oversight

Legislation to increase transparency and state oversight of transactions involving corporate investors is also being considered at the state level. Corporate acquisitions of physician practices often fall under the radar because they do not meet the monetary threshold for reporting and review by federal governing agencies. This is concerning, because many strategies employed by private equity firms have anticompetitive effects that may impact cost, quality, and access to care. When implemented thoughtfully, legislation to increase oversight may allow state governing bodies to identify and mitigate transactions that may have anticompetitive effects or other harmful impacts on patient care.

A handful of state laws impose requirements that certain transactions – namely those involving corporate investors and falling under a specified threshold below the one required by the Hart-Scott-Rodino Act – be reported to the state attorneys general (AG). Indiana, for example, passed such a law in 2024, and Connecticut, Vermont, and New Mexico are among states considering such legislation in the 2025 session.[33,34] More aggressive proposals go beyond transparency and grant the state AG authority to block any transaction it deems anticompetitive or otherwise inappropriate under statute. To that end, legislation may enumerate specific characteristics that constitute "anticompetitive effects," or, importantly, may name other factors that might render a transaction unlawful, such as compromised quality of care or decreased access to care for patients. California and Massachusetts considered such legislation in 2024.[35] In 2025, a bill passed in Massachusetts that, among other things, broadened the definition of "material change transaction" to include transactions involving private equity, real estate investment trusts, and MSOs,

thereby subjecting them to market impact review and potential referral to the AG for determination as to whether there is unfair competition or anti-competitive behavior.[36]

The business model employed by corporate investors in health care often allows a firm to control an acquired entity while paying only a small fraction of the total purchase price upfront. The acquired health care practice or hospital is then forced to take on debt to cover the remaining cost. When this debt load is combined with cost-cutting efforts to increase short-term profits – efforts that are often high-risk strategies given the relatively small amount of capital at stake for the private equity firm – the results can be unsustainable.[37] In recent years, this has been particularly evident in private equity's acquisition of hospitals, where private equity ownership has led to bankruptcies, service reductions, and closures that restrict patient access to care. Examples of such casualties include the 2019 bankruptcy of Hahnemann University Hospital in Pennsylvania, the bankruptcy and closure of several Steward hospitals and related physician practices over the past several years in Massachusetts, and the recent devastation of Prospect Medical hospitals in California, Connecticut, Pennsylvania, and Rhode Island.[38] These closures have also led to the loss of liability tail coverage and/or employment for many physicians.

As proposed in CA AB 3129, access to care was included as a factor that attorney general offices might consider in determining whether to approve a proposed transaction. Other proposed legislative solutions to protect patient access to care following the acquisition of a hospital or health system are multifaceted.[39] While there has not been significant activity in state legislatures, proposed federal legislation may serve as a guide for policy solutions implementable at the state level. Senator Edward Markey's (D-MA) 2024 Health Over Wealth Act is instructive: legislation could mandate an acquired system to establish escrow accounts that would cover operating and capital expenditures for a specified period of time in case of a threatened closure or service reduction; it may impose notice requirements for any service disruptions; and, in order to increase an acquiring firm's stake in the transaction and reduce the debt load taken on by the acquired system, it could require that a minimum financial investment be made by investors upfront.[40]
AMA POLICY

Board of Trustees Report 9-I-24, "Corporate Practice of Medicine Prohibition," took a strong stance on restricting CPOM arrangements. The report amended Policy H-215.981 by adding three new clauses that ask the AMA to vigorously oppose any effort to pass legislation or regulation that removes or weakens state laws prohibiting CPOM; oppose CPOM and support the restriction of ownership and operational authority of physician medical practices to physicians or physician-owned groups; and create a state CPOM template to assist state medical associations and national medical specialty societies as they navigate the intricacies of corporate investment in physician practices and health care generally at the state level and develop the most effective means of prohibiting CPOM in ways that are not detrimental to the sustainability of physician practices. In its report, the Board of Trustees recommended that AMA policy distinguish between corporate investment, corporate ownership, and corporate control in physician practices.

The Council has addressed this topic in three reports since 2013. In CMS 6-I-13 the Council discussed state CPOM doctrines and associated restrictions. Ultimately, the Council recommended the AMA maintain a balanced policy on CPOM and stated that the detrimental effects of CPOM can be mitigated by having strong policies in place to protect the independent medical judgment of physicians and patient-physician relationships. This report amended H-215.981 and reaffirmed other policies on physician employment. In CMS 11-A-19, the Council highlighted the risks and benefits of entering into corporate partnerships and noted that physician opinions vary regarding corporate investor involvement in physician practices. The report mentioned that although there has been a great deal of angst among physicians regarding private equity investment in practices, other physicians and physician groups have readily and successfully partnered with these firms. This report established Policy H-160.891, which created guidelines for physicians to consider when entering into corporate partnerships. In CMS 2-I-22, the Council provided a more detailed look at private equity investment in physician practices and shared emerging data on the impact these investments have had on physicians and patients. The report amended H-160.891 by adding two new clauses and established new Policy H-160.887.

The AMA has extensive policy on CPOM, consolidation, and related issues. 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. Policy H-160.960 states that 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. Policy H-380.987 states that antitrust relief for physicians is a priority of the AMA.

Policy H-225.947 states that when physicians are seeking employment as their mode of practice they should strive for arrangements where physician clinical autonomy is preserved. Similarly, Policy D-225.977 states that the AMA will continue to assess the needs of employed physicians, ensuring autonomy in clinical decision-making and self-governance.

Policy H-285.951 supports physicians' right to enter into whatever contractual arrangement 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, groups, and hospital departments to create conflicts of interest, due to the use of financial incentives in the management of medical care. Additionally, this policy states that 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.

Policy H-275.937 highlights the sanctity of the patient-physician relationship by stating that the relationship between a physician and a patient is fundamental and is not to be constrained or adversely affected by any considerations other than what is best for the patient. The existence of other considerations, including financial or contractual concerns, is and must be secondary to the fundamental relationship. The policy also states that some models of medical practice may result in an inappropriate restriction of the physician's ability to practice quality medicine and this may create negative consequences for the public. Physicians must take actions they consider necessary to assure that medical practice models do not adversely affect the care that they render to their patients. Furthermore, Policy H-225.950 states that in any situation where the economic or other interests of the employer are in conflict with patient welfare, patient welfare must take priority. Additionally, this policy notes that 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. Policy H-140.978 states that physicians must not deny their patients access to appropriate medical services based upon the promise of personal financial reward, or the avoidance of financial penalties.

Related Policy H-385.926 states that the AMA supports the freedom of physicians to choose their method of earning a living (fee-for-service, salary, capitation, etc.), as long as physicians are charging patients fair fees and provide adequate fee information prior to the provision of services. This policy ensures physician autonomy in business decisions, but affirms that decisions, especially around pricing and fees, should be done in good conscience and be fair and transparent for patients.

DISCUSSION

The Council has recently written several reports, and the AMA has extensive policy to guide physician relationships with CPOM. In this report, the Council aims to strengthen existing guidelines for physicians considering corporate partnerships, support capital reserve requirements for firms interested in investing in the health care sector, and support increased enforcement of existing regulations on CPOM. It is important to note that CPOM is not new, but the recent rise in corporate investment in the health care sector raises cause for concern, particularly as it relates to patient safety and physician autonomy in clinical and operational decision-making.

There are risks and benefits associated with corporate investment and partnership. Corporate investment can offer a way for a practice to avoid selling to a hospital or health system, manage human resources, information technology and other administrative tasks on behalf of the practice, offer lucrative deals for physician-owners wanting to retire or sell their practice, and help with medical liability costs. Risks to physicians include a loss of control of business decisions and/or clinical autonomy, drastic cost cutting measures, loss of employment or replacement by NPPs, restrictive non-compete agreements, loss of liability tail coverage, or increased pressure to meet lofty financial targets. For physician-owners, there is the possibility of debt or bankruptcy after the corporate investor has extracted profits and exited the partnership.

The corporate investor could also go bankrupt, as has happened most recently with Prospect Medical Holdings in January 2025, and with Steward Health and Hahnemann University Hospital in recent years. The Council discussed the importance of financial stability of private equity firms and other investors before investments are made. Because the nature of private equity investment relies heavily on investing with debt (leveraged buyouts), investments can be risky and can lead to bankruptcy if not managed properly. Anecdotally, this has led to several hospital and practice closures around the country. The *Kaiser Health News* collection "Patients for Profit: How Private Equity Hijacked Health Care" provides several examples of where this has happened in the United States and the detrimental effect it can have on patients, physicians, and communities. While an important consideration, the Council believes that it is

outside the purview of the AMA to dictate specific financial requirements for corporate investors. Instead, the Council stresses the importance of due diligence on the part of physician-owners considering these partnerships to ensure that an interested corporate investor has the resources required to support a successful business relationship. With the intent to avoid future hospital closures, the Council recommends that the AMA support capital reserve requirements and leverage standards that preserve access to care for patients by preventing the closure of health care facilities and the limiting of essential health services.

Another consideration for physicians is control over final billing and coding designations. When administrative tasks are outsourced, there is opportunity for errors or intentional upcoding by third-party companies outside of the physician's direct supervision. As it is the physician's ultimate responsibility to ensure that billing and coding are accurate for the services provided, Policy H-385.939 outlines how false claims attributed to them could result in reputational, financial, or even criminal consequences.

During deliberations on this report, the Council discussed the relationship between NPPs and private equity. Theoretically, if physicians are reluctant to enter into corporate partnerships, private equity and other corporate entities may seek to instead invest in health care practices affiliated with NPPs, such as nurse practitioners and/or physicians assistants. The Council recognizes that this could be a result of physician resistance to corporate partnerships but ultimately believes it would be out of scope for the Council to recommend policy on business models for NPPs since the AMA is an organization representing physicians and not NPPs. Informally, the Council believes that like physicians, all allied health professionals should exercise due diligence when considering partnerships with corporate entities.

It is important to enforce regulations on transparency of these transactions as well as the ownership of group practices, hospitals, and health systems, including corporate and private equity ownership and relationships. Additionally, corporate and private equity acquisitions should be reviewed for their potential to disrupt access to care and conditions should be placed to ensure physician independence, quality of care, minimization of conflicts of interest, and avoidance of excess market consolidation. It is also important to support regulations that prevent the closure of essential services, such as emergency departments or labor and delivery units, whenever possible. The importance of transparency is highlighted in Policy H-160.960, which states that patients must be informed when a corporate entity purchases a private medical facility.

Because of the intricacies involved in corporate entity transactions, the Council believes it would be difficult to unwind the mergers and acquisitions that have already taken place, both by corporate investors as well as by nonprofit entities or other types of firms (i.e., nonprofit hospitals, health systems, independent practices). However, to boost competition in already consolidated markets, current laws on CPOM need to be enforced and new businesses need to be able to enter the market. Where possible, mergers and acquisitions should be scrutinized by the appropriate parties (FTC, Department of Justice, state attorneys general, etc.) to ensure they are following antitrust laws and to determine the effect the transaction may have on the market. Pursuing transparency in ownership of health care practices, as well as transparency in pricing, could boost competition as well as allow patients to make an informed choice when it comes to the care they receive.

Given the breadth and depth of AMA policy on this topic, the Council recommends strengthening existing guidelines to promote physician due diligence and protection when considering a relationship with a corporate entity. Specifically, the Council recommends broadening policy to include other corporate structuring, not just corporate investors, including language about conflict resolution, more explicitly stating which clinical and operational decisions should remain under the direction of physicians, including considerations and protections for billing and coding responsibility, supporting physician engagement in organizational governance following a merger or acquisition, and supporting enforcement of CPOM doctrines. The Council recommends supporting capital reserve requirements for corporate entities considering investment in health care facilities in order to provide stable financing in order to preserve access to care for patients and fulfillment of contractual obligations to physicians. Finally, the Council recommends reaffirming policy on the importance of preserving physician autonomy and clinical decision-making.

RECOMMENDATIONS

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

1) That our American Medical Association (AMA) amend Policy H-160.891, "Corporate Investors," by addition and deletion, including a change in title:

CORPORATE INVESTORS AND OTHER CORPORATE ENTITIES, H-160.891

1) Our American Medical Association encourages physicians who are contemplating corporate investor partnerships or corporate entity relationships, including those under "friendly" physician professional corporation (PC) arrangements with Management Service Organizations (MSOs), 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/entity.
   b. Due diligence should be conducted that includes, at minimum, review of the corporate investor/entity'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/entity 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~~ relationships 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~~ relationships 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~~ relationships, and application of restrictive covenants, including any changes in the scope or implementation of any current or proposed restrictive covenants based on the corporate relationship.
   h. Physicians should consider corporate procedures ~~investor processes~~ for medical staff representation on the board of directors and medical staff leadership selection as well as processes for resolution of conflict between medical staff leadership and the corporate entity.
   i. Physicians should retain responsibility for clinical governance, patient welfare and outcomes, physician clinical autonomy, and physician due process under corporate ~~investor partnerships~~ relationships.
   j. Prior to entering into a relationship with a corporate entity, physicians and the corporate entity should explicitly identify the types of clinical and business decisions that should remain in the ultimate control of the physician, including but not limited to:
      i. Determining which diagnostic tests are appropriate;
      ii. Determining the need for referrals to, or consultation with another physician or licensed health professional;
      iii. Being responsible for the ultimate overall care of the patient, including treatment options available to the patient;
      iv. Determining how many patients a physician shall see in a given period of time or how many hours a physician should work;
      v. Determining the content of patient medical records;
      vi. Selecting, hiring, or firing physicians, other licensed health care professionals, and/or other medical staff based on clinical competency or proficiency;
      vii. Setting the parameters under which a physician or physician practice shall enter into contractual relationships with third-party entities;
      viii. Making decisions regarding coding and billing procedures for patient care services; and
      ix. Approving the selection of medical equipment and medical supplies.

k. ~~j.~~ Each individual physician should have the ultimate decision for medical judgment in patient care and medical care processes, including supervision of non- physician practitioners.

l. Clear protection and dispute resolution processes for physicians advocating on patient care and quality issues should be incorporated into an agreement between physicians and corporate entities.

m. ~~k.~~ Physicians should retain primary and final responsibility for structured medical education inclusive of undergraduate medical education including the structure of the program, program curriculum, selection of faculty and trainees, as well as education and disciplinary issues related to these programs.

2) Our AMA supports improved transparency regarding corporate investments in and/or relationships to physician practices, subsidiaries and/or related organizations that interact with the physician group and/or patients of the physicians, and subsequent changes in health care prices, quality, access, utilization, and physician payment.

3) Our AMA encourages national medical specialty societies to research and develop tools and resources on the impact of corporate investor ~~partnerships~~ relationships on patients and the physicians in practicing in that specialty.

4) Our AMA supports consideration of options for gathering information on the impact of private equity and corporate investors/entities on the practice of medicine.

5) Our AMA supports meaningful physician representation in any corporate governance structure (e.g., seats on the board of directors, and/or other relevant leadership bodies) of any entity with which a physician practice, hospital, or other health care organization establishes a corporate relationship.

2) That our AMA amend Policy H-215.981, "Corporate Practice of Medicine," by addition:

CORPORATE PRACTICE OF MEDICINE, H-215.981

1) Our American Medical Association vigorously opposes any effort to pass federal legislation or regulation preempting state laws prohibiting the corporate practice of medicine.

2) Our AMA vigorously opposes any effort to pass legislation or regulation that removes or weakens state laws prohibiting the corporate practice of medicine.

3) Our AMA opposes the corporate practice of medicine and supports the restriction of ownership and operational authority of physician medical practices to physicians or physician-owned groups.

4) Our AMA, at the request of state medical associations, 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.

5) 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.

6) Our AMA will work with interested state medical associations, the federal government, and other interested parties to develop and advocate for regulations and appropriate legislation pertaining to corporate control of practices in the healthcare sector such that physician clinical autonomy and operational authority are preserved and protected.

7) Our AMA will create a state corporate practice of medicine template to assist state medical associations and national medical specialty societies as they navigate the intricacies of corporate investment in physician practices and health care generally at the state level and develop the most effective means of prohibiting the corporate practice of medicine in ways that are not detrimental to the sustainability of physician practices.

8) Our AMA supports enforcement of existing regulations and legislation pertaining to corporate control of practices in the health care sector to ensure that physician clinical autonomy and operational authority is preserved and protected.

9) Our AMA supports capital reserve requirements and leverage standards that preserve access to care for patients and fulfillment of contractual obligations to physicians and trainees by

providing stable financing for hospitals, clinics, and other health care facilities. (Modify HOD Policy)

3) That our AMA reaffirm Policy H-285.910, The Physician's Right to Engage in Independent Advocacy on Behalf of Patients, the Profession and the Community, which provides a recommended clause to include in physician employment agreements and which states that in caring for patients physicians shall have the unfettered right to exercise independent and professional judgment and be guided by personal and professional beliefs as to what is in the best interests of patients, the profession, and the community. Furthermore, nothing in the employment agreement shall prevent physicians from exercising their own medical judgment and employers may not retaliate against the physician in any way based on the physician's right to exercise their medical judgment.
4) That our AMA rescind Policy D-160.904, as it is accomplished by this report.
5) That our AMA rescind Policy D-215.982, as it is accomplished by this report.

Fiscal Note: Less than $500.

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Appendix A

Characteristics of private equity (PE)-acquired and non-PE-acquired practice sites for 10 physician specialties and by specialty, 2021

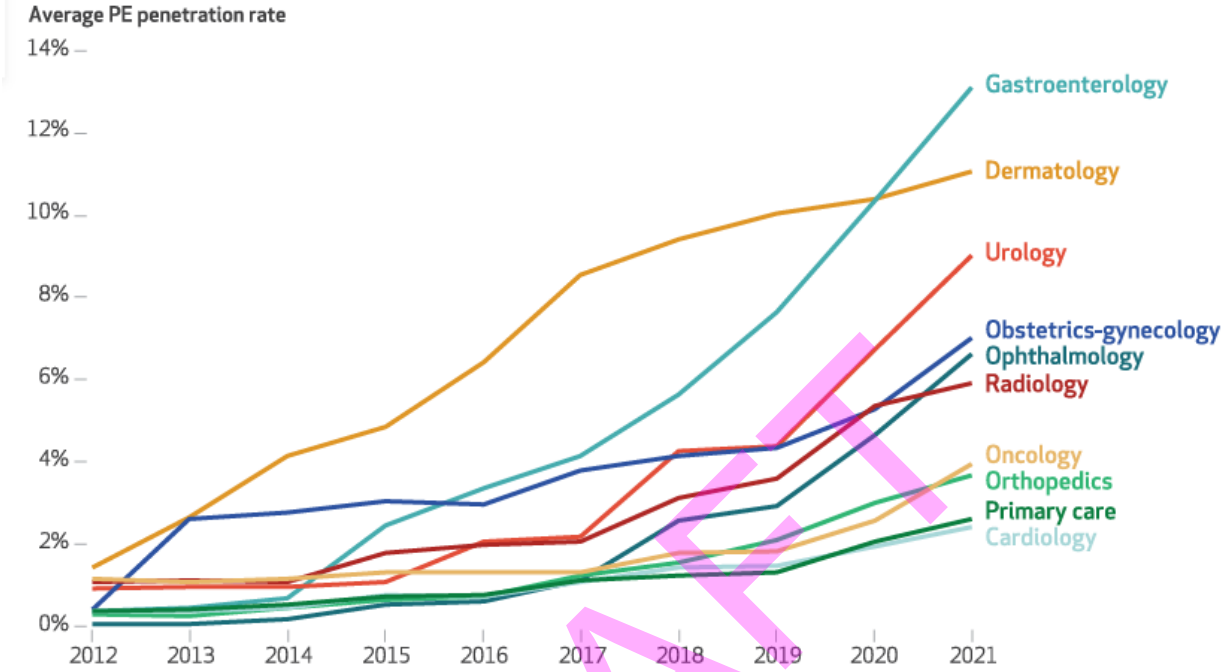
	PE-acquired practice sites (*N* = 5,779)		Non-PE-acquired practice sites (*N* = 131,552)	
Characteristics	**Number**	**Percent**	**Number**	**Percent**
No. of practice owners[a]	243	100.0	6,717	100.0
No. of physicians	14,656	100.0	328,335	100.0
No. of female physicians	5,372	36.7**	132,413	40.3
Age, years (SE)	53.3** (0.02)	—[b]	52.3 (0.09)	—[b]
Geographic region				
South	2,768	47.9	50,459	38.3
Northeast	1,157	20.0	29,212	22.2
Midwest	1,085	18.8	23,511	17.9
West	769	13.3	28,370	21.6
Specialty				
Primary care	1,440	24.9	72,412	55.1
Dermatology	827	14.3	5,818	4.4
Obstetrics-gynecology	798	13.8	10,944	8.3
Gastroenterology	697	12.1	4,468	3.4
Ophthalmology	648	11.2	8,966	6.8
Oncology	368	6.4	5,062	3.8
Urology	346	6.0	3,384	2.6
Radiology	257	4.4	4,991	3.8
Orthopedics	237	4.1	8,094	6.2
Cardiology	161	2.8	7,413	5.6

SOURCE Authors' analysis of data from the Irving Levin Associates Healthcare M&A Database, PitchBook private equity and merger and acquisition database, and OneKey Database provided by IQVIA. The PitchBook data presented here have not been reviewed by PitchBook analysts. The PitchBook database is dynamic; data for this exhibit are as of June 15, 2022. **NOTES** Specialties were identified at the physician level. Physicians who worked at multiple locations were counted as a fraction of physicians using full-time equivalents. If a practice included multiple specialties, counts were documented separately for each specialty, equivalent to each specialty being considered as a separate practice. We conducted a two-sample *t*-test on age and chi-square tests for the proportion of female physicians. [a]Practice owners are PE firms in the PE-acquired category and other corporate owners in the non-PE-acquired category. [b]Not applicable. **$p < 0.05$

Health Affairs. Private Equity-Acquired Physician Practices and Market Penetration Increased Substantially, 2012-21. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2023.00152

Appendix B

Trends in private equity (PE) penetration at the physician level in the US among 10 physician specialties, 2012–21



SOURCE Authors' analysis of data from the Irving Levin Associates Healthcare M&A Database, PitchBook private equity and merger and acquisition database, and OneKey Database provided by IQVIA (2020–21) and SK&A Office Based Physicians Database provided by IMS Health (now IQVIA) (2012–19). The PitchBook data presented here have not been reviewed by PitchBook analysts. The PitchBook database is dynamic; data for this figure are as of June 15, 2022. **NOTE** Average PE penetration rates at the physician level in each year by specialty were calculated by weighting each Metropolitan Statistical Area (MSA)-level market share by the number of full-time-equivalent physicians in that MSA by specialty, equivalent to the US penetration rate.

Health Affairs. Private Equity-Acquired Physician Practices and Market Penetration Increased Substantially, 2012-21. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2023.00152

Council on Medical Service Report 3-A-25
Regulation of Corporate Investment in the Health Care Sector
Policy Appendix

Corporate Investors, H-160.891

1. Our American Medical Association (AMA) encourages 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.
    j. Each individual physician should have the ultimate decision for medical judgment in patient care and medical care processes, including supervision of non- physician practitioners.
    k. Physicians should retain primary and final responsibility for structured medical education inclusive of undergraduate medical education including the structure of the program, program curriculum, selection of faculty and trainees, as well as education and disciplinary issues related to these programs.
2. Our AMA supports improved transparency regarding corporate investment in physician practices and subsequent changes in health care prices.
3. Our AMA encourages 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.
4. Our AMA supports consideration of options for gathering information on the impact of private equity and corporate investors on the practice of medicine.

(CMS Rep. 11, A-19; Appended: CMS Rep. 2, I-22; Reaffirmed: BOT Rep. 14, A-23)

Corporate Practice of Medicine, H-215.981

1. Our American Medical Association (AMA) vigorously opposes any effort to pass federal legislation or regulation preempting state laws prohibiting the corporate practice of medicine.
2. Our AMA vigorously opposes any effort to pass legislation or regulation that removes or weakens state laws prohibiting the corporate practice of medicine.
3. Our AMA opposes the corporate practice of medicine and supports the restriction of ownership and operational authority of physician medical practices to physicians or physician-owned groups.
4. Our AMA, at the request of state medical associations, 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.
5. 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.
6. Our AMA will work with interested state medical associations, the federal government, and other interested parties to develop and advocate for regulations and appropriate legislation pertaining to corporate control

of practices in the healthcare sector such that physician clinical autonomy and operational authority are preserved and protected.

7. Our AMA will create a state corporate practice of medicine template to assist state medical associations and national medical specialty societies as they navigate the intricacies of corporate investment in physician practices and health care generally at the state level and develop the most effective means of prohibiting the corporate practice of medicine in ways that are not detrimental to the sustainability of physician practices.

(Res. 247, A-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CMS Rep. 7, A-11; Modified: CMS Rep. 6, I-13; Reaffirmed: CMS Rep. 07, A-17; Modified: Res. 713, A-18; Reaffirmed: CMS Rep. 11, A-19; Reaffirmed: CME Rep. 01, I-22; Modified: Res. 710, A-24, Modified: BOT Rep. 09, I-24)

The Physician's Right to Engage in Independent Advocacy on Behalf of Patients, H-285.910
Our American Medical Association endorses the following clause guaranteeing physician independence and recommends it for insertion into physician employment agreements and independent contractor agreements for physician services:

Physician's Right to Engage in Independent Advocacy on Behalf of Patients, the Profession, and the Community

In caring for patients and in all matters related to this Agreement, Physician shall have the unfettered right to exercise independent professional judgment and be guided by personal and professional beliefs as to what is in the best interests of patients, the profession, and the community. Nothing in this Agreement shall prevent or limit Physician's right or ability to advocate on behalf of patients' interests or on behalf of good patient care, or to exercise their own medical judgment. Physician shall not be deemed in breach of this Agreement, nor may Employer retaliate in any way, including but not limited to termination of this Agreement, commencement of any disciplinary action, or any other adverse action against Physician directly or indirectly, based on Physician's exercise of their rights under this paragraph.
(Res. 8, A-11; Reaffirmed: CEJA Rep.1, A-21; Modified: Speakers Rep. 02, I-24)

The Regulation of Private Equity in the Health Care Sector, D-160.904
Our American Medical Association will propose appropriate guidelines for the use of private equity in healthcare, ensuring that physician autonomy and operational authority in clinical care is preserved and protected.
(Res. 710, A-24)

The Corporate Practice of Medicine, Revisited, D-215.982
Our American Medical Association will revisit the concept of restrictions on the corporate practice of medicine, including, but not limited to, private equities, hedge funds and similar entities, review existing state laws and study needed revisions and qualifications of such restrictions and/or allowances, in a new report that will study and report back by Annual 2025 with recommendations on how to increase competition, increase transparency, support physicians and physician autonomy, protect patients, and control costs in already consolidated health care markets; and to inform advocacy to protect the autonomy of physician-directed care, patient protections, medical staff employment and contract conflicts, and access of the public to quality health care, while containing health care costs.
(Res. 702, A-24)

Corporate Practice of Medicine, H-160.887
Our American Medical Association acknowledges that the corporate practice of medicine:

1. has the potential to erode the patient-physician relationship.
2. may create a conflict of interest between profit and best practices in residency and fellowship training.

(CMS Rep. 2, I-22)

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.
(Res. 3, I-92; Modified by CMS Rep. 1, A-95; Reaffirmed: CMS Rep. 7, A-05; Reaffirmed: CMS Rep. 1, A-15; Reaffirmed: CMS Rep. 11, A-19)

Antitrust Relief as a Priority of the AMA, H-380.987
Our American Medical Association will continue its aggressive efforts to achieve appropriate negotiations rights and opportunities and necessary antitrust relief for physicians, by whatever means. Achieving this important goal will remain a top priority for the Association.
(Sub. Res. 223, A-93; Reaffirmed by BOT Rep. 33, A-96; Reaffirmation A-97; Reaffirmation A-00; Reaffirmation I-00; Reaffirmation A-04; Reaffirmation A-05; Reaffirmed: BOT Rep. 10, I-05; Reaffirmation A-06; Reaffirmation A-08; Reaffirmation I-10; Reaffirmed: Res. 215, A-11; Reaffirmed: BOT action in response to referred for decision Res. 201, I-12; Reaffirmed in lieu of Res. 218, A-15; Reaffirmed: CMS Rep. 05, A-17; Reaffirmed: Res. 206, A-19)

Physician Employment Trends and Principles, H-225.947
1. Our American Medical Association (AMA) encourages physicians who seek employment as their mode of practice to strive for employment arrangements consistent with the following principles: A. Physician clinical autonomy is preserved. B. Physicians are included and actively involved in integrated leadership opportunities. C. Physicians are encouraged and guaranteed the ability to organize under a formal self-governance and management structure. D. Physicians are encouraged and expected to work with others to deliver effective, efficient and appropriate care. E. A mechanism is provided for the open and transparent sharing of clinical and business information by all parties to improve care. F A clinical information system infrastructure exists that allows capture and reporting of key clinical quality and efficiency performance data for all participants and accountability across the system to those measures.
2. Our AMA encourages continued research on the effects of integrated health care delivery models (that employ physicians) on patients and the medical profession.
(CMS Rep. 5, I-15; Reaffirmed: CMS Rep. 05, A-17; Reaffirmed: CMS Rep. 07, A-19)

Physician Independence and Self-Governance, D-225.977
1. Our American Medical Association (AMA) will continue to assess the needs of employed physicians, ensuring autonomy in clinical decision-making and self-governance.
2. Our AMA will promote physician collaboration, teamwork, partnership, and leadership in emerging health care organizational structures, including but not limited to hospitals, health care systems, medical groups, insurance company networks and accountable care organizations, in order to assure and be accountable for the delivery of quality health care.
(Res. 801, I-11; Modified: BOT Rep. 6, I-12; Reaffirmed: CCB/CLRPD Rep. 1, A-22)

Financial Incentives Utilized in the Management of Medical Care, H-285.951
Our American Medical Association 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.
(CMS Rep. 3, I-96; Reaffirmed by CMS Rep. 15, A-98; Reaffirmation: A-99; Reaffirmed: CMS Rep. 12, I-99; Reaffirmation: A-00; Reaffirmation: A-01; Reaffirmed in lieu of Resolution 901, I-05; Modified: BOT Rep. 38, A-06; Reaffirmed: CMS Rep. 01, A-16; Reaffirmed: CMS Rep. 11, A-19)

American Medical Association Principles for Physician Employment, H-225.950

1. **Addressing Conflicts of Interest**
    a. 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.
    b. In any situation where the economic or other interests of the employer are in conflict with patient welfare, patient welfare must take priority.
    c. Employed physicians should be free to exercise their personal and professional judgment in voting, speaking and advocating on any manner 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. Employed physicians also should enjoy academic freedom to pursue clinical research and other academic pursuits within the ethical principles of the medical profession and the guidelines of the organization.
    d. A physician's paramount responsibility is to their patients. Additionally, given that an employed physician occupies a position of significant trust, they owe a duty of loyalty to their 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.
        i. No physician should be required or coerced to perform or assist in any non-emergent procedure that would be contrary to their religious beliefs or moral convictions.
        ii. No physician should be discriminated against in employment, promotion, or the extension of staff or other privileges because they either performed or assisted in a lawful, non-emergent procedure, or refused to do so on the grounds that it violates their 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 they generate, 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 their care. When a physician's employment status is unilaterally terminated by an employer, the physician and their 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 their 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 their 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 their 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.
        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.
        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.

Our AMA will disseminate the AMA Principles for Physician Employment to graduating residents and fellows and will advocate for adoption of these Principles by organizations of physician employers such as, but not limited to, the American Hospital Association and Medical Group Management Association.

(BOT Rep. 6, I-12; Reaffirmed: CMS Rep. 6, I-13; Modified in lieu of Res. 2, I-13; Modified: Res. 737, A-14; Reaffirmed: BOT Rep. 21, A-16; Reaffirmed: CMS Rep. 05, A-17; Reaffirmed: CMS Rep. 07, A-19; Reaffirmed: CMS Rep. 11, A-19; Modified: BOT Rep. 13, A-19; Reaffirmation: A-22; Reaffirmed: BOT Rep. 29, A-24; Modified: Speakers Rep. 02, I-24)

4. REQUIRING PAYMENT FOR PHYSICIAN SIGNATURES

Reference committee hearing: see report of Reference Committee G.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See Policies D-320.978 and H-70.908

At the 2024 Annual Meeting, the House of Delegates referred Resolution 108, which was sponsored by the Mississippi State Medical Association, and asked the American Medical Association (AMA) to advocate that insurance companies be required to pay a physician for any required physician signature and/or peer-to-peer review which is requested or required outside of a patient visit.

BACKGROUND

Physician signatures are an integral part of health care delivered by a physician, as they serve as an identifier as to who provided services, verify care, assign legal responsibility, and demonstrate that services have been accurately documented to allow eligibility for payment.[1,2,3] Ensuring program integrity, signatures verify that the services provided were accurately and thoroughly documented and reviewed.[4] Physician signatures also assure patient safety by serving to identify which physician is responsible for the patient's care and attesting that they have carefully reviewed the patient's medical information.[5] Further, most health care regulations require signatures on medical records to verify the legitimacy of services provided and proper payment. The state of Illinois, for example, requires that, "all physician's orders and plans of treatment shall have the authentication of the physician…" as "authentication means an original written signature or an electronic signature system that allows for the verification of a signer's credentials."[6]

Physician signatures are required throughout the entire course of treatment for a patient, including prescriptions, medical orders, progress notes, discharge summaries, referrals, evaluations, re-evaluations, surgical reports, pathology reports, diagnosis/treatment plans, and claim forms.[7,8,9] For a prior authorization (PA), a physician's signature is typically required to authenticate the medical necessity of the requested treatment, meaning they must personally sign the document to indicate their approval and agreement with the information provided, usually including their full name and credentials.[10,11]

A peer-to-peer medical review is a dialogue between a treating physician, usually by telephone, and a medical director from a health insurance company, where the physician is required to explain the medical necessity of a treatment or

procedure for a patient.[12] Typically, it is a discussion between medical peers to clarify a patient's case when coverage is disputed and occurs by request after a payer denies coverage for services. Denials are usually made for medical orders, services, and inpatient status but can occur for medications or medical devices.[13] While the process can be tedious and frustrating, in some circumstances, it can be expeditious when it gives the treating physician the opportunity to speak with another physician.[14] However, it can be less effective when the health plan reviewer is a physician from another specialty or subspecialty, knows little about the disease or treatment in determination, or may not be licensed in the same state.[15] Further, the process approaches futility when the assigned reviewer is not a physician.[16]

REPORTING PHYSICIAN SIGNATURES AND PEER-TO-PEER REVIEW

CPT Assistant, a digital monthly newsletter which serves as a companion to the *Current Procedural Terminology* (CPT®) code set, published an October 2024 article providing coding guidance for PA-related activities within evaluation and management (E/M) services.[17] The article describes how PA-related work of providing signatures can be reported with CPT code 99080 (*Special reports such as insurance forms, more than the information conveyed in the usual medical communications or standard reporting form*).[18] Code 99080 can be appropriately reported when a physician spends time solely on completing special reports or signing forms independent of PA-related work performed on the date of an E/M encounter, excluding time spent on the telephone or in other conversations.[19]

The article also describes how the PA-related work of peer-to-peer review can be captured in the CPT code set. When selecting a code based on total time, physicians or other qualified health care professionals may include both face-to-face and non-face-to-face time, including time spent on PA-related work, on the same date of the encounter.[20] Alternatively, if E/M reporting is based on medical decision making (MDM), the review can be accounted for in the MDM Risk Element by incorporating social drivers of health and elevating to moderate complexity. For peer-to-peer reviews that occur on a different day than the E/M encounter, a separate code for prolonged physician services can be reported.[21] A summary of the codes referenced in the article can be found in Appendix A.[22]

AMA POLICY

Policy D-320.978 advocates for the fair reimbursement of established and future CPT codes for administrative burdens. Policy D-320.993 supports the development of more stringent state laws and regulations that provide compensation to physicians for the administrative burden and costs of health plan documentation requirements. Policy D-330.919 tasks the AMA to re-engage with the Centers for Medicare & Medicaid Services to re-evaluate Medicare signature requirements. Policy H-155.976 directs the AMA to seek comprehensive reforms to reduce administrative inefficiencies, address the need to reduce administrative costs and burdens, and minimize the administrative burdens imposed on physicians Policy H-225.965 supports that, unless otherwise required by law or regulation, a single signature may document the validity of entries in the medical record. In addition, it is important to note that Policy H-70.919 delineates that the CPT Editorial Panel is the body charged with developing new and revised CPT codes, descriptors, guidelines, parenthetical statements and modifiers independent of the AMA. Therefore, the AMA cannot direct the activities of the CPT Editorial Panel, including the identification of potential gaps in the nomenclature surrounding the reporting of physician signatures and peer-to-peer review.

DISCUSSION

Resolution 108-A-24 asked the AMA to advocate for payment for physician signatures and/or peer-to-peer review requested or required outside of a patient visit. The Council understands the burden associated with required physician signatures and peer-to-peer reviews before, during, and after the treatment of a patient. However, we also believe that physician signatures are necessary to identify who provided services, ensure integrity, verify PA treatment necessity, assign legal responsibility, satisfy federal and state requirements, and demonstrate that services have been accurately documented to allow eligibility for payment. Similarly, peer-to-peer reviews may allow a treating physician the chance to communicate the necessity of treatment as well as insight into new procedures or drugs not previously considered. Therefore, the Council recognizes that its recommendations must take each position into consideration.

Additionally, the Council's recommendations must not infringe on PA reform advocacy, which is a priority for the AMA. We are skeptical that the burden of physician signatures is confined to the PA process, as physician signatures are required throughout the entirety of a patient's treatment. Therefore, the Council recommends broadening policy to recognize this issue.

Recently, *CPT Assistant* provided coding guidance for PA-related activities, delineating how services such as signing forms may be appropriately reported with CPT codes. The Council believes that this guidance outlines infrastructure sufficient for the appropriate reporting of such services, thereby allowing eligibility for payment.

While Policy D-320.978 advocates for fair payment of established and future CPT codes for administrative burdens related to PA, the Council recommends underscoring this existing policy by creating a new, standalone policy, expanding it to include advocacy for fair payment of "all administrative tasks." The Council believes this fulfills the resolution's request, embeds seamlessly within existing policy, and provides an impactful solution.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 108-A-24 and the remainder of the report be filed:

1. That our American Medical Association (AMA) advocate for fair payment of CPT codes that accurately describe the myriad of administrative tasks performed by physicians, which can include the prior authorization process, appeals, or denials of services (visits, tests, procedures, medications, devices, and claims), whether pre- or post-service denials.

2. That our AMA amend Policy D-320.978 by deletion as follows:

   1. Our American Medical Association will continue its strong state and federal legislative advocacy efforts to promote legislation that streamlines the prior authorization process and reduces the overall volume of prior authorizations for physician practices.
   2. Our AMA will continue partnering with patient advocacy groups in prior authorization reform efforts to reduce patient harms, including care delays, treatment abandonment, and negative clinical outcomes.
   3. Our AMA will oppose inappropriate payer policies and procedures that deny or delay medically necessary drugs and medical services.
   ~~4. Our AMA will advocate for fair reimbursement of established and future CPT codes for administrative burdens related to:~~
      ~~a. the prior authorization process.~~
      ~~b. appeals or denials of services (visits, tests, procedures, medications, devices, and claims), whether pre- or post-service denials.~~

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

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Council on Medical Service Report 4-A-25
Requiring Payment for Physician Signatures
Policy Appendix

Fair Reimbursement for Administrative Burdens D-320.978

1. Our American Medical Association (AMA) will continue its strong state and federal legislative advocacy efforts to promote legislation that streamlines the prior authorization process and reduces the overall volume of prior authorizations for physician practices.
2. Our AMA will continue partnering with patient advocacy groups in prior authorization reform efforts to reduce patient harms, including care delays, treatment abandonment, and negative clinical outcomes.
3. Our AMA will oppose inappropriate payer policies and procedures that deny or delay medically necessary drugs and medical services.
4. Our AMA will advocate for fair reimbursement of established and future CPT codes for administrative burdens related to:
    a. the prior authorization process.
    b. appeals or denials of services (visits, tests, procedures, medications, devices, and claims), whether pre- or post-service denials.

(Res. 701, A-22)

Insurance Coverage Appeals D-320.993

Our AMA will:
(1) continue to support the development of more stringent state laws and regulations that provide compensation to physicians for the administrative burden and costs of the health plan documentation requirements, such as the appeal process;
(2) continue to advocate to ensure that physicians receive prompt, fair payment from health plans through educational products, seminars and advocacy efforts;
(3) continue to encourage health plans to implement online appeal processes to reduce the administrative burden and cost to physicians and their patients when claims are denied inappropriately;
(4) continue to encourage health plans to streamline, provide transparency, and lessen the administrative burdens and costs that are incurred by physicians through the health plans appeals processes;
(5) remain an active participant in the standards development activities of several standards development organizations and data content committees; and

(6) continue in its leadership role in the National Uniform Claims Committee and its work with the standards development organizations.
(BOT Rep. 23, A-06 Modified: CMS Rep. 01, A-16 Reaffirmation: I-17)

Reduction of Burdensome CMS Signature Compliance Requirements D-330-919
Our AMA will re-engage the Centers for Medicare & Medicaid Services to re-evaluate Medicare signature requirements.
(Res. 813, I-10 Reaffirmed: Res. 708, A-18)

Administrative Costs and Access to Health Care H-155.976
Our American Medical Association supports accurate calculations of the administrative costs of government programs (Medicare, Medicaid, TRICARE, etc.) and private health insurance plans. It is the policy of the AMA:
(1) to begin immediately to seek comprehensive reforms to reduce the administrative inefficiencies, burdens and expenses involved in paying for health care services and to urge that proposals to increase access to health care also address the need to reduce administrative costs and burdens;
(2) that state and county medical societies and national medical specialty societies be urged to utilize the joint Guidelines for Health Benefits Administration in discussions with health care payers directed toward improving the efficiency of utilization management programs and minimizing the administrative burdens they impose on physicians and hospitals;
(3) that the AMA strongly encourage further study of the cost-effectiveness of all types of utilization management systems and programs and report further results of such study to the Federation as they become available;
(4) that state medical societies be urged to work for enactment of the AMA model state legislation governing: (a) clarity and readability of contract language and uniform policy provisions; (b) liability of review entities for injury to beneficiaries; (c) physician involvement in the review process; and (d) confidentiality of medical information requested by review entities; and
(5) that this information be conveyed to the American public through appropriate mechanisms.
(Res. 202, A-90 CMS Rep. A, A-90 Reaffirmed: BOT Rep. 40, I-93 CMS Rep. 12, A-95 Appended: Res. 715, I-02 Reaffirmation A-07 Reaffirmed in lieu of Res. 828, I-08 Reaffirmation
I-11 Reaffirmation: A-17)

Activities of The Joint Commission and a Single Signature to Document the Validity of the Contents of the Medical Record H-225.965
The AMA supports the authentication of the following important entries in the medical record, history and physical examinations, operative procedures, consultations, and discharge summaries. Unless otherwise specified by the hospital or medical staff bylaws, or as required by law or regulation, a single signature may document the validity of other entries in the medical record.
(BOT Rep. 58, A-96 Reaffirmed: CLRPD Rep. 2, A-06 Modified: CMS Rep. 01, A-16 Reaffirmation: I-18)

Use of CPT Editorial Panel Process H-70.919
Our AMA reinforces that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers.
(BOT Rep. 4, A-06 Reaffirmation A-07 Reaffirmation I-08 Reaffirmation A-09 Reaffirmation
A-10 Reaffirmation A-11 Reaffirmation I-14 Reaffirmed: CMS Rep. 4, I-15 Reaffirmation A-16 Reaffirmed in lieu of: Res. 117, A-16 Reaffirmed in lieu of: Res. 121, A-17 Reaffirmation: A-18 Reaffirmation: I-18 Reaffirmed: Res. 816, I-19)

APPENDIX A

Reporting Prior Authorization Activities Provided as Part of Evaluation and Management Services

- 99203 - Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.

- 99204 - Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.

- 99205 - Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 60 minutes must be met or exceeded. (For services 75 minutes or longer, use prolonged services code 99417)

- 99213 - Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.

- 99214 - Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.

- 99215 - Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded. (For services 55 minutes or longer, use prolonged services code 99417)

- 99358 - Prolonged evaluation and management service before and/or after direct patient care; first hour. Code 99359 can be used for each additional half hour.

- 99452 - Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or other qualified health care professional.

- 99080 - Special reports such as insurance forms, more than the information conveyed in the usual medical communications or standard reporting form.

5. MEDICAID ESTATE RECOVERY REFORM

Reference committee hearing: see report of Reference Committee A.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policy H-290.952

At the 2024 Annual Meeting, the House of Delegates (HOD) referred Resolution 104, which was sponsored by the Medical Student Section and asked the American Medical Association (AMA) to oppose federal or state efforts to impose liens on or seek adjustment or recovery from the estate of individuals who received long-term services or supports coverage under Medicaid. The Board of Trustees assigned this item to the Council on Medical Service for a report back to the House of Delegates. This report describes federal Medicaid estate recovery requirements, discusses the pros and cons of estate recovery, and makes policy recommendations for future reforms.

BACKGROUND

Since the Medicaid program's inception in 1965, states have been permitted to try to collect repayments for certain Medicaid services after older enrollees had died. In 1982, the Tax Equity and Fiscal Responsibility Act gave states the option to utilize property liens to prevent Medicaid enrollees from evading estate recovery efforts by transferring their homes to someone else shortly before their death. The Omnibus Budget Reconciliation Act of 1993 (OBRA 93) mandated estate recovery efforts targeting certain deceased enrollees who had used Medicaid long-term services and supports (LTSS), including nursing facility services and home and community-based services (HCBS), while allowing

states some discretion in how estate recovery programs are implemented. Under OBRA 93, states must attempt to recover payments from the estates of individuals who received Medicaid LTSS when they were aged 55 or older; enrollees of any age expected to reside permanently in long-term care facilities; and, under certain circumstances, individuals with long-term care insurance.[1]

For the age 55 and older group, federal law stipulates that states must pursue estate payments for amounts that are at least equal to the costs of a patient's nursing facility care, HCBS, and hospital services and prescriptions provided while an enrollee was receiving LTSS. States have the option to also pursue estate recovery for the costs of other Medicaid-covered services, except for Medicare cost-sharing assistance that is provided to individuals who are dually eligible for Medicaid and Medicare. According to KFF, 37 states go beyond minimum federal estate recovery requirements and apply recoupment efforts to optional Medicaid services, including 32 states that try to recover the costs of all Medicaid services (as long as LTSS services were provided); 28 states that target some people under age 55; and five states that focus on certain optional benefits.[2]

Generally speaking, and depending on a specific state's policies, elements of an individual's estate that can be subject to recovery efforts include cash, checking and savings accounts, stocks and bonds, remaining funds in certain types of trusts (e.g., Qualified Income Trust and/or Irrevocable Funeral Trust) and any other items of value, including an individual's home. Life insurance policies are generally protected unless the beneficiary is the Medicaid enrollee's estate.[3]

Federal law also places some parameters around estate recovery efforts. For example, states are not permitted to seek recovery from the estate of a deceased Medicaid enrollee who is survived by a spouse until the spouse has died, and once the spouse has died, states can waive recovery if they determine efforts will not be cost effective. Similarly, states must exempt or defer recovery from the estates of enrollees who are survived by a child under 21 or a child of any age who is blind or has a disability.[4] As such, states may not try to take the homes of deceased enrollees that are occupied by a surviving spouse, child under 21, child of any age who is blind or has a disability, or a sibling who has an equity stake in that home. However, states are allowed to impose liens on the property of enrollees who are receiving institutionalized care and are not expected to return home, unless the home is occupied by the individual's spouse, child under age 21, child of any age who is blind or has a disability, or sibling who has an equity interest in the home.[5] Once survivors have died or a surviving child has turned 21, states can—and often do—proceed with attempting to recoup payments from estates. Pursuant to court judgments, states are also permitted to impose liens to pay for Medicaid benefits that were incorrectly provided.

OBRA 93 required states to establish procedures for waiving estate recovery due to undue hardships, which the Centers for Medicare & Medicaid Services (CMS) has stated could include: 1) an estate that is the sole income-producing asset for survivors (e.g., family farm); 2) a home of modest value, defined as roughly half the average home value in the county; and 3) other compelling circumstances. Although states are not required to implement these particular hardship examples, most (49) have reported adopting at least one of the three, including 35 states that said they use the "sole income-producing asset" criteria.[6] Notably, only 15 states report waiving estate recovery for homes of modest value.[7]

For Medicaid managed care organization (MCO) enrollees who would be subject to estate recovery under fee for service (FFS), states can seek recoupment of MCO capitation payments rather than the costs of Medicaid services that were provided. In states that pursue estate recovery for all Medicaid services, the total capitation payment for the period the individual was enrolled in the MCO must be sought. If the state applies estate recovery to some, but not all services, the state must pursue recoupment of the part of the capitation payment attributed to those services.[8] According to KFF, 30 states report trying to recoup payments for MCO capitation payments which, notably, can exceed the amount that Medicaid had actually spent on the enrollee.

Medicaid Long-Term Services and Supports (LTSS)

LTSS refers to the broad range of clinical health and related services provided to help people who have functional or cognitive limitations with activities of daily living (ADL) when these individuals need extra care either at home or in a facility. ADLs include eating, bathing, dressing, and instrumental tasks like medication management, house cleaning, and meal preparation. LTSS are intended to help individuals with self-care needs over an extended time period, which differentiates them from post-acute services, such as home health or skilled nursing facility (SNF) care, that are designed to help individuals recover after a hospitalization.[9]

Older adults and people living with chronic illnesses and disabilities are among the estimated nine million users of Medicaid LTSS, a figure that includes the 7.8 million enrollees who received HCBS in 2022 and 1.5 million individuals who received LTSS that year in an institutional setting.[10] The significantly larger share of people receiving HCBS reflects a shift over the years in the provision of LTSS from nursing homes and other facilities to home and community settings. Over half (57 percent) of enrollees receiving Medicaid LTSS are under 65, although—not surprisingly—more than two-thirds of individuals receiving institutional care are 65 and older.[11] Importantly, these statistics exclude individuals receiving unpaid LTSS that is generally provided by family members and friends outside of Medicaid, as well as individuals paying for LTSS (including assisted living or nursing home care) out of pocket. Although more people have private long-term care insurance than was the case years ago, in 2021 only about 80,000 people filed claims for such benefits.[12] Of note, insurance coverage for LTSS is profoundly different than coverage for other health care services in that it is quite limited outside of Medicaid and, within Medicaid, LTSS is only available to people meeting strict eligibility requirements who must spend down their income and assets to qualify.

Although nursing facility services are a mandatory benefit under Medicaid, coverage for most HCBS—other than home health—is optional and, therefore, varies by state. Complex eligibility rules regarding income, assets, and functional limitations also vary significantly by state, as do LTSS eligibility pathways. In general, applicants for Medicaid LTSS must "spend down" their income and assets in order to qualify for LTSS, and "look-back" rules are in place to try to keep people from transferring assets to others to become Medicaid-eligible. Although data are somewhat lacking on this topic, analyses have found that advantaged groups are more likely to engage in estate planning to circumvent "look-back" and estate recovery requirements.[13]

As the largest payer, Medicaid covers the costs of roughly 60 percent of total LTSS expenditures in the United States. Additional payments are made out of pocket by individuals and by private long-term care insurers, the Department of Defense, the Department of Veterans Affairs, and state and local governments.[14] In 2022, Medicaid LTSS spending totaled just over $200 billion, which included $129.4 billion for HCBS and $71 billion for institutional care. The average expenditure per user on institutional care was over $48,000, significantly higher than average per-person spending on HCBS ($16,491).[15] Demonstrating the need for LTSS, approximately 700,000 people are on waiting lists for HCBS.[16] In 2020, CBO estimated that, in 2030, $160 billion will be spent on HCBS and $80 billion on institutional care.[17] Recognizing that people are aging and living longer, which will impact the use of and spending for LTSS, the Council on Medical Service has addressed long-term care in this country and presented reports on LTSS financing reforms (Council Report 5-A-18) and financing structures for HCBS (Council Report 4-N-21).

PROS AND CONS OF MEDICAID ESTATE RECOVERY

The Federal Estate Recovery Mandate was established as a program integrity tool intended to help ensure that Medicaid LTSS recipients use their own resources to cover the costs of their care. Proponents of estate recovery underscore that such efforts are needed to ensure that families are not transferring or otherwise protecting their financial resources in order to qualify for Medicaid LTSS and that Medicaid funds are used to care for the neediest enrollees. Additionally, the recovery of assets may help supplement Medicaid funding in some states and even federally, since a portion of the money recovered must be paid to the federal government for the share of the services that were federally funded. Within federal parameters, states have discretion in how aggressively they choose to pursue estate recovery and, therefore, there is wide variability in how states administer their recovery programs.

Criticisms over the years have highlighted that Medicaid estate recovery primarily targets individuals and families who are poor, that families of color are disproportionately affected, and that the process contributes to wealth inequality and intergenerational poverty. To qualify for Medicaid LTSS in the first place, individuals must have limited incomes and have spent down most of their financial resources, though the value of a person's home and certain other assets are not counted in eligibility assessments. Due to the high cost of long-term care in this country, many middle-income people also qualify for Medicaid once their savings have been spent down. However, critics also note that middle- and higher-income people frequently use estate planning vehicles (e.g., trusts) to protect their assets and evade recovery efforts, while people who cannot afford estate planning services tend to give up more to the state, thus widening estate recovery disparities. The lack of available data prevents a thorough understanding of how many people shelter assets from state Medicaid programs, but it is not an unusual practice. Notably, the Medicaid and CHIP Payment Access Commission (MACPAC) has concluded from its surveys and interviews that estate recovery is not very effective in recouping money from people who may have the means to cover LTSS themselves.[18]

Advocates concerned about estate recovery efforts have noted that estate recovery programs can dissuade people in need of LTSS from applying for Medicaid services. Critics also argue that very little payment is collected by most states and that recovered dollars represent a small slice of what Medicaid spends on LTSS. In 2019, when an estimated $733 million was recovered overall from estates, only eight states recouped more than one percent of the cost of FFS LTSS and 28 states recovered less than 0.5 percent.[19] Based in part on each state's priorities and program administration, amounts recovered vary significantly by state. For example, in 2019, Iowa recovered over 14 percent of FFS LTSS spending in the state while Hawaii, Louisiana, and West Virginia recovered only 0.02 percent. Moreover, five states with the largest recoveries (Massachusetts, New York, Pennsylvania, Ohio, and Wisconsin) recouped nearly half of all collections in the U.S.[20] As noted by the authors of Resolution 104-A-24, the administrative costs of implementing estate recovery programs can be substantial, thus diminishing the utility of such efforts. Although little data are available on state administrative costs, there seems to be a wide range of spending on estate recovery across states. According to MACPAC's data from five states, the administrative costs of recovery ranged from 3.7 percent to 32.1 percent of the amount collected. MACPAC's research also suggests that states could collect more from estates if their program efforts mirrored those in states that recoup the most money.[21]

REFORM PROPOSALS

At the national level, MACPAC published a thorough analysis of the state-of-play in a 2021 report to Congress on estate recovery reforms. This report recommended that Congress amend the Social Security Act to:

1. Make Medicaid estate recovery optional for the populations and services for which it is required under current law;
2. Allow states providing LTSS under managed care arrangements to pursue estate recovery based on the cost of care when the cost of services used by an enrollee was less than the capitation payment made to an MCO; and
3. Direct the Department of Health and Human Services Secretary to set minimum standards for hardship waivers so that states are not allowed to pursue recovery for: a) any asset that is the sole income-producing asset of survivors; b) homes of modest value; and c) any estate valued under a certain threshold.[22]

Federal legislation from the last Congress includes H.R. 7573, which was sponsored solely by Democrats and prohibits all estate recovery efforts, and H.R. 8094, which was introduced by a Republican House member and would prohibit states from pursuing estate recovery when the individual's home is transferred to someone who is eligible for medical assistance or has an income below 138 percent of the Federal Poverty Level (FPL).[23]

Although states must meet minimum federal requirements for estate recovery, within those parameters, they can implement their own reforms. Examples of recent state activity include legislation in Maine and Massachusetts that scaled back recovery efforts to federal minimum requirements. Additionally, Georgia, Illinois, Massachusetts, and South Carolina have established cost effectiveness thresholds that essentially waive recovery of estates worth less than $25,000.[24] Illinois has also begun requiring the state Medicaid agency to publicly report data on estate recovery. Some states, like Massachusetts, also provide enrollees with more thorough explanations of estate recovery requirements when they are applying for Medicaid LTSS.

RELEVANT AMA POLICY

AMA policy does not specifically address Medicaid estate recovery efforts, although numerous policies focus on long-term care and LTSS. Under Policy H-280.991, the AMA maintains that programs to finance long-term care should:

- Assure access to needed services when personal resources are inadequate to finance care;
- Prevent impoverishment of the individual or family in the face of extended or catastrophic service costs.
- Cover needed services in a timely, coordinated manner in the least restrictive setting;
- Provide coverage for the medical components of long-term care through Medicaid for all individuals with income below 100 percent of the FPL; and
- Provide sliding scale subsidies for the purchase of LTC insurance coverage for individuals with income between 100-200 percent of the FPL.

Although not specific to Medicaid estate recovery, Policy H-290.982 supports increasing investments in HCBS; allowing states to use long-term care eligibility criteria which distinguish between people who can be served in a home or community-based setting and those who can only be serviced in a nursing facility; buy-ins for home and

community-based care for people with incomes and assets above Medicaid eligibility limits; and grants to states to develop new long-term care infrastructures and encourage expansion of long-term care financing to middle-income families who need assistance. Policy H-280.945 also supports incentivizing states to expand access to HCBS. Policy D-280.982 directs the AMA to:

- Advocate for business models in long-term care for the elderly which incentivize and promote the ethical and equitable use of resources to maximize care quality, staff and resident safety, and resident quality of life, and which hold patients' interests as paramount over maximizing profit; and
- Advocate for further research into alternatives to current options for long-term care to promote the highest quality and value LTSS models as well as functions and structures which best support these models for care.

DISCUSSION

The Council reviewed the literature on Medicaid estate recovery, met with an expert, and deliberated at length about potential reforms. At the request of the Medical Student Section, which sponsored referred Resolution 104-A-24, the Council limited its study to estate recovery and, therefore, does not make recommendations regarding Medicaid LTSS eligibility requirements (e.g., spend-down rules), which are equally complex and should be addressed separately.

Of note, the Council's deliberations took place at a time of heightened unease among state medical associations, national medical specialty societies, the AMA, and many states and advocacy groups regarding potential reductions in Medicaid funding, which would have deleterious effects on state budgets and Medicaid programs. At the time this report was written, Congress had not enacted any Medicaid cuts; however, many states were considering how to prepare for federal Medicaid changes. For context, it is also important to point out that the AMA has not received any inquiries or requests for assistance with estate recovery reforms. Still, because estate recovery is not directly addressed in AMA policy, the Council agrees that new policy is needed and that, given the uncertainties around federal Medicaid funding, this policy should retain state flexibility. Accordingly, the Council crafted recommendations that support and encourage meaningful estate recovery reforms without requiring states to abandon the practice or take other immediate actions.

Medicaid LTSS provides a critical safety net for lower-income people who have few resources and need assistance with ADLs, including older adults with chronic illnesses or dementia and younger people living with disabilities. The Council recognizes that demand for critical LTSS services is likely to grow as the U.S. population ages and people live longer, and that Medicaid services should be available to those most in need of LTSS. We do not believe that Medicaid should pay for the long-term care costs of people who have financial means to do so themselves; however, because LTSS is exorbitantly expensive and not covered by most insurers, we understand the challenges of preventing people from sheltering their assets and misusing the system.

As discussed in this report, federal law requires states to perform estate recovery as a condition of their participation in Medicaid. Based on surveys and interviews with key stakeholders, MACPAC reported that states primarily recoup funds from modest-sized estates and that individuals with more financial means often evade recovery efforts, raising equity concerns. We acknowledge these concerns and believe that additional guardrails may be needed. We also recognize that states and other stakeholders, including physicians, hold differing views on the benefits and harms of estate recovery programs. For example, in some states, the return on investment may not be worth the costs of administering estate recovery programs; however, states that recoup the most funds may not want to forego that revenue, especially in a challenging fiscal environment. For these reasons, the Council decided not to oppose estate recovery efforts outright. Instead, we recommend support for specific reforms intended to help maintain Medicaid as a safety net and ensure that, as intended, LTSS are provided to people most in need. To acknowledge the variance in estate recovery across states and allow states more flexibility than they currently have, the Council recommends that the AMA support making Medicaid estate recovery optional, instead of mandatory. This recommendation allows states to decide whether (or not) to continue their estate recovery programs, which is consistent with longstanding AMA policy allowing states some flexibility in implementing their Medicaid programs.

When Medicaid estate recovery is pursued, the Council recommends supporting the following additional reforms:

- First, the Council learned that more than half of states apply recoupment efforts beyond LTSS and attempt to recover the costs of some or all other Medicaid-covered services provided to an enrollee. We do not believe it is

appropriate to pursue recovery beyond the costs of LTSS care, and, therefore, recommend that estate recovery be limited to the costs of LTSS and not other Medicaid services that may have been utilized.

- The Council also recommends support for developing standards for hardship waivers that prohibit claims against a sole income-producing asset of heirs; homes of modest value; and any estate less than a specified threshold value. This language mirrors one of MACPAC's recommendations and was also used by CMS to describe sample hardship waiver criteria. The Council discussed recommending a specified threshold value but believe that other stakeholders are better equipped to determine an appropriate threshold amount.
- Relatedly, the Council recommends support for exempting estates when the value of the recovery is projected to be less than the cost of recoupment efforts. We do not believe it makes sense to pursue estate recovery when the return would be so low.
- When MCOs are utilized, the Council recommends basing estate recovery on the costs of LTSS care, instead of the capitation amount, when the cost of LTSS is lower. Similar to the first reform (see above), we do not believe that estates should be pursued for amounts exceeding the cost of care that was provided. Our recommended approach would also be easier for families to understand since they may not know the amount of capitation that was paid for them.
- Similarly, the Council feels strongly that LTSS enrollees and their families must be better educated about estate recovery requirements so they are not surprised by a state's recoupment efforts after the enrollee has died. Although states are required to provide basic information to enrollees, it is not always adequate or easy to find. Accordingly, the Council recommends supporting education at the time of enrollment in LTSS, and during any renewal process, that is appropriate to enrollees' language and health literacy abilities.
- To ensure that available hardship waivers are offered to eligible enrollees, the Council recommends screening patients for hardship waivers and assisting them with filing such waivers, if eligible.
- Finally, the Council also recommends supporting data collection and public reporting on estate recovery programs. We found data to be lacking and believe more information is needed to accurately evaluate the impacts and effectiveness (or not) of estate pursuits.

RECOMMENDATIONS

The Council on Medical Service recommends that the following recommendations be adopted in lieu of Resolution 104-A-24, and that the remainder of the report be filed:

1. That our American Medical Association (AMA) oppose federal or state efforts to impose liens on or seek adjustment of recovery from the estate of individuals who received long-term services or supports coverage under Medicaid.
2. That our AMA support the following when Medicaid estate recovery is pursued:
    a. Limiting recoupment to the costs of long-term services and supports (LTSS) and not for other Medicaid services that were provided;
    b. Establishing standards for hardship waivers that prohibit claims against a sole income-producing asset of heirs; homes of modest value; and any estate less than a specified threshold value;
    c. Exempting estates from recovery efforts when the value of the recovery is projected to be less than the cost of recoupment efforts;
    d. Basing estate recovery on the costs of LTSS care when managed care organizations are utilized, instead of the capitation amount, when the cost of LTSS is lower than the capitation amount;
    e. Providing education regarding state Medicaid estate recovery requirements at the time of enrollment in LTSS, and during any renewal process, that is appropriate to enrollees' language and health literacy abilities;
    f. Screening patients for hardship waivers and assisting them with filing, if eligible; and
    g. Collecting and making publicly available important data regarding estates that have been pursued and amounts that have been recovered.

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

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6. PRESCRIPTION MEDICATION PRICE NEGOTIATION

Reference committee hearing: see report of Reference Committee A.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
REMAINDER OF REPORT FILED
See Policies D-110.987, H-110.959 and H-110.987

At the 2024 Annual Meeting, the House of Delegates referred Resolution 113, which was sponsored by the New England Delegation, and asked our American Medical Association (AMA) to support drug price negotiation for all payers, advocate that any medication in which the price rises faster than inflation be automatically added to the negotiation schedule, and support extending the annual Medicare cap on out-of-pocket prescription drug spending to all payers. The following report discusses the history and current state of medication price negotiation, out-of-pocket caps, AMA efforts on the topic, and offers recommendations in line with the spirit of the resolution.

BACKGROUND

Enactment of the Inflation Reduction Act of 2022 (IRA) has had far-reaching impacts in the health care sector, particularly regarding Medicare drug pricing.[1] Most notably, the IRA allows the Centers for Medicare & Medicaid Services (CMS) to directly negotiate the prices of certain high-cost drugs.[2,3] CMS initially selected 10 medications that are considered "high expenditure," are single source, and do not have a biosimilar/generic alternative. Additionally, manufacturers are required to pay rebates to the federal government if the price of medications for Medicare Part B or Part D beneficiaries are raised faster than the rate of overall inflation as measured by the Consumer Price Index for All Urban Consumers (CPI-U).[1,2]

At the time this report was written, there had not been significant movement in either direction regarding implementation of the drug pricing regulations by the Trump administration. However, it seems likely that they will choose to maintain current drug pricing practices put in place by the Biden administration, implement modifications to these practices, or repeal them altogether.[4] A focus on reducing drug prices through Medicare negotiations remains a cause with bipartisan support. Over half of all Americans report believing that Medicare drug pricing should be a "top priority" of the current administration.[5] CMS released a statement declaring that the current administration intends to focus on the issue by negotiating drug prices,[6] although recent actions may indicate a change in focus from the Biden administration. For example, shortly after taking office, President Trump signed executive orders rescinding regulations designed to lower Medicare beneficiaries' drug spending. Specifically, the two-dollar generic out-of-pocket (OOP) cap was removed and the reduction of Medicare payment for accelerated Food and Drug Administration (FDA) medications was reduced.[7] Additionally, three ongoing projects through the CMS Innovation Center designed to explore strategies to lower drug prices were halted .[7] It is also possible that the administration will not directly support nor reject the Medicare negotiations, thereby indirectly supporting drug industry opposition. For example, the administration may choose not to defend the existing laws and regulations against legal challenge or may propose rules designed to exempt more drugs from negotiations.[4]
Pharmaceutical prices are typically categorized in three ways: public list price, net price, and OOP expense for the patient.[8] The public list price of a drug is set by the manufacturer and is typically the starting point for negotiations. The net price of a drug is the amount that is actually paid by the plan sponsor or, in the case of public plans, the government. This price is determined through either negotiation, mostly done by pharmacy benefit managers (PBMs), or in some rare cases by the payer itself. This is also the price that is typically dictated by legislation or regulations when applicable. Finally, patient OOP cost is the amount that the patient pays to receive the medication.[8,9] There are many elements that are incorporated in price determination, such as the number of medications available to treat the same condition, the route of administration of the medication, and the payer. These elements are used to set the prices that are paid by patients and plans.[8,9] Without PBMs, this process is relatively straightforward. Manufacturers sell prescription drugs to pharmacies who, in turn, sell the drug to the patient at a price determined by their insurance coverage and plan. However, the addition of PBMs to this process increases complexity and reduces transparency. These benefit managers become the "middlemen" between manufacturers, pharmacies, insurance companies, and consumers, which allows them to determine the actual OOP cost to the patient.[8,10]

PRICE NEGOTIATION

Private payers engage in drug price negotiation, primarily relying on PBMs to handle the negotiations. PBMs work directly with drug manufacturers to negotiate drug prices and associated rebates to find the lowest cost for the payer. While, in theory, this should lead to beneficiaries having access to lower cost medications, in reality PBMs often favor the higher priced drugs. This is due to the rebates, calculated as a percentage of the list price, that are kept by the PBM and payer, and rarely directly benefit beneficiaries.[11] These rebates are not typically passed on to the patient and, as a result, patients may end up paying a higher price and/or not benefiting from the PBM negotiations.[11,12] Additionally, a significant portion of PBMs are vertically integrated with payers, stifling competition. This lack of competition, which is not just a result of vertical integration but also the process of rebate negotiation, often results in higher insurance premiums for beneficiaries and lower pharmaceutical reimbursement rates.[12] While the negotiation practices of private payers, often via PBMs, may not be as advantageous for patients as it should be, the bottom line is that these payers do currently negotiate drug prices to lower overall insurer costs.

Historically, public payers have not negotiated drug prices in the manner that was implemented by the aforementioned IRA. Since its inception in 2022, the IRA has allowed CMS to negotiate the price of Medicare Part B and D prescription drugs. This negotiation process began in 2024 for Part D and included 10 drugs in the initial negotiation cycle.[1] The Maximum Fair Prices (MFPs) for these 10 drugs will go into effect in January 2026. These drugs include

blood thinners and medications to treat diabetes, heart failure, psoriasis, rheumatoid arthritis, blood cancers, and Crohn's disease. Medicare negotiated prices ranged from a price drop as small as $6 and as large as $22,027. Not surprisingly, the drug with the highest list price, Stelara,® showed the most significant price decrease while the drug with the lowest list price, NovoLog®/Fiasp,® yielded the smallest price reduction. A full and regularly updated table of the Medicare negotiated drug prices can be accessed via the Peterson-KFF Health System Tracker. In early 2025, CMS announced 15 additional drugs that will be included in the Medicare drug pricing negotiation schedule. Assuming the cycle of negotiation continues as intended, the MFPs for these drugs will go into effect January 2027.[2,3] CMS projects that the negotiated MFPs will save approximately $1.5 billion in its first year.[2] In order for prescription drugs to be eligible for negotiation, they must meet certain criteria. Specifically, they must be covered by Medicare and be a single brand-name drug or biologic that does not have a therapeutically equivalent generic or biosimilar that is being marketed. Additionally, eligible biologics must be 11 years past the earliest FDA approval or licensure and name-brand small-molecule drugs must be at least seven years past approval/licensure. Until 2028, negotiation is limited to Part D plans adding 15 drugs each year through 2028. In 2029 Part B plans will be included and the number of negotiated drugs will increase to 20.[1,3,13]

Importantly, there is no "trigger" that automatically includes a medication in future negotiations. However, under the IRA if the cost of a drug rises faster than inflation, manufacturers are required to provide Medicare with rebates.[3] This provision is designed to discourage manufacturers from unnecessarily raising drug prices without valid reasoning, as in 2015 when the manufacturer for Daraprim® increased the price by over 5,000 percent overnight.[3,13] Though a medication's price increasing faster than inflation *might* be a reason for inclusion, it is not *necessarily* a reason. There are valid reasons that a drug price may increase, such as when a medication's treatment value increases or an increase in the cost of raw materials.[14,15] While it is important to discourage unnecessary hikes in drug prices, it is also important to ensure that medications are accessible to patients when needed. Therefore, drugs should not be automatically included in negotiations without complete assessment from appropriate regulators, legislators, and/or experts. A discussion surrounding the criteria states have utilized to select regulated or negotiated medications can be found in CMS Report 8-A-25.

Pharmaceutical manufacturers have pursued litigation to stop these government negotiation practices, citing that the negotiated prices may harm competition and, as a result, innovation. At the time this report was written, there were nine open legal cases against the federal government and/or CMS.[16] These lawsuits generally center around the claim that the program will violate the Fifth Amendment by forcing manufacturers to provide selected medications to the government without fair compensation, that the program limits corporate free speech, and that associated penalties are "excessive fines" which is in violation of the Eighth Amendment. Some cases also claim that the negotiation program violates portions of the Due Process Clause by not allowing for adequate separation of powers.[14,15] To date, none of these legal challenges have been successful in blocking or minimizing the drug negotiation. However, most of these cases are still ongoing and one has recently found minor traction via an appeals court.[17] Most experts following these cases agree that it is likely one will end up being heard by the United States Supreme Court. Although the voracity with which the current administration will defend the program is uncertain, potentially mitigating the need for a Supreme Court ruling.[15,16]

IMPACT OF PRICE NEGOTIATION

While experts do agree that reducing the amount patients pay for drugs will improve medication adherence, and as a result health outcomes, there is some debate regarding whether price negotiation, and particularly the establishment of MFPs, are the best method to reduce drug prices. Some experts suggest that increasing drug price negotiation is a tactic that could be used in tandem with other tactics to lower drug prices in the U.S.[18] Specifically, the Congressional Budget Office (CBO) analyzed a bill asserting more aggressive negotiation and found that it could yield over $450 billion in savings for Medicare over a 10-year period. It is estimated that if the negotiated prices were expanded to commercial insurance plans, anticipated savings to the system could reach the trillion-dollar mark over 10 years.[17] These experts stress that drug price negotiation alone is not likely to solve the problem of U.S. drug prices. However, in tandem with other efforts such as rebate reform, administrative simplification, and increased transparency, costs could be reduced.[17]

Other experts have voiced concerns surrounding the increased use of price negotiation. Many drug manufacturers claim that the implementation of negotiation and MFPs will stifle innovation and potentially prevent, or slow, the development of new pharmaceuticals.[18] Importantly, much of the resistance to price negotiation has come from entities

that benefit from the current system, such as manufacturers, potentially calling the motives of these challenges into question.[14,15,18]

In addition to the lowered costs that may result from negotiation, the price transparency required in the IRA may improve pricing.[17,19] The public access to a drug's Medicare Negotiated Price, the MFP, is a relatively novel level of transparency that may encourage private payers to follow the lead on CMS negotiated prices. While the current legislation does not require private payers to follow the set MFPs, it is common for private insurance companies to eventually follow the lead of CMS.[18] Research has demonstrated that increases in transparency throughout the drug pricing system could be a significant help in lower drug prices overall.[17]

Federal efforts, like the Prescription Pricing for the People Act of 2025, have been introduced to regulated PBM business practices and drug pricing. Additionally, the Transparency in Coverage rule, released in 2020, outlines the requirements for payers/plans to disclose negotiated rates and historical net price for prescription drugs. In addition to federal efforts, a number of states have enacted laws related to portions of the drug pricing process. These laws center around affordability reviews, consumer cost sharing, PBMs, increased transparency, and purchasing processes. However, since none of these state laws have been enacted at a federal level, no impact has been seen nationally.[20] Due to the lack of transparency in the drug pricing process, the result of each specific element, be it negotiation, PBMs, or another aspect, is difficult to assess.

OUT-OF-POCKET CAPS

In addition to introducing CMS drug price negotiations, the IRA also lowered the prescription drug OOP cap for Medicare Part D beneficiaries. Historically, this cap has been between $3,300 and $3,800. Starting in 2025, this has been lowered to $2,000 due to elimination of the coinsurance cost in the catastrophic coverage phase. Experts estimate that if this cap had been implemented in 2021, 1.5 million beneficiaries would have saved in OOP costs.[21]

While the IRA did not expand the prescription drug OOP cap to non-Medicare payers, most, if not all, plans have caps on annual OOP spending. Research has demonstrated that median annual OOP spending on medical expenses ranged between $360 and $1,500 with the top 10 percent spending at least $7,000.[22] Importantly, this is for all medical spending, not just prescription drugs. Because many private payers do not separate prescription drug OOP costs from overall OOP medical costs, it is challenging to make a direct comparison to Medicare levels.[21] Researchers and other experts agree that high OOP costs can be detrimental to patients, some suggesting spending caps as a potential solution to this issue.[23,24] The financial burden of high OOP costs can often lead to patients accruing significant medical debt and potentially forgoing future, necessary treatment. If a patient cannot afford their OOP cost, they may delay or skip treatment altogether, leading to lower medication adherence and poorer health outcomes. OOP caps could have potential to increase prescription drug affordability for patients in turn potentially leading to better health outcomes.[23,24]

While experts agree that high OOP costs can be detrimental to patients, some voice concerns around the unintended consequences of OOP caps such as disproportionate financial burdens to lower income patients.[24,25] If all beneficiaries are given a uniform cap, this may be affordable for some but not for others. Even more importantly, these caps are often not paid for by insurers but rather shifted to patients through premium increases. These premium raises could, and often do, make insurance unaffordable for many beneficiaries. Some experts argue that this could be mitigated by adding income-based eligibility requirements for OOP costs or income-proportional caps.[23,24,25] Nonetheless, it is essential to ensure that the potential economic impacts of universal OOP caps be weighed against the potential benefits to ensure that patients still have access to reasonably priced insurance coverage.

AMA POLICY AND ADVOCACY

The AMA has undertaken robust advocacy efforts to lower drug costs for patients, especially around regulation and increasing the transparency of PBMs. Specifically, over the past two years the AMA has written a number of letters to payers, regulators, and legislators and testified before both the House and Senate regarding regulation of PBMs. The AMA also has an ongoing grassroots campaign, TruthinRx, designed to support patients and physicians in understanding and fighting the lack of transparency through education and advocacy. Additionally, the AMA has expressed support to federal legislators to implement drug price negotiation, regulators in reducing patient OOP costs, and for reasonable OOP caps on drug spending. The AMA is continuing to work with legislators, regulators, drug

manufacturers, and payers to ensure that patients not only have access to affordable medications but also affordable health coverage.

In addition to the advocacy on drug pricing transparency and affordability, the AMA has extensive policies that address the issue. Policies H-110.980 and H-110.987 outline the AMA's efforts to ensure that patients have access to affordable medications. These policies discuss AMA standards for drug affordability, process transparency, and patient access. Policy H-110.980 highlights different strategies and approaches, such as supporting increased transparency and promoting value-based pricing, that the AMA utilizes to ensure that medications are accessible and affordable. Policies H-110.986 and H-110.979 expand on this support for value-based strategies to manage drug coverage. Specifically, H-110.986 discusses AMA support for adding value metrics into drug prices and H-110.979 outlines AMA advocacy for formulary development to incorporate value-based processes. In conjunction with the aforementioned policies that address all payer types, Policy D-330.954 focuses on managing prescription drug prices in Medicare and outlines support for price negotiation. Finally, Policies D-110.987, D-120.988, and D-120.934 target PBMs and the need for increased regulation and transparency. Policy D-120.934 outlines AMA steps to ensure that PBMs do not prevent physicians from appropriately treating patients, Policy D-120.988 details prevention of appropriate treatment by PBMs, and Policy D-110.987 discusses the impacts of these, and other, negative PBM practices.

The AMA also has policy and ongoing advocacy to address concerns from experts surrounding unintended consequences of introducing OOP caps or extending drug price negotiations. Policies H-320.939 and D-320.982, along with the AMA's Fix Prior Auth grassroots campaign, work to mitigate concerns regarding increases in utilization management/prior authorization. Policy
H-320.939 outlines the efforts that the AMA has made to reduce the amount of utilization management and fix the system as a whole. Policy D-320.982 outlines strategies, including emerging technology, that could be used to assist in minimizing the impact of utilization management on patients and physicians. Finally, Policies H-165.828, H-290.954, and H-165.824 outline AMA efforts to support the affordability of health insurance for all. Policy H-165.828 centers around the AMA efforts to ensure that health coverage is affordable for all patients, while Policies H-165.824 and H-290.954 center on ACA and public plan affordability.

DISCUSSION

Despite the current uncertainty of Medicare drug price negotiations, the practice of negotiation has been a part of drug pricing in the private sector for decades. The current drug pricing system, hallmarked by close relationships between private insurers and their PBM negotiators, is complicated and opaque. As a result, the system often still yields drug prices that remain unaffordable for many patients. While this system is not simple to fix, it is possible that the current CMS negotiation efforts may be a step in the right direction. While some experts voice concern that negotiation may stifle innovation, many anticipate that it has the potential to save both consumers and public payers significant amounts of money, helping prescriptions become more affordable. Regardless of the impact of price negotiation, it is clear that payers of all types participate in the negotiation process. For private payers this is often done by PBMs and for public payers via CMS. The Council believes that when used responsibly, prescription drug price negotiation has real potential to make significant changes, and that the AMA should support utilization of all ongoing efforts, to make drug prices affordable. The AMA has a strong body of policy and ongoing advocacy to address drug affordability. Therefore, the Council recommends the reaffirmation of Policy H-110.987, which details the AMA's efforts to encourage regulators, legislators, physicians, and patients to work together towards transparency and affordability in drug pricing. To ensure that this support is explicit for all medications, including those used to manage health and prevent future complications, the Council recommends the adoption of new HOD policy as outlined in Recommendation 1. Additionally, as outlined in the report, PBMs are exceptionally influential in setting drug prices, as they are currently faced with little regulation. Therefore, the Council recommends that Policy D-110.987 be reaffirmed, as it outlines how the AMA continues to hold legislators and regulators accountable to ensure that PBMs are monitored and transparency is increased. The Council believes that this new HOD policy, along with the suggested reaffirmations, will ensure that efforts to increase medication affordability continue.

As previously discussed, OOP costs are another aspect of drug pricing that elicit affordability concerns for patients. Researchers agree that high OOP medical costs can cause significant financial burden to patients and adverse health outcomes. Specifically, when OOP costs are higher, patients are less likely to adhere to treatment and often experience worse health outcomes. However, blanket OOP caps may not be a simple solution to the problem. Experts have called the actual impact of these caps into question and expressed concern that payers might shift costs to patients via

premium increases. It is clear that OOP caps need to be handled in a manner that balances the potential positives and negatives. Therefore, the Council recommends the adoption of new HOD policy that supports the establishment of a reasonable OOP prescription drug cap while maintaining patient premiums. The Council believes that this new policy captures the intent of the third resolve of Resolution 113-A-24 while balancing potential unintended consequences.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 113-A-24, and the remainder of the report be filed:

1. That our American Medical Association (AMA) support efforts to ensure that patients have affordable access to medications.
2. That our AMA encourage all payers, both public and private, in efforts to establish a reasonable and affordable cap on patient out-of-pocket prescription drug spending in a manner that does not increase patient premiums.
3. That our AMA reaffirm Policy H-110.987, which supports efforts to ensure drug prices are affordable to patients.
4. That our AMA reaffirm Policy D-110.987, which supports efforts to increase PBM transparency and regulation.
5. That our AMA oppose drug payment methodologies that result in physician practices being paid at less than the cost of acquisition, inventory, storage, and administration of relevant drugs and other necessary related clinical services.

Fiscal Note: Less than $500

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Prescription Medication Price Negotiation
Policy Appendix

Additional Mechanisms to Address High and Escalating Pharmaceutical Prices, H-110.980
1. Our American Medical Association (AMA) will advocate that the use of arbitration in determining the price of prescription drugs meet the following standards to lower the cost of prescription drugs without stifling innovation:
a. The arbitration process should be overseen by objective, independent entities.
b. The objective, independent entity overseeing arbitration should have the authority to select neutral arbitrators or an arbitration panel.

c. All conflicts of interest of arbitrators must be disclosed and safeguards developed to minimize actual and potential conflicts of interest to ensure that they do not undermine the integrity and legitimacy of the arbitration process.
d. The arbitration process should be informed by comparative effectiveness research and cost-effectiveness analysis addressing the drug in question.
e. The arbitration process should include the submission of a value-based price for the drug in question to inform the arbitrator's decision.
f. The arbitrator should be required to choose either the bid of the pharmaceutical manufacturer or the bid of the payer.
g. The arbitration process should be used for pharmaceuticals that have insufficient competition; have high list prices; or have experienced unjustifiable price increases.
h. The arbitration process should include a mechanism for either party to appeal the arbitrator's decision.
i. The arbitration process should include a mechanism to revisit the arbitrator's decision due to new evidence or data.
2. Our AMA will advocate that any use of international price indices and averages in determining the price of and payment for drugs should abide by the following principles:
a. Any international drug price index or average should not be used to determine or set a drug's price, or determine whether a drug's price is excessive, in isolation.
b. The use of any international drug price index or average should preserve patient access to necessary medications.
c. The use of any international drug price index or average should limit burdens on physician practices.
d. Any data used to determine an international price index or average to guide prescription drug pricing should be transparent and updated regularly.
3. Our AMA supports the use of contingent exclusivity periods for pharmaceuticals, which would tie the length of the exclusivity period of the drug product to its cost-effectiveness at its list price at the time of market introduction. (CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20; Modified: CMS Rep. 4, A-22)

Pharmaceutical Costs, H-110.987
1. Our American Medical Association (AMA) encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports:
a. drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase;
b. legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and

c. the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10 percent or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation. (CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19; Appended: Res. 113, I-21; Reaffirmed in lieu of: Res. 810, I-22; Reaffirmed: Res. 801, I-23; Reaffirmed: Res. 801, I-23)

Value-Based Management of Drug Formularies, H-110.979
Our American Medical Association: (1) will advocate that pharmacy benefit managers (PBMs) and health plans use a transparent process in formulary development and administration, and include practicing network physicians from the appropriate medical specialty when making determinations regarding formulary inclusion or placement for a particular drug class; (2) will advocate that any refunds or rebates received by a health plan or PBM from a pharmaceutical manufacturer under an outcomes-based contract be shared with impacted patients; and (3) opposes indication-based formularies in order to protect the ability of patients to access and afford the prescription drugs they need, and physicians to make the best prescribing decisions for their patients. (CMS Rep. 6,
I-20)

Incorporating Value into Pharmaceutical Pricing, H-110.986
1. Our American Medical Association (AMA) supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles:
a. value-based prices of pharmaceuticals should be determined by objective, independent entities;
b. value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes;
c. processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role;
d. processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients;
e. processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and
f. value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.
2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.
3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size. (CMS Rep. 05, I-16; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: CMS-CSAPH Rep. 01, A-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: CSAPH Rep. 2, I-19; Reaffirmed: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 6, I-20; Reaffirmed: Res. 113, A-23)

Prescription Drug Prices and Medicare, D-330.954
1. Our American Medical Association (AMA) will support federal legislation which gives the Secretary of the Department of Health and Human Services the authority to negotiate contracts with manufacturers of covered Part D drugs.
2. Our AMA will work toward eliminating Medicare prohibition on drug price negotiation.
3. Our AMA will prioritize its support for the Centers for Medicare & Medicaid Services to negotiate pharmaceutical pricing for all applicable medications covered by CMS. (Res. 211, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 201, I-11Appended: Res. 206, I-14; Reaffirmed: CMS Rep. 2, I-15; Appended: Res. 203, A-17; Reaffirmed: CMS Rep. 4, I-19; Reaffirmed: CMS Rep. 3, I-20; Reaffirmed: Res. 113, I-21; Reaffirmed: CMS Rep. 4, A-22; Reaffirmed in lieu of: Res. 810, I-22)

The Impact of Pharmacy Benefit Managers on Patients and Physicians, D-110.987
1. Our American Medical Association (AMA) supports the active regulation of pharmacy benefit managers (PBMs) under state departments of insurance.
2. Our AMA will 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. Our AMA supports 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. Our AMA supports 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. Our AMA supports 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. Our AMA encourages increased transparency in how DIR fees are determined and calculated. (CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 6, I-20)

Inappropriate Actions by Pharmacies and Pharmacy Benefit Mangers, D-120.988
Our American Medical Association, in cooperation with pharmacy benefit managers, pharmacy companies, and other drug retailing organizations, shall develop model procedures that physicians may use when prescribing off-formulary pharmaceuticals that are medically indicated and that these procedures be in compliance with the Health Insurance and Portability and Accountability Act of 1996. (Res. 528, A-02; Reaffirmation I-04; Reaffirmation A-06; Reaffirmed: CSAPH Rep. 01, A-16)

Evaluating Actions by Pharmacy Benefit Manager and Payer Policies on Patient Care, D-120.934
1. Our American Medical Association (AMA) will take steps to implement AMA Policies H-120.947 and D-35.981 that prescriptions must be filled as ordered by physicians or other duly authorized/licensed persons, including the quantity ordered.
2. Our AMA will work with pharmacy benefit managers, payers, relevant pharmacy associations, and stakeholders to: (a) identify the impact on patients of policies that restrict prescriptions to ensure access to care and urge that these policies receive the same notice and public comment as any other significant policy affecting the practice of pharmacy and medicine; and (b) prohibit pharmacy actions that are unilateral medical decisions.
3. Our AMA will report back at the 2018 Annual Meeting on actions taken to preserve the purview of physicians in prescription origination. (Res. 233, I-17; Reaffirmed: CMS Rep. 05, A-23)

Prior Authorization and Utilization Management Reform, H-320.939
1. Our American Medical Association (AMA) will continue its widespread prior authorization (PA) advocacy and outreach, including promotion and/or adoption of the Prior Authorization and Utilization Management Reform Principles, AMA model legislation, Prior Authorization Physician Survey and other PA research, and the AMA Prior Authorization Toolkit, which is aimed at reducing PA administrative burdens and improving patient access to care.
2. Our AMA will oppose health plan determinations on physician appeals based solely on medical coding and advocate for such decisions to be based on the direct review of a physician of the same medical specialty/subspecialty as the prescribing/ordering physician.
3. Our AMA 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.

4. Our AMA will advocate for health plans to minimize the burden on patients, physicians, and medical centers when updates must be made to previously approved and/or pending prior authorization requests. (CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18; Appended: Res. 812, I-18; Reaffirmed in lieu of: Res. 713, A-19; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: Res. 811, I-19; Reaffirmed: CMS Rep. 4, A-21; Appended: CMS Rep. 5, A-21; Reaffirmation: A-22)

Prior Authorization Reform, D-320.982
Our American Medical Association will explore emerging technologies to automate the prior authorization process for medical services and evaluate their efficiency and scalability, while advocating for reduction in the overall volume of prior authorization requirements to ensure timely access to medically necessary care for patients and reduce practice administrative burdens. (Res. 704, A-19; Reaffirmation: A-22)

Health Insurance Affordability, H-165.828
1. Our American Medical Association (AMA) supports modifying the eligibility criteria for premium credits and cost-sharing subsidies for those offered employer-sponsored coverage by lowering the threshold that determines whether an employee's premium contribution is affordable to the level at which premiums are capped for individuals with the highest incomes eligible for subsidized coverage in Affordable Care Act (ACA) marketplaces.
2. Our AMA supports legislation or regulation, whichever is relevant, to fix the ACA's "family glitch," thus determining the eligibility of family members of workers for premium tax credits and cost-sharing reductions based on the affordability of family employer-sponsored coverage and household income.
3. Our AMA encourages the development of demonstration projects to allow individuals eligible for cost-sharing subsidies, who forego these subsidies by enrolling in a bronze plan, to have access to a health savings account (HSA) partially funded by an amount determined to be equivalent to the cost-sharing subsidy.
4. Our AMA supports capping the tax exclusion for employment-based health insurance as a funding stream to improve health insurance affordability, including for individuals impacted by the inconsistency in affordability definitions, individuals impacted by the "family glitch," and individuals who forego cost-sharing subsidies despite being eligible.
5. Our AMA supports additional education regarding deductibles and cost-sharing at the time of health plan enrollment, including through the use of online prompts and the provision of examples of patient cost-sharing responsibilities for common procedures and services.
6. Our AMA supports efforts to ensure clear and meaningful differences between plans offered on health insurance exchanges.
7. Our AMA supports clear labeling of exchange plans that are eligible to be paired with a Health Savings Account (HSA) with information on how to set up an HSA.
8. Our AMA supports the inclusion of pregnancy as a qualifying life event for special enrollment in the health insurance marketplace. (CMS Rep. 8, I-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmation: A-17)

Improving Medicaid and CHIP Access and Affordability, H-290.954
1. Our American Medical Association (AMA) opposes premiums, copayments, and other cost-sharing methods for Medicaid and the Children's Health Insurance Program, including Section 1115 waiver applications that would allow states to charge premiums or copayments to Medicaid beneficiaries.
2. Our AMA encourages the Centers for Medicare & Medicaid Services to amend existing Section 1115 waivers to disallow states the ability to charge premiums or copayments to Medicaid beneficiaries. (Res. 803, I-23)

Improving Affordability in the Health Insurance Exchanges, H-165.824
1. Our American Medical Association (AMA) will:
a. support adequate funding for and expansion of outreach efforts to increase public awareness of advance premium tax credits.
b. support expanding eligibility for premium tax credits up to 500 percent of the federal poverty level.
c. support providing young adults with enhanced premium tax credits while maintaining the current premium tax credit structure which is inversely related to income.
d. encourage state innovation, including considering state-level individual mandates, auto-enrollment and/or reinsurance, to maximize the number of individuals covered and stabilize health insurance premiums without undercutting any existing patient protections.
2. Our AMA supports:
a. eliminating the subsidy "cliff," thereby expanding eligibility for premium tax credits beyond 400 percent of the federal poverty level (FPL).

b. increasing the generosity of premium tax credits.
c. expanding eligibility for cost-sharing reductions.
increasing the size of cost-sharing reductions. (CMS Rep. 02, A-18; Appended: CMS Rep. 02, A-19; Reaffirmed: CMS Rep. 3, I-21)

7. IMPACT OF PATIENT NON-ADHERENCE ON QUALITY SCORES

Reference committee hearing: see report of Reference Committee G.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See Policies D-450.958, H-390.837, H-450.918y, H-450.947 and H-450.966

Policy D-450.950 was adopted at the 2024 Annual Meeting and asks our American Medical Association (AMA) to study the issue of patients and parents not adhering to physicians' recommendations such as preventive screenings and vaccinations resulting in a deficiency of quality metrics by physicians for which the physicians are penalized and identify equitable and actionable solutions. This report discusses quality of care metrics, measuring patient adherence, the role of coding in value-based care (VBC), patient adherence models, and includes several policy recommendations.

BACKGROUND

The National Academy of Medicine defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[1] Quality metrics assess the effectiveness of health care processes, outcomes, patient perceptions, and organizational structures or systems to meet assigned goals, such as safe, efficient, patient-centered, equitable, and timely care.[2] Increasingly, these quality measures are being linked to payment to ensure quality health care. For Medicare and Medicaid beneficiaries, the Centers for Medicare & Medicaid Services (CMS) uses measures in its various quality initiatives that include quality improvement, pay for reporting, and public reporting. Private payers are also increasingly measuring the performance of physicians, with the intent to provide financial incentives to improve health care delivery and establish transparency programs to allow comparison among physicians. While more than half of health care payments are still fee-for-service, CMS continues to expand its value-based payment and alternative payment model programs.[3] In 2022, CMS launched its National Quality Strategy which, "aims to promote the highest quality outcomes and safest care for all individuals" and instills a person-centered approach to the broader goal of quality by focusing on the overall care trajectory across the continuum of care. Further, the approach seeks to reduce provider burden, advance equity, aid in the transition from manual to digital reporting, and clarify comparison between quality and VBC programs.

Broadly speaking, quality can be measured in three ways: structure, process, and outcome.[4] Structural measures focus on the attributes of a setting in which the care is received. Some examples of structural measures include whether the health care organization uses electronic medical records, the number or proportion of board-certified physicians, or the ratio of providers to patients.[5] Process measures assess the interaction between the physician and patient and include the percentage of people receiving preventive services (such as mammograms or immunizations) or the percentage of people with diabetes who have their blood sugar evaluated and controlled.[6] Lastly, outcome measures address morbidity or quality of life. Examples of outcome measures include the percentage of patients who die because of surgery (surgical mortality rates) or the rate of surgical complications or hospital-acquired infections.[7] Some other examples of measurable care include: patients' reports on the care and service they receive from the hospital (process, structure, or outcome), provision of care instructions upon hospital discharge for certain conditions (process), percentage of patients receiving recommended hospital care for specific conditions such as heart attack (process), pneumonia care (process), and prevention of surgical infection (outcome), rates at which patients fall and incur injury during a hospital stay (outcome), and number of beds and the types of services available (structure).[8]

Unique challenges have arisen during the transition to VBC. For instance, the distinct values, perspectives, and self-interests of health care stakeholders have made it difficult to clarify what should be assessed. Beyond this, the considerable variety of quality measures has caused confusion as they do not share a common theme. Further, the increased requirement to report quality measures (quantity or complexity) leads to increased reporting burden. While

the Medicare Merit-based Incentive Payment System (MIPS) is well intentioned, the reporting requirements are burdensome to physician practices and often appear to be irrelevant. MIPS is not unique in that the nature of having to report any quality measures creates a burden. It may be presumed that improving care is ancillary to "checking a box." Further, despite the current efforts to prioritize effective and relevant metrics to determine quality care, the problems within the current framework remain. According to the Commonwealth Fund, many primary care physicians have decided not to participate in value-based models based on "imperfect performance measures," as they believe that quality suffers because of these measures.[9] Indeed, commercial insurers often use the same, or similar, quality measures as CMS to adjust physician payment.

Beyond poor outcome scores, a physician can feel the negative impacts of VBC in a myriad of ways. For instance, there is financial risk associated with changing the payment structure. If the physician, or practice, does not meet targets or costs exceed what is expected, this can be a significant deterrent to VBC.[10] The financial risk can be especially pronounced if the practice does not have the infrastructure or resources to manage the consequences. Beyond this, data interoperability brought forth by fragmented health care data systems makes it difficult to obtain a complete understanding of the patient and their outcomes, which is critical for VBC.[11] Additionally, the administrative burden associated with VBC can be onerous, a transition to VBC may require a workflow redesign, and lack of technology and resources may impede the ability of the physician or practice to participate in VBC.[12]

Ideally, VBC would improve the quality of care and patient experience while decreasing health care costs. However, it is unclear whether that is the case. In some studies, there is evidence demonstrating its benefits.[13] Other studies contradict those sentiments.[14,15] Patient non-adherence to medication protocol, for instance, continues to be a significant issue.[16] One recent estimate revealed that morbidity and mortality associated with non-optimized prescription drug regimens, with non-adherence playing a significant role, cost $528.4 billion per year on average in the United States (U.S.).[17] Beyond this, health care costs have continued to rise during the transition to VBC. The cost of disease progression, readmissions, wasted resources, labor burden, and insurance costs represent three to ten percent of total health care costs in the U.S.[18] Indeed, one meta-analysis showed that all-cause non-adherence costs ranged from $5,271 to $52,341 per person.[19]

Poor patient adherence can obscure a prescribed treatment's effectiveness, or whether it results in avoidable hospitalization, increased mortality, and/or increased health care costs. Physicians may change the regimen with the belief that the health care provided is not improving the patient's outcome, thereby unintentionally negatively impacting a patient, and further complicating the cost or complexity of the health care provided. In addition, a physician may receive a poor-quality score despite providing evidence-based care.[20] However, if a physician provides care that focuses on the patient's experience (e.g., choosing a lower cost alternative treatment at the patient's request) and the patient fails to improve, the physician is deemed to have provided poor quality care. For diabetes patients, for example, an individual may have a remarkably high blood sugar level when they begin seeing their physician. Over time, the blood sugar level may improve significantly due to the provision of evidence-based care, but the physician's care will be rated as poor quality if it does not meet a certain threshold.[21] Alternatively, if a patient cannot afford medication and the physician provides alternative mechanisms that are cost-effective but do not significantly improve blood sugar levels, the care is considered "poor quality."

Similarly, a physician may have a low MIPS score despite providing evidence-based care. One study suggests that MIPS score was inconsistently associated with performance on process and outcome measures as the MIPS program may be ineffective at measuring and incentivizing quality improvement among U.S. physicians.[22] Further, it was found that physicians caring for medically complex and socially vulnerable patients were more likely to receive low MIPS scores, even when they delivered relatively high-quality care.[23] In another study, it was proposed that safety-net hospitals are more likely to serve patients with higher risk factors and thus have worse performance measures, on average.[24] Hospital-based value-based payment programs may unintentionally increase financial penalties for social safety-net hospitals. Therefore, some VBC payment systems may be ineffective at evaluating and providing payment for quality of care in certain circumstances.

Furthermore, to understand the limitations of quality measures, it is important to consider disparities, structural racism, and discrimination. In 2003, the Institute of Medicine published the report, "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care," which provided specific recommendations to reduce disparities by improving financing, allocation of care, communication, and community-based care.[25] The report outlined that racial and ethnic disparities are consistent across a range of illnesses and health care services. Racial and ethnic disparities remain even after adjustment for socioeconomic differences and other health care access related factors.[26] Moreover, while

disparities based on race or ethnicity are pervasive, it is important to note that other forms of discrimination impact the health of a patient. For instance, sex, gender, sexual orientation, disability, and socioeconomic status can impede effective health care and create disparate outcomes. Further, while discrimination, bias, and disparities are prevalent in health care, they are also ubiquitous throughout society. Outcome measures evaluate physicians by the outcome of the patient, but many factors outside the physician's control, yet affect a patient's access. In some circumstances, a physician may help by creating alternative options for payment, testing, or treatment. However, many social drivers of health (SDOH) are beyond the control of a physician.

MEASURING PATIENT ADHERENCE

Patient adherence emphasizes the patient's active involvement and decision-making process in following treatment recommendations, suggesting that the patient understands, agrees with, and takes responsibility for their health behaviors. As VBC relies on outcome-based measures, patient adherence becomes a critical factor for tying physician payment to measurement since measures assume patient adherence with prescribed treatments. Unfortunately, patient adherence is contingent on many factors outside the control of a physician. Further, tying physician payment to measures that focus on patient adherence may improperly penalize physicians who are otherwise providing quality care.

The World Health Organization (WHO) defines adherence as "the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider."[27] Measuring adherence involves objective, subjective, and biomedical strategies. Subjective strategies can include questionnaires, diaries, and interviews. Objective strategies can include counting remaining dosages, table counts, patterns of missed dosages, treatment attendance, or electronic monitoring devices which record the time and date when a medication container was opened. Biochemical measures usually involve the detection of a metabolite or marker in bodily fluids. There are drawbacks to each of the methods. For instance, subjective ratings may lead to overestimates of adherence and underestimates of non-adherence. Objective strategies, such as electronic monitoring devices or the use of pharmacy databases may be expensive and time consuming. Biochemical measures might not account for variability in areas such as drug-drug interactions, drug-food interactions, and individual pharmacokinetics of the drug. The most accurate approach may include a combination of all three.

Patient adherence research has focused on the determinants of non-adherence, extent of non-adherence, and strategies to improve adherence. Failure to address the patient's perspective in adherence research has led to a lack of progress in research as well as the lack of understanding physicians' prescribing practices. Furthermore, individual bias, or prejudice, is a key factor when understanding non-adherence. Physician bias, for instance, may impact care. A physician may unintentionally associate the patient's attributes with the care they receive because of ignorance of social or cultural norms.[28] Additionally, physicians, like others in our society, are affected by stereotypes.[29] These impediments to good health care outcomes, and effective care, may make it difficult for a patient to follow physician recommendations.

Furthermore, patient non-adherence to screening tests and vaccinations continues to be a significant impediment to quality metrics. Despite the importance of chronic disease screening, underutilization persists. Even though there is a preponderance of data explicating the usefulness of vaccines, there continues to be concern about their side effects. Parents may be hesitant to vaccinate their children due to concerns about long-term side effects, a lack of trust in medical authorities, and doubt about the benefits of vaccines.[30] Globally, while there was an improvement in vaccination rates in 2022 as compared to 2021, they still remain below 2019 rates.[31] In screening for lung cancer, patient adherence was found to be lower for high-risk individuals – people who smoke, those who are not white, or individuals older than 65.[32] Therefore, it was suggested that interventions to promote adherence should prioritize current smokers and smokers from minority populations.[33] While lung cancer screening is underutilized by minority populations, cancer screening, in general, continues to be underutilized for all populations despite its benefits to reduce morbidity and mortality.[34] Further, adherence to recommended blood-based screening is underutilized, which is troubling as it is an option for early detection and management of cancers or other chronic diseases.[35]

However, some key themes within studies give credence to ways to improve adherence. Physician recommendations significantly improve cancer screening rates among most populations.[36] While physician recommendations are necessary to improve adherence, they are not the only consideration, as the quality and content of the patient/parent-physician discussion also play key roles in the level of adherence since they foster shared decision making.[37] Limited success is also seen with vaccine counseling, as it continues to be the most significant way to improve vaccination

rates, especially when coupled with technology such as sending text message reminders and allowing patients to make vaccine reservations.[38]

THE ROLE OF CODING IN VALUE-BASED CARE

As mentioned previously, SDOH factors outside of the control of a physician may impact health care outcomes. Some of these factors may be captured in the *Current Procedural Terminology* (CPT®) nomenclature, particularly with Category II codes.[39] Category II CPT codes are optional, supplemental codes used for performance measurement and intended to facilitate data collection about quality of care by reporting certain services and/or test results that support performance measures.[40] In addition to performance measure codes, performance measure modifiers are used to account for reporting measure exceptions due to the inability to meet the denominator action of the measure for medical, patient, or system reasons.[41]

Research has been compiled toward understanding how the CPT code set can help physicians adapt to VBC arrangements. Recently, the AMA developed an issue brief in conjunction with Manatt Health Strategies, "Accelerating the Adoption of Value-Based Care with the CPT Code Set," which outlines how the CPT code set supports current VBC arrangements and opportunities for continued evolution.[42] The issue brief synthesizes the feedback received from 34 organizations representing VBC provider organizations, health plans, integrated delivery systems, VBC enablement organizations, and health technology organizations, identifying three areas where codes are successfully enabling VBC adoption.[43] Interviewees suggested a variety of opportunities for the CPT code set to support accelerated adoption of VBC models, such as, "considering how CPT might address new types of health care services being delivered, such as how to best account for the delivery of services cognizant of patients' SDOH factors."[44] However, it is important to note that revision or expansion of the CPT code set must be done independent of the AMA HOD, as Policy H-70.919 attests that the CPT Editorial Panel maintains autonomy in the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements, and modifiers.

There are limitations associated with Category II CPT codes, namely that CMS has replaced most Category II CPT codes with Healthcare Common Procedure Coding System (HCPCS) Level II codes. HCPCS Level II codes identify professional services and temporary procedures (G codes) as well as medical services (M codes) and can be used to report services such as the administration of a vaccine, ultrasound, or mammogram.[45] Furthermore, HCPCS Level II codes are used in the MIPS Value Pathways program to identify specific subsets of measures and activities to meet MIPS reporting requirements.[46] While HCPCS Level II codes were initially developed for Medicare claims, many private payers have adopted them. HCPCS Level II codes were selected as part of the Health Insurance Portability & Accountability Act (HIPAA) standard procedural code set for describing services, health care equipment, or supplies not represented in CPT.[47] One of the advantages of HCPCS Level II codes is that they allow for more specificity than CPT codes. For example, HCPCS Level II codes can identify durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies (like surgical bandaging or splints/casts).[48] While HCPCS Level II codes provide a standardized system for reporting across different payers, they have some drawbacks, as well. The complexity of the HCPCS Level II coding nomenclature necessitates specialized knowledge and can present obstacles for health care systems.[49] Additionally, selecting an incorrect code may lead to improper payment or a denial of claims which can result in recoupment or actions against the physician. Furthermore, the code set is updated throughout the year, which can make it difficult to stay up to date on the coding infrastructure.

WORLD HEALTH ORGANIZATION MULTIDIMENSIONAL ADHERENCE MODEL (WHO-MAM)

In 2003, the WHO released, "Adherence to Long Term Therapies: Evidence for Action," which provided a critical review of what is known about and potential solutions to improve adherence.[50] The report was developed as a result of the WHO Adherence to Long-term Therapies Project, a global initiative launched in 2001 by the Noncommunicable Diseases and Mental Health Cluster of the WHO. The tenets include:[51]

- Poor adherence to treatment of chronic diseases is a worldwide problem of striking magnitude.
- The impact of poor adherence grows as the burden of chronic disease grows worldwide.
- The consequences of poor adherence to long-term therapies are poor health outcomes and increased health care costs.
- Improving adherence also enhances patients' safety.
- Adherence is an important modifier of health system effectiveness.

- Increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments.
- Health systems must evolve to meet new challenges.
- Patients need to be supported, not blamed.
- Adherence is simultaneously influenced by several factors.
- Patient-tailored interventions are required.
- Adherence is a dynamic process that needs to be followed up.
- Health professionals need to be trained in adherence.
- Family, community, and patients' organizations: a key factor for success in improving adherence.
- A multidisciplinary approach towards adherence is needed.

In addition, the report introduced five dimensions of adherence. The multidimensional interplay between these factors determines adherence to treatment. As the report mentions, "the common belief that patients are solely responsible for taking their treatment is misleading and most often reflects a misunderstanding of how other factors affect people's behavior and capacity to adhere to their treatment." However, the model may provide a solution to equitably promote adherence to physician recommendations. The dimensions of adherence include:[52]

A. Social and economic factors – negative impacts can include poor socioeconomic status, poverty, illiteracy, low level of education, unemployment, lack of effective social support networks, unstable living conditions, long distance from treatment center, high cost of transport, high cost of medication, changing environmental situations, culture and lay beliefs about illness and treatment, and family dysfunction.
B. Health care team and system-related factors – negative impacts can include poorly developed health services with inadequate or non-existent payment by health insurance plans, poor medication distribution systems, lack of knowledge and training for health care providers on managing chronic diseases, overworked health care providers, lack of incentives and feedback on performance, short consultations, weak capacity of the system to educate patients and provide follow-up, inability to establish community support and self-management capacity, lack of knowledge on adherence and of effective interventions for improving it.
C. Condition-related factors – condition-related factors represent illness-related demands faced by the patient.
D. Therapy-related factors – the most notable therapy-related factors are the complexity of the medical regimen, duration of treatment, previous treatment failures, frequent changes in treatment, the immediacy of beneficial effects, side-effects, and the availability of medical support to deal with them.
E. Patient-related factors – patient-related factors represent the resources, knowledge, attitudes, beliefs, perceptions, and expectations of the patient.

ADDITIONAL ADHERENCE MODELS

Besides WHO-MAM, there are other models to consider that could provide a roadmap to equitably improve adherence, such as:

- Medication Adherence Model (MAM):[53] This option was developed to address medication adherence in patients with hypertension. Its three core concepts are: a) purposeful action; b) patterned behavior; and c) feedback. Patients' initiating and sustaining medication adherence are dependent on the deliberate decision to take medications based on perceived need, effectiveness, and safety (Purposeful Action). Then they establish medication-taking patterns through access, routines, and remembering (Patterned Behavior). Individuals use information, prompts, or events (Feedback) during the appraisal process to evaluate health treatment that, in return, influences individuals' levels of Purposeful Action and Patterned Behavior.

- Hierarchical Model for Medication Adherence (HMMA):[54] The HMMA was developed in consideration of Maslow's hierarchy of needs. In this model, an individual acquires certain skills/beliefs/behaviors at lower levels to achieve the higher level of medication adherence behavior. At the base level, every individual should have adequate health literacy. Once the patient understands their disease and treatment, the beliefs component comes into play. The next phase in the model is an individual's belief in their medicines. The final stage of the hierarchical model is self-efficacy.

- Transtheoretical Model (TTM):[55] The TTM is a theory of change that a common set of change processes can be replicated across behaviors and situations. TTM posits that health behavior change involves progress through six stages of change: precontemplation, contemplation, preparation, action, maintenance, and termination. The stages

are transtheoretical and integrate principles of change from across a variety of theories. Each stage brings an individual closer to behavioral changes.

- Three Factor Heuristic Model:[56] The model comprises three important clinical actions: (1) insuring that patients have the right information and know how to adhere – including listening to patients' concerns, encouraging their participation and partnership in decision-making, building trust and empathy, and enhancing recall; (2) helping patients believe in their treatment and become motivated to commit to it - that is, addressing the cognitive, social, cultural normative and contextual factors that affect patients' beliefs, attitudes and motivation; and (3) assisting patients to overcome practical barriers to treatment adherence and develop a workable strategy for long-term disease management - including assessing and enhancing patients' social support, identifying and treating their depression and helping patients overcome cost-related treatment barriers.

- Health Belief Model (HBM):[57] HBM allows physicians, and other health care professionals, access and assess the patient's behavior by breaking down their beliefs. Following the HBM, a health care provider should: verify the patient's understanding of the potential consequences of their disease; make sure the patient knows that they are susceptible to those consequences, and that they have a degree of control over the outcome; assess the patient's understanding of the benefits of the treatment to ensure they fully understand those benefits; and make sure that the patient has a realistic understanding of side effects to ensure that if side effects manifest, they do not undermine the perceived value of the behavior change.

- Theory of Planned Behavior (TPB):[58] TPB suggests that people will at least form the intention to conduct a given behavior if all three of the domains – beliefs about a behavior, the perception of a subjective norm, and the perception of control – come together. TPB adds an important social element because people are social and have strong reactions to behaviors that are perceived to affect social standing. To apply the TPB, health care providers should consider the following suggestions: ask the patient how difficult they think it will be to carry out suggestions and follow the prescription, ask the patient what they think might lead to failure, inquire about the degree to which the people close to the patient will either help or hinder behavior changes, and discuss the patient's perception of what other people or society in general might feel about the condition or treatment behaviors.

While there is an array of options to help assuage non-adherence, it is important to highlight that no one option is the "gold-standard." Indeed, none of the options boast a wide array of studies to verify legitimacy. Therefore, more research should be compiled to evaluate the most effective models.

IMPROVING PATIENT ADHERENCE

There may be opportunities to help improve patient adherence in an equitable way. According to the WHO report, some innovative interventions can target the patient, physician, and the health care system as outlined below. For example, the AMA Improving Health Outcomes (IHO) Group supports physicians, care teams and the patients they serve to prevent cardiovascular disease. IHO found that a lack of blood pressure measurement protocol contributes to variation and inaccurate measurements. As a result, patients with uncontrolled hypertension are sub-optimally treated, which frequently leads to non-adherence of medications and treatment plans. In response, IHO created the MAP (Measure Accurately, Act Rapidly, and Partner with Patients) Framework to address the systemwide problem.[59]

While the WHO report did not identify a single intervention as most effective, promising methods include a combination of the following strategies:[60]

- Patient Education
- Behavioral Skills
- Self-Rewards
- Social Support
- Telephone Follow-up

Further, it was found that the most effective interventions directed at patients aim to enhance self-regulation or self-management capabilities, such as:[61]

- Self-Monitoring
- Goal Setting
- Stimulus Control
- Behavioral Contracting
- Commitment Enhancement
- Creating Social Support
- Relapse Prevention
- Corrective Feedback

However, as the WHO's report outlines, "even the most efficacious patient-focused interventions have no substantial effects on adherence behavior over the long term." Therefore, further study is required to understand viable options to improve adherence behavior long-term.

AMA POLICY

Policy H-450.947 outlines Principles for Pay-for-Performance and Guidelines for Pay-for-Performance, which support the formation, implementation, and assessment of fair and ethical Pay-for-Performance programs. Further, the principles and guidelines reinforce the importance of a patient-centered approach and evidence-based performance measures.

Policy H-450.966 supports the need for the AMA, national medical specialty societies, state medical associations, and physicians to actively participate in the development, implementation, and assessment of quality and performance measures. Policy H-410.960 encourages physicians to support the development and usage of quality improvement standards and indicators for measurement of quality practice.

Policy H-390.837 encourages CMS to simplify MIPS, advocates for appropriate scoring adjustments for physicians treating high-risk beneficiaries in the Medicare Access and CHIP Reauthorization Act (MACRA) system, and urges CMS to study whether the MACRA system disincentives physicians to provide care to sicker Medicare patients. In addition, there are several policies that are more specific about the removal of measures or metrics within quality scores. Policy D-450.955 supports asking CMS to remove pain scores from quality metrics that impact payment from nursing facilities, while Policy D-450.958 advocates that CMS remove pain survey questions from the Hospital Consumer Assessment of Healthcare Providers and Systems and Clinician and Group Consumer Assessment of Healthcare Providers and Systems and encourages health care systems not to link physician compensation and attainment to patient pain scores.

DISCUSSION

While the Council recognizes the importance of performance measures and values their contribution to VBC, many require patient adherence which is not always controlled by the physician. In addition, the Council believes that physicians have a significant role to play in the development, assessment, and implementation of quality measures.

Quality metrics are specific, quantifiable measures used to evaluate the quality of care provided to patients. The metrics assess various aspects of health care delivery, including patient outcomes, safety, efficiency, and patient satisfaction. While these metrics are important in the evaluation of the care provided, unique challenges have been identified. For instance, quality metrics may not account for the progression of a patient. While a patient may get significantly better, they may not meet a certain threshold indicating so-called "good" care. Further, patient adherence may be a significant issue. A patient may not take medication because of social stigma or cultural differences. Beyond this, quality metrics do not consider the systemic issues that impede quality of care. Structural racism is a significant factor in the health care outcomes of patients, as is discrimination in other forms – such as disability, sex, gender, and socioeconomic status. Therefore, the Council supports the modification of quality measures and removal of outcome scores that are unfairly tied to patient non-adherence. Further, the Council recommends amending Policy D-450.958, to remove patient outcomes and patient non-adherence to treatment from the HCAHPS and to remove patient outcomes and adherence to treatment from the evaluation of physician compensation, retention, promotion, and

provider network participation. The Council recommends reaffirming Policy H-450.947, which outlines the Principles for Pay-for-Performance and Guidelines for Pay-for-Performance to highlight best practices when developing VBC.

Significant problems continue to exist with MIPS, leading the Council to believe that the unique challenges of MIPS are an organic extension of the issues related to VBC. As such, the Council recommends reaffirming Policy H-390.837, which encourages CMS to improve MIPS to a simplified quality and payment system. Furthermore, the Council believes that physicians must have a significant role in the assessment of quality and performance measures. Therefore, the Council recommends reaffirming Policy H-450.966, which provides the principles to consider while assessing quality and performance measures and the need for the AMA, national medical specialty societies, and state medical associations to be involved in the assessment, as well as the development and implementation of quality measures.

The importance of patient adherence in VBC cannot be overstated. VBC relies on outcome measures which are determined by the ability of the patient to adhere to prescribed treatments. However, patient adherence is contingent on many factors outside a physician's control. Research on patient adherence is lacking, specifically a patient's perspective, which has led to a lack of knowledge about how to address long-term adherence. Therefore, the Council recommends that additional research be conducted to understand patient non-adherence, and potential models or strategies to improve adherence. Furthermore, many models have been developed to address patient adherence and holistically improve health care outcomes. The most notable is the WHO-MAM, which was introduced in 2003, providing a critical review of what is known about and potential solutions to equitably improve adherence. Fourteen tenets captured the findings of the report, and five dimensions of adherence were outlined to diagram the multidimensional interplay that determines adherence. Therefore, the Council recommends support for these types of models to provide guidance to improve patient adherence.

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) support the removal of physician outcome scores that are unfairly tied to patient non-adherence.
2. That our AMA support the development of models that provide guidance for physicians, medical practices, and health care teams to improve patient adherence in an individualized, continuous, and multidisciplinary way.
3. That our AMA support additional research to understand the intricacies of non-adherence and potential models/strategies to improve adherence.
4. That our AMA amend Policy D-450.958, "Pain Medicine," by addition and deletion, including a change in title:

   PAIN MEDICINE AND PATIENT ADHERENCE IN QUALITY CARE ASSESSMENT,
   D-450.958
   Our AMA: (1) ~~continues to advocate that the Centers for Medicare & Medicaid Services (CMS) remove the pain survey questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); (2)~~ continues to advocate that the Centers for Medicare & Medicaid Services ~~CMS~~ not incorporate items linked to pain scores and adherence to physician recommendations as part of the Consumer Assessment of Healthcare Providers and Systems ~~CAHPS~~ Clinician and Group Surveys and the Hospital Consumer Assessment of Healthcare Providers and Systems scores in future surveys; and (2) ~~(3)~~ encourages hospitals, clinics, health plans, health systems, and academic medical centers not to link physician compensation, employment retention or promotion, faculty retention or promotion, and provider network participation to patient satisfaction scores relating to the evaluation and management of pain and better adherence to physician recommendations.

5. That our AMA reaffirm Policy H-450.947, which outlines the Principles for Pay-for-Performance and Guidelines for Pay-for-Performance.
6. That our AMA reaffirm Policy H-450.966, which provides the principles to consider while assessing quality and performance measures and the need for the AMA and state medical societies to be involved in the assessment, as well as the development and implementation, of quality measures.
7. That our AMA reaffirm Policy H-390.837, which encourages the Centers for Medicare & Medicaid Services (CMS) to revise the Merit-Based Incentive Payment System to a simplified quality and payment system, asks the AMA to advocate for appropriate scoring adjustments for physicians treating high risk beneficiaries in the Medicare Access and CHIP Reauthorization Act (MACRA) program, and urges CMS to continue studying whether MACRA creates a disincentive for physicians to provide care to sicker Medicare patients.

8. Rescind Policy D-450.950, as having been completed with this report.

Fiscal Note: Less than $500.

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Council on Medical Service Report 7-A-25
Impact of Patient Non-adherence on Quality Scores
Policy Appendix

Quality Management H-450.966

1. Our AMA continues to advocate for quality management provisions that are consistent with AMA policy.
2. Our AMA seeks an active role in any public or private sector efforts to develop national medical quality and performance standards and measures.
3. Our AMA continues to facilitate meetings of public and private sector organizations as a means of coordinating public and private sector efforts to develop and evaluate quality and performance standards and measures.
4. Our AMA emphasizes the importance of all organizations developing, or planning to develop, quality and performance standards and measures to include actively practicing physicians and physician organizations in the development, implementation, and evaluation of such efforts.
5. Our AMA urges national medical specialty societies and state medical associations to participate in relevant public and private sector efforts to develop, implement, and evaluate quality and performance standards and measures.
6. Our AMA advocates that the following principles be used to guide the development and evaluation of quality and performance standards and measures under federal and state health system reform efforts:
    a. Standards and measures shall have demonstrated validity and reliability.
    b. Standards and measures shall reflect current professional knowledge and available medical technologies.
    c. Standards and measures shall be linked to health outcomes and/or access to care.
    d. Standards and measures shall be representative of the range of health care services commonly provided by those being measured.
    e. Standards and measures shall be representative of episodes of care, as well as team-based care.
    f. Standards and measures shall account for the range of settings and practitioners involved in health care delivery.
    g. Standards and measures shall recognize the informational needs of patients and physicians.
    h. Standards and measures shall recognize variations in the local and regional health care needs of different patient populations.
    i. Standards and measures shall recognize the importance and implications of patient choice and preference.
    j. Standards and measures shall recognize and adjust for factors that are not within the direct control of those being measured.
    k. Data collection needs related to standards and measures shall not result in undue administrative burden for those being measured.

BOT Rep. 35, A-94 Reaffirmed: CMS Rep. 10, I-95 Reaffirmed: CMS Rep. 7, A-05 Modified: CMS Rep. 6, A-13 Reaffirmed in lieu of Res. 714, A-14 Reaffirmed in lieu of Res. 814, I-14 Reaffirmed in lieu of Res. 208, A-15 Reaffirmed in lieu of Res. 223, A-15 Reaffirmed in lieu of Res. 203, I-15 Reaffirmed in lieu of Res. 216, I-15 Reaffirmed: BOT Rep. 20, A-16 Reaffirmed: CMS Rep. 02, I-17 Reaffirmation: A-22

Quality Patient Care Measures H-410.960
Our American Medical Association encourages all physicians to be open to the development and broader utilization of evidence-based quality improvement guidelines (pathways, parameters) and indicators for measurement of quality practice.
Res. 811, I-02 Reaffirmed: CSAPH Rep. 1, A-12 Reaffirmed: CSAPH Rep. 1, A-22

Pay-for-Performance Principles and Guidelines H-450-947
The following *Principles for Pay-for-Performance and Guidelines for Pay-for-Performance* are the official policy of our AMA.

PRINCIPLES FOR PAY-FOR-PERFORMANCE PROGRAMS
Physician pay-for-performance (PFP) programs that are designed primarily to improve the effectiveness and safety of patient care may serve as a positive force in our health care system. Fair and ethical PFP programs are patient-centered and link evidence-based performance measures to financial incentives. Such PFP programs are in alignment with the following five AMA principles:
1. Ensure quality of care - Fair and ethical PFP programs are committed to improved patient care as their most important mission. Evidence-based quality of care measures, created by physicians across appropriate specialties, are the measures used in the programs. Variations in an individual patient care regimen are permitted based on a physician's sound clinical judgment and should not adversely affect PFP program rewards.
2. Foster the patient/physician relationship - Fair and ethical PFP programs support the patient/physician relationship and overcome obstacles to physicians treating patients, regardless of patients' health conditions, ethnicity, economic circumstances, demographics, or treatment compliance patterns.
3. Offer voluntary physician participation - Fair and ethical PFP programs offer voluntary physician participation, and do not undermine the economic viability of non-participating physician practices. These programs support participation by physicians in all practice settings by minimizing potential financial and technological barriers including costs of start-up.
4. Use accurate data and fair reporting - Fair and ethical PFP programs use accurate data and scientifically valid analytical methods. Physicians are allowed to review, comment and appeal results prior to the use of the results for programmatic reasons and any type of reporting.
5. Provide fair and equitable program incentives - Fair and ethical PFP programs provide new funds for positive incentives to physicians for their participation, progressive quality improvement, or attainment of goals within the program. The eligibility criteria for the incentives are fully explained to participating physicians. These programs support the goal of quality improvement across all participating physicians.

GUIDELINES FOR PAY-FOR-PERFORMANCE PROGRAMS
Safe, effective, and affordable health care for all Americans is the AMA's goal for our health care delivery system. The AMA presents the following guidelines regarding the formation and implementation of fair and ethical pay-for-performance (PFP) programs. These guidelines augment the AMA's "Principles for Pay-for-Performance Programs" and provide AMA leaders, staff and members with operational boundaries that can be used in an assessment of specific PFP programs.
Quality of Care
- The primary goal of any PFP program must be to promote quality patient care that is safe and effective across the health care delivery system, rather than to achieve monetary savings.
- Evidence-based quality of care measures must be the primary measures used in any program.
1. All performance measures used in the program must be prospectively defined and developed collaboratively across physician specialties.
2. Practicing physicians with expertise in the area of care in question must be integrally involved in the design, implementation, and evaluation of any program.
3. All performance measures must be developed and maintained by appropriate professional organizations that periodically review and update these measures with evidence-based information in a process open to the medical profession.
4. Performance measures should be scored against both absolute values and relative improvement in those values.
5. Performance measures must be subject to the best-available risk- adjustment for patient demographics, severity of illness, and co-morbidities.
6. Performance measures must be kept current and reflect changes in clinical practice. Except for evidence-based updates, program measures must be stable for two years.
7. Performance measures must be selected for clinical areas that have significant promise for improvement.

- Physician adherence to PFP program requirements must conform with improved patient care quality and safety.
- Programs should allow for variance from specific performance measures that are in conflict with sound clinical judgment and, in so doing, require minimal, but appropriate, documentation.
- PFP programs must be able to demonstrate improved quality patient care that is safer and more effective as the result of program implementation.
- PFP programs help to ensure quality by encouraging collaborative efforts across all members of the health care team.
- Prior to implementation, pay-for-performance programs must be successfully pilot-tested for a sufficient duration to obtain valid data in a variety of practice settings and across all affected medical specialties. Pilot testing should also analyze for patient de-selection. If implemented, the program must be phased-in over an appropriate period of time to enable participation by any willing physician in affected specialties.
- Plans that sponsor PFP programs must prospectively explain these programs to the patients and communities covered by them.

Patient/Physician Relationship

- Programs must be designed to support the patient/physician relationship and recognize that physicians are ethically required to use sound medical judgment, holding the best interests of the patient as paramount.
- Programs must not create conditions that limit access to improved care.

1. Programs must not directly or indirectly disadvantage patients from ethnic, cultural, and socio-economic groups, as well as those with specific medical conditions, or the physicians who serve these patients.
2. Programs must neither directly nor indirectly disadvantage patients and their physicians, based on the setting where care is delivered or the location of populations served (such as inner city or rural areas).

- Programs must neither directly nor indirectly encourage patient de-selection.
- Programs must recognize outcome limitations caused by patient non-adherence, and sponsors of PFP programs should attempt to minimize non-adherence through plan design.

Physician Participation

- Physician participation in any PFP program must be completely voluntary.
- Sponsors of PFP programs must notify physicians of PFP program implementation and offer physicians the opportunity to opt in or out of the PFP program without affecting the existing or offered contract provisions from the sponsoring health plan or employer.
- Programs must be designed so that physician nonparticipation does not threaten the economic viability of physician practices.
- Programs should be available to any physicians and specialties who wish to participate and must not favor one specialty over another. Programs must be designed to encourage broad physician participation across all modes of practice.
- Programs must not favor physician practices by size (large, small, or solo) or by capabilities in information technology (IT).

1. Programs should provide physicians with tools to facilitate participation.
2. Programs should be designed to minimize financial and technological barriers to physician participation.

- Although some IT systems and software may facilitate improved patient management, programs must avoid implementation plans that require physician practices to purchase health-plan specific IT capabilities.
- Physician participation in a particular PFP program must not be linked to participation in other health plan or government programs.
- Programs must educate physicians about the potential risks and rewards inherent in program participation, and immediately notify participating physicians of newly identified risks and rewards.
- Physician participants must be notified in writing about any changes in program requirements and evaluation methods. Such changes must occur at most on an annual basis.

Physician Data and Reporting

- Patient privacy must be protected in all data collection, analysis, and reporting. Data collection must be administratively simple and consistent with the Health Insurance Portability and Accountability Act (HIPAA).
- The quality of data collection and analysis must be scientifically valid. Collecting and reporting of data must be reliable and easy for physicians and should not create financial or other burdens on physicians and/or their practices. Audit systems should be designed to ensure the accuracy of data in a non-punitive manner.

1. Programs should use accurate administrative data and data abstracted from medical records.
2. Medical record data should be collected in a manner that is not burdensome and disruptive to physician practices.
3. Program results must be based on data collected over a significant period of time and relate care delivered (numerator) to a statistically valid population of patients in the denominator.

- Physicians must be reimbursed for any added administrative costs incurred as a result of collecting and reporting data to the program.

- Physicians should be assessed in groups and/or across health care systems, rather than individually, when feasible.
- Physicians must have the ability to review and comment on data and analysis used to construct any performance ratings prior to the use of such ratings to determine physician payment or for public reporting.
1. Physicians must be able to see preliminary ratings and be given the opportunity to adjust practice patterns over a reasonable period of time to more closely meet quality objectives.
2. Prior to release of any physician ratings, programs must have a mechanism for physicians to see and appeal their ratings in writing. If requested by the physician, physician comments must be included adjacent to any ratings.
- If PFP programs identify physicians with exceptional performance in providing effective and safe patient care, the reasons for such performance should be shared with physician program participants and widely promulgated.
- The results of PFP programs must not be used against physicians in health plan credentialing, licensure, and certification. Individual physician quality performance information and data must remain confidential and not subject to discovery in legal or other proceedings.
- PFP programs must have defined security measures to prevent the unauthorized release of physician ratings.
Program Rewards
- Programs must be based on rewards and not on penalties.
- Program incentives must be sufficient in scope to cover any additional work and practice expense incurred by physicians as a result of program participation.
- Programs must offer financial support to physician practices that implement IT systems or software that interact with aspects of the PFP program.
- Programs must finance bonus payments based on specified performance measures with supplemental funds
- Programs must reward all physicians who actively participate in the program and who achieve pre-specified absolute program goals or demonstrate pre-specified relative improvement toward program goals.
- Programs must not reward physicians based on ranking compared with other physicians in the program.
- Programs must provide to all eligible physicians and practices a complete explanation of all program facets, to include the methods and performance measures used to determine incentive eligibility and incentive amounts, prior to program implementation.
- Programs must not financially penalize physicians based on factors outside of the physician's control.
- Programs utilizing bonus payments must be designed to protect patient access and must not financially disadvantage physicians who serve minority or uninsured patients.
- Programs must not financially penalize physicians when they follow current, accepted clinical guidelines that are different from measures adopted by payers, especially when measures have not been updated to meet currently accepted guidelines.
2. Our AMA opposes private payer, Congressional, or Centers for Medicare and Medicaid Services pay-for-performance initiatives if they do not meet the AMA's "Principles and Guidelines for Pay-for-Performance."
BOT Rep. 5, A-05 Reaffirmation A-06 Reaffirmed: Res. 210, A-06 Reaffirmed in lieu of Res. 215, A-06 Reaffirmed in lieu of Res. 226, A-06 Reaffirmation I-06 Reaffirmation A-07 Reaffirmation A-09 Reaffirmed: BOT Rep. 18, A-09 Reaffirmed in lieu of Res. 808, I-10 Modified: BOT Rep. 8, I-11 Reaffirmed: Sub. Res. 226, I-13 Appended: BOT Rep. 1, I-14 Reaffirmed in lieu of Res. 203, I-15 Reaffirmed in lieu of Res. 216, I-15 Reaffirmation I-15 Reaffirmed: BOT Rep. 20, A-16 Reaffirmed in lieu of: Res. 712, A-17 Reaffirmation: A-18 Reaffirmation: A-22

MACRA and the Independent Practice of Medicine H-390.837

1. Our AMA, in the interest of patients and physicians, encourages the Centers for Medicare and Medicaid Services and Congress to revise the Merit-Based Incentive Payment System to a simplified quality and payment system with significant input from practicing physicians, that focuses on easing regulatory burden on physicians, allowing physicians to focus on quality patient care.
2. Our AMA will advocate for appropriate scoring adjustments for physicians treating high-risk beneficiaries in the MACRA program.
3. Our AMA will urge CMS to continue studying whether MACRA creates a disincentive for physicians to provide care to sicker Medicare patients.

Alt. Res. 206, A-17 Reaffirmed: BOT Action in response to referred for decision: Res. 237, I-17

Remove Pain Scores from Quality Metrics D-450.955

Our AMA will work with the Centers for Medicare and Medicaid Services to remove uncontrolled pain scores from quality metrics that impact reimbursement for services rendered in the nursing facilities and from the five-star rating system for nursing facilities.
Res. 236, A-16

Pain Medicine D-450.958
Our AMA: (1) continues to advocate that the Centers for Medicare & Medicaid Services (CMS) remove the pain survey questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); (2) continues to advocate that CMS not incorporate items linked to pain scores as part of the CAHPS Clinician and Group Surveys (CG-CAHPS) scores in future surveys; and (3) encourages hospitals, clinics, health plans, health systems, and academic medical centers not to link physician compensation, employment retention or promotion, faculty retention or promotion, and provider network participation to patient satisfaction scores relating to the evaluation and management of pain.
BOT Rep. 5, I-15

Use of CPT Editorial Panel Process H-70.919
Our AMA reinforces that the CPT Editorial Panel is the proper forum for addressing CPT code set maintenance issues and all interested stakeholders should avail themselves of the well-established and documented CPT Editorial Panel process for the development of new and revised CPT codes, descriptors, guidelines, parenthetic statements and modifiers.
BOT Rep. 4, A-06 Reaffirmation A-07 Reaffirmation I-08 Reaffirmation A-09 Reaffirmation A-10 Reaffirmation A-11 Reaffirmation I-14 Reaffirmed: CMS Rep. 4, I-15 Reaffirmation A-16 Reaffirmed in lieu of: Res. 117, A-16 Reaffirmed in lieu of: Res. 121, A-17 Reaffirmation: A-18 Reaffirmation: I-18 Reaffirmed: Res. 816, I-19

8. PRESCRIPTION DRUG AFFORDABILITY BOARDS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Policy D-110.984 was adopted at the 2024 Annual Meeting and asks our American Medical Association (AMA) to study how upper payment limits (UPLs) established as a part of prescription drug affordability boards (PDABs) impact physician reimbursement and patient access to medications. The following informational report discusses the background of PDABs, the current state of these boards, potential impacts on patients and physicians, and existing AMA policy on the topic.

BACKGROUND

Drug prices in the United States (U.S.) make up nine to ten percent of total medical spending each year, or over $700 billion annually.[192] Research demonstrates that over the last 65 years, the prices of prescription medications have increased faster than both inflation and non-prescription medications.[193] This is due largely to high-priced branded drugs, which make up about 80 percent of U.S. drug spending.[1] American spending is also significantly higher than other comparable nations, with estimates of spending on prescription drugs over 200 percent higher per capita. This higher level of spending does not appear to result from American patients purchasing a higher quantity of medication, as the same study found that U.S. consumers purchased 12 percent fewer days of medications than patients in the other similar nations.[2] Rather, the high drug costs in the U.S. are a result of an incredibly complex, and largely opaque, system. While not all-encompassing, experts specify that the higher spending comes from a combination of higher transaction prices, selection of more expensive medications, monopoly pricing, patent extensions/gaming, and influential rebates.[1,2,194]

In an attempt to combat high drug prices and patient out-of-pocket (OOP) costs for medications, some states have begun to pass legislation to implement PDABs.[195,196] The first PDAB was established in Maryland in 2019 and in recent years more states have enacted legislation creating PDABs.[5] However, few states have actually begun to implement the work that is outlined in legislation, making the impact of these PDABs difficult to assess. Generally, PDABs are designed to both evaluate the jurisdiction's (typically a state's) spending on prescription drugs and to establish methods for lowering this spending. While there is a wide variety in the makeup, scope, and power of these boards, most focus on a specific set of prescription medications and release reports evaluating the state's spending and recommendations to increase affordability.[197] PDABs are often made up of health care providers, advocates, payer representatives, and patients/patient group representatives. Members are typically selected via an application process or by gubernatorial/congressional appointment.[6,198]

The majority of the states that have enacted PDABs utilized the National Academy for State Health Policy's (NASHP) model legislation, originally released in 2017 and updated in 2022, which includes references to federal legislation on drug pricing.[199] This model legislation is designed to give states the authority to establish a framework that defines which medications are "unaffordable." The NASHP model bill includes PDAB authority to define upper payment limits (UPLs) for medications that are designated as "unaffordable."[8] UPLs are designed to set a maximum price for a specific drug based on its cost-effectiveness and affordability.[7] UPLs are intended to prevent price gouging and ensure that patients have access to essential medications. While state PDABs do not automatically have authority to establish UPLs, some states have chosen to include this authority.[7,8]

STATE PDABs

As of March 2025, 11 states (CO, ME, MD, MA, MN, NH, NJ, NY, OH, OR, and WA), have enacted legislation and some have begun to implement PDABs.[200] Details of each of the existing state PDABs can be found in Appendix A. Some states have limited the impact of PDABs to only public plan enrollees, others have incorporated the boards as a part of Medicaid plans only, while other states have indicated the intent for expansion to all enrollees, regardless of payer type. While many states have chosen not to include UPLs, four states, Colorado, Maryland Minnesota, and Washington, have included authority to establish UPLs.[9,201]

Each state has outlined different methods for selecting board members and medications, funding the work, and the reach of authority. Some states, like New York and Massachusetts have incorporated PDAB authorities into existing governmental organizations, NY Medicaid and MA Health and Human Services, respectively.[202,203] As a result, no additional funding or employees were allocated to those states' boards. However, other states have made significant investments in establishing a PDAB. For example, Oregon, Washington, and New Jersey have allocated at least $1.5 million each for the startup of the boards.[204,205,206] Funding origins are also diverse with some states, like Colorado, listing it as a state budget line while others have alternative funding sources.[207] Specifically, states like Oregon and Maryland plan to generate future funding via fees on drug manufactures, insurance carriers, wholesale distributors, and/or Pharmacy Benefit Managers (PBMs).[13,208]

States also vary in the makeup of boards and the impacted population(s). In addition to the employees that some states have hired (or plan to hire) to run the PDAB, states have chosen various methods to select board members. Most states utilize/plan to utilize a combination of appointments from congressional leaders and/or the governor. However, the makeup of expertise on the board varies from state to state.[6,8] Many states encourage or require that patients or patient advocates be a part of the board, while other states, like Colorado and Washington, require a certain level of drug pricing policy or clinical expertise for a certain subset of board members.[14,16] Further, states vary in the length of time board members can serve and if they must be confirmed by the state legislature. Additionally, states vary greatly in the populations that will be impacted by the outcome of PDAB decisions. Many states, like Maine, Maryland, and New Hampshire, have chosen to focus only on public plan beneficiaries.[17,209,210] However, other states, like Colorado, Minnesota, and Washington, have chosen to focus on all consumers with minor exceptions for plans preempted by the Employee Retirement Income Security Act that chose to opt out.[14,16,211]

In addition to the differences in the structure and authority of PDABs, states differ in which drugs are eligible to be covered. A few states have relatively open criteria while others have more stringent requirements. States like New Hampshire and Maine focus on any prescription medications that are purchased by public payers and may cause "affordability challenges."[18,19] However, the majority of states have more strict criteria typically centering around drugs with high wholesale acquisition cost (WAC) launch prices, have substantial percentage WAC increases, those with a certain WAC price, and/or generics that are not a specified percentage less expensive than the reference medication. For example, in Maryland for a drug to be considered by the PDAB it must meet the following criteria:

- if the medication is brand name and has a WAC of $30,000+ or a $3,000+ price increase in 12 months; or
- if the medication is a biosimilar and has a WAC that is less than 15 percent lower than the reference medication; or
- if the medication is generic and has a WAC of more than $100 for a 30-day prescription or an increase in WAC over 200 percent.[17]

While the details vary by state, those with more specific criteria tend to be comparable to the aforementioned requirements in Maryland. However, Oregon has unique criteria in that the legislation outlines the selection of 10 drugs to be reviewed each calendar year. One of the selected drugs must be an insulin product and the other nine are

selected from the state's Prescription Drug Price Transparency Program, excluding any medication designed to treat a Food and Drug Administration (FDA) designated rate disease or condition.[13] Additionally, some states, like Ohio, have chosen to not focus on specific drugs but, rather, to focus on strategies to reduce overall drug spending, increase transparency, and optimize resources and bargaining power.[212]

An important distinction in state legislation is whether PDABs are given the authority to set UPLs. Of the 11 states that have enacted PDAB legislation, only four have granted authority to set UPLs: Colorado, Maryland (pending legislative approval), Minnesota, and Washington. Within states with UPL authority, Washington is only able to set UPLs for up to 12 drugs, while Colorado and Minnesota do not have a limit for establishing UPLs on PDAB-reviewed drugs.[14,16,17,20] Each of these states have unique processes for establishing the UPL based on a combination of cost and value measures. For example, in Washington if a drug is ruled as "unaffordable" by the board, the following must be taken into account when setting an UPL: the cost of administering the medication; the cost of delivering the drug to the patient, if the drug is included in the FDA drug shortage list; and any relevant administrative costs related to the delivery and/or production of the drug. Additionally, the board must monitor the drug for future drug shortages and can suspend the UPL should a shortage occur. Finally, the board must assess the value that the drug has for those who utilize it to enhance health and/or elongate life.[14] While each state with UPL authority has different specific requirements, they all generally follow the above-mentioned requirements. Nonetheless, at the time this report was written, no state had set an UPL.

Of important note, some state PDABs have faced legislative and legal challenges that limit their implementation. For example, in 2019, Ohio successfully passed legislation outlining the creation and implementation of a state PDAB. However, in 2021, an amendment to the statute that originally authorized the PDAB was made that essentially nullifies the state's PDAB in practice.[213] In addition to legislative challenges, PDABs are facing legal challenges, often from drug manufacturers. For example, after Colorado's PDAB ruled that the drug Enbrel® was "unaffordable," paving the way for the establishment of a UPL, the drug's manufacturer, Amgen, sued the state, claiming that the PDAB law violates several state constitutional provisions and attempts to regulate federal health care programs.[214] At the time this report was written, the outcome of this case is unknown. However, it is highly likely that more lawsuits will begin to materialize as additional states make claims of unaffordability and, in some cases, establish UPLs.

State Example: Colorado

The Council highlights Colorado as an example in this report as its PDAB is perhaps the furthest along in the process and includes UPLs authority. In 2021, legislation to establish a PDAB in Colorado became law. The board is overseen by the Division of Insurance of the Colorado Department of Regulatory Agencies (DORA). The board consists of up of five members who have advanced degree(s) or experience in health care economics or clinical medicine and are appointed by the governor and confirmed by the state senate. The board began meeting in late 2021 and in 2024, Colorado's PDAB voted to determine the affordability of the first five drugs. This process included presentations by experts, testimony from witnesses, including open public testimony, and deliberation of the board members. Two medications were ruled as "not unaffordable" and the other three were ruled "unaffordable" to Colorado consumers. For the three medications that were ruled "unaffordable," the PDAB is working to establish UPLs. Per the original design, the board has a preset process that was anticipated to take approximately six months. However, due to certain barriers, such as legal challenges from the manufacturer, this process has been drawn out and UPLs have not yet been established for the three medications ruled "unaffordable." The first UPL rulemaking hearing was scheduled to be held in early March 2025, which will begin the process of establishing the payment limit for the specific medication.[16]

POTENTIAL IMPACTS

PDABs and UPLs are novel to the drug pricing landscape and, as a result, much of the information regarding their impact is speculative. Many states have established policies to create PDABs, but the majority of boards have either not yet started meeting or started very recently. While researchers have theorized how these boards and/or limits may impact patients and physicians, data to establish firm, research-based conclusions of the actual impacts are not available at this time.

Proponents of PDABs and UPLs explain that these strategies are designed to rein in out-of-control drug prices, ensure that patients have access to their medications at a reasonable price, and lower state drug spending.[215,216] Supporters point to similar practices in the non-medical communities, such as public utility commissions. Each state has its own public utility commission which works to regulate providers to ensure that the prices that consumers pay for public utilities are fair for all involved. While these commissions have been relatively successful in controlling utility costs,

the difference between the structure of utility pricing and delivery and drug pricing and delivery is quite significant.[217] Additionally, it is a reasonably common practice for states to set payment rates for health care services to ensure they are affordable and accessible to patients. For example, fee schedules are commonly set by state and federal governments that list the maximums that a physician or provider is paid for a service. Some anticipate that PDABs and UPLs could function in a similar way to control costs.[25] Supporters of PDABs believe that by focusing on the drug payment rate specifically, patent preemption (i.e., breaking the patent) is avoided while also allowing for control of drug cost. At the core, those who champion PDABs argue that medications are exceptionally expensive and these boards will lower drug prices, thus making drugs more accessible and affordable to patients.[24,25]

While most experts agree that prescription medications in the US are prohibitively expensive, some experts have expressed concern regarding the impact that PDABs and UPLs may have on patients and physicians.[7,218] Concern has been expressed that the implementation of these boards will negatively impact patient access to medications. One specific concern centers around medication formulary placement. If a medication is given an UPL, payers may choose to place it on a less desirable formulary tier. This could result in patients not being able to access the most effective medication affordably and/or increase required utilization management for that medication.[7,27] Further, this could result in limits to physician payment and disrupt physician/practice ability to purchase medications in a fiscally responsible manner. This is especially salient if the drug's UPL is less than the acquisition cost, as purchasers would not be able to affordably stock the medication.[10]

Concern also has been raised that patient assistance programs could suffer for selected medications. These concerns are particularly salient for patients who are on essential, specified, and expensive prescriptions, especially HIV, cancer, and Hepatitis C treatments/medications.[27] For example, research has suggested that patients on HIV medications saved 91 percent of their OOP costs due to copay assistance programs. Should these medications be given UPLs, it is possible that manufacturers could reassess assistance programs. This could lead to a situation where the medication cost may be below the UPL, but patients may be required to pay greater OOP costs due to lessened or removed assistance programs.[7,27] Research has suggested that even a minor increase in patient OOP spending impacts patient adherence. For example, a recent study found that a minor increase from $0 to $10 OOP cost doubled the abandonment rate for patients using oral HIV pre-exposure prophylaxis (PrEP). This study, along with others linking increases in patient OOP costs to lower treatment adherence, exemplifies the potential impact of even a small change to programs designed to relieve patient OOP costs.[219] There is ample concern that the implementation of PDABs, especially those with UPL authority, could significantly impact programs designed to relieve patient OOP costs potentially impacting treatment adherence.[27]

Additionally, advocacy groups have recently raised concerns around the disproportionate impact of PDABs on people with disabilities. While the states that have released lists of selected medications are still relatively limited, initial lists indicate that the vast majority of selected medications are disproportionately used to treat conditions that are likely or highly likely to be classified as "disabling" under the Americans with Disabilities Act (ADA).[220,221] Even while Washington state has the lowest rate of medications used to treat potentially disabling diagnoses, it still amounts to over 86 percent. Across the published lists, each state has at least one HIV antiretroviral, with medications to treat cancer, genetic disorders, autoimmune disorders, and endocrine disorders also disproportionately represented.[29] Serious concerns have been raised that the selection of these medications could cause disparate impacts on the disability community and limit patient access to essential medications. Experts explain that the potential downline supply chain disruptions and lack of guaranteed patient cost savings, paired with the aforementioned unknown impact on patient assistance programs, could lead to significant barriers in patient access.[29,30]

While it remains to be seen how PDABs and their UPLs will impact patients and physicians, it is important to acknowledge the enforcement potential of these boards. Experts agree that while PDABs are likely very well intentioned, there is not much enforcement to back up the recommendations that are made. This is especially relevant for states that have not granted UPL authority to their PDAB. However, even among the states that have given authority to grant UPLs, there are significant questions as to whether these limits will impact actual drug prices. For example, there is current discussion as to whether these UPLs will apply to insurers that are not regulated by the state. In other words, federal or interstate plans may be outside the scope of authority for state PDABs.[23,222] Without effective enforcement, which no PDAB seems to have at the present time, it is unlikely that manufacturers, payers, and PBMs will adhere to the suggested prices.

AMA POLICY AND ADVOCACY

The AMA has a robust body of policy to ensure that prescription medications are affordable and accessible to patients. Specifically, Policy H-110.997 outlines support for programs that are designed to mitigate the cost of prescription medications, physician autonomy to prescribe the most appropriate and effective medication to their patient, and for payers to cover prescribed medications. Policy H-110.987 builds on the aforementioned policy to ensure that pharmaceutical companies and their proxies are not participating in anticompetitive behaviors or mergers/acquisitions that unduly raise the cost of prescription medications. This policy also addresses the need to ensure that prescription prices are reasonable and do not exceed the pace of inflation. Policy H-330.864 focuses specifically on reforming Medicare drug reimbursement and ensuring that it is done in a manner that allows for patient access and also reimburses physicians fairly. Finally, Policy H-100.964 outlines AMA support to ensure that prescription medications are covered by payers in a manner that keeps them affordable and accessible to patients.

Additionally, the AMA has a robust history of drug pricing advocacy. Over the last few years, numerous letters and testimonies have been sent to regulators (CMS 2023, CMS 2024), legislators (House 2023, House 2023(a), Senate 2024), and payers (NAIC 2023) working to mitigate the high price of prescription drugs and ensure that patients are able to afford their medications. In addition to this advocacy work, the AMA has a longstanding grassroots campaign, TruthinRx, that is designed to increase transparency of drug pricing and decrease costs.

In addition to policy and advocacy surrounding drug pricing, AMA policy addresses concerns raised by sceptics of PDABs and UPLs. The AMA has a long history of working to lessen utilization management, especially prior authorization via campaigns (e.g., Fix Prior Auth) and policy. Specifically, Policies H-320.939 and D-320.982 outline the AMA's stance against prior authorization and efforts to ensure that physicians are not overburdened by these requirements. Additionally, Policy H-125.991 outlines the AMA's efforts to ensure that payer formularies are fair and inclusive of physician-prescribed medications.

DISCUSSION

Proponents of PDABs believe that they will do what they intend—lower drug prices in the U.S. and create a more affordable system for patients. However, critics voice concerns around the actual impacts. Concern has been expressed that PDABs, especially those with the authority to establish UPLs, may increase physician administrative burden, increase costs for patients and physicians, and disproportionately impact patients with ADA disabling conditions. Additionally, concerns have been raised that if UPLs are set below the acquisition cost for a physician administered drug, there may be an adverse impact on medication availability and could result in market distortions. Others question the actual enforcement authority these boards have, or will have, on regulating drug prices. Since PDABs and UPLs are relatively new, it will take time to see if these strategies result in their intended goal—to lower drug prices and make prescription medications more affordable for patients.

CONCLUSION

The Council believes that the AMA has robust advocacy efforts and clear policy supporting the need for prescription drugs to be affordable and accessible to patients. However, due to the relative recency of PDABs, there is no research yet available on actual impacts or outcomes of the boards. Therefore, the Council will continue to monitor this issue and report back when a reasonable body of research has been established in which to form conclusions and guide additional, well-informed policy on the impact of PDABs and UPLs on patients and physicians.

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State	Initiative	Budget/Funding	UPL Authority?	Membership	Populations	Drug Inclusion Criteria
Colorado	CO SB 175-2021	State budget line. *Approximately $750,000/year.*	Yes.	2 FTE and 2 PTE employee allocation. Additional contractors approved with board review. Additional $250,000 allocated. The Board consists of 5 members appointed by the governor and confirmed by the senate. All must have either an advanced degree and experience or expertise in health care economics or clinical medicine.	All consumers. *Exemption for state funded plans that choose to opt out.*	Drugs that meet 3+ of the following: - Brand-name drugs and biologics that have a wholesale acquisition cost (WAC) of $30,000+ - Brand-name drugs and biologics that have a WAC increase of 10%+ in the last 12 months - Biosimilars that launch at a WAC that is not at least 15% less than the reference - Generics that have a WAC of over $100/30 days
Maine	ME LD 120 (2021)	Absorbed by existing budgets.	No.	0 FTE. Board supported by the Office of Affordable Health Care. The Board consists of 13 members, 6 appointed by the Senate President, 5 by the Speaker of the House, 2 state commissioners (non-voting).	Public plan beneficiaries.	Drugs that are purchases by public payers and may cause "affordability challenges."
Maryland	MD HB 768-2019	Start up costs provided by the State budget. Annual funding from fees on drug manufacturers, PBMs, carriers, and wholesale distributors. *2024 budget: 1.4 million+*	Yes. *If legislative approval is gained.*	5 FTE and 1 PTE. Additional contractors approved with board review. Additional $250,000 allocated. The Board consists of 5 members appointed by the governor, President of the Senate, Speaker of	Public plan beneficiaries. *Have indicated potential to attempt expansion to all payers.*	Drugs that meet the following criteria: - Brand-name that launch with a WAC of over $30,000/yr - Brand-name with a price increase of $3,000+/year - Biosimilars that launch at a WAC that is not at least 15% less than the reference

				the House, Attorney General, and jointly by the House Speaker and Senate President.		- Generics that have a WAC of over $100/30 days OR increased by 200%+ in the last year
Massachusetts	HB 4000 – Section 46 of FY 2020 Budget	No additional funding appropriated.	No.	Implemented through MA Medicaid agency and Health Policy Commission.	Medicaid beneficiaries.	Drugs covered by Medicaid that cost more than $25,000/yr per person or $10 million to the program. Excludes medications in which a supplemental rebate agreement is reached.
Minnesota	MN SF 2744-Section 62J.85	Base appropriation of at least $500,000/year from the State budget.	Yes.	1 FTE with the potential for more. Board to be supported by the Commissioner of Health and Attorney General. The Board consists of 9 members. 7 voting members appointed by the governor, 1 nonvoting member appointed by the senate majority leader, and 1 nonvoting member appointed by the speaker of the house.	All consumers. *Plans preempted by ERISA can choose to opt out.*	Drugs that meet the following criteria: - Brand name/biologics that have a WAC increase of over 15% or more than $3,000 annually or during the course of treatment after adjusting for Consumer Price Index - Brand name/biologics with a WAC of over $60,000 per year or course of treatment - Biosimilars that launch at a WAC that is not at least 20% less than the reference - Generics that have a WAC of over $100/30 days, a course of treatment, or one unit - Generics that have a price increase by 200%+ in the last year The Board may identify additional drugs that impose significant affordability challenges.
New Hampshire	NH HB 1280-2020	Appropriation of approximately $350,000/annually.	No.	N/A	Public plan beneficiaries.	Drugs that are purchases by public payers and may cause "affordability challenges."

				The Board consists of two members appointed by the president of the senate, two members appointed by the speaker of the house, and one appointed by the governor.		
New Jersey	P.L. 2023, c. 106	Appropriation of $1.5 million to implement the initial bill.	No.	The Board consists of 5 public members; 3 appointed by the governor; 1 on recommendation of the senate president, and 1 on recommendation of the house speaker. Will work in tandem with the Drug Affordability Council/Drug Affordability Unit.	N/A	Drug practice reports are reviewed and the board is able to make recommendations to increase affordability.
New York	PHL Sec 280-2017	No additional funding appropriated.	No.	Implemented through NY Medicaid Agency's Medicaid Drug Benefit Cap.	Medicaid beneficiaries.	- Drugs that will exceed the state's Medicaid drug cap (set annually) - Newly launched drugs that are "high cost" or meet the following o Brand-name that launch with a WAC of over $30,000/yr o Brand-name with a price increase of $3,000+/year o Biosimilars that launch at a WAC that is not at least 15% less than the reference o Generics that have a WAC of over $100/30 days o Gene therapies

Ohio	OH HB 166-133 2019	N/A. 2021 amendment to the authorizing statute mitigated authority. Board is still technically intact.	No.	The board is comprised of 17 individuals. 6 state employees (director of administrative services; director of health; Medicaid director; director of mental health and addiction services; administrator of workers' compensation) and 12 members who work in drug affordability and availability and are appointed by the governor, senate president, and house speaker (3 appointments each).	N/A.	Not focused on specific drugs, instead the Board is tasked in creating reports including the following information: - How the state can best achieve drug price transparency - Avenues/payment models to increase/create affordability - Levering the state's purchasing power - Creating efficiencies to reduce costs - Outcomes to be measured to improve state's purchasing of drugs - How existing resources cab be optimized
Oregon	OR SB 844-2021	$1.7+ million appropriated to the Department of Consumer and Business Services with the intent for reimbursement from manufacturer fees. The ongoing budget will come from fees.	No.	5 FTE. The Board consists of 5 members all appointed by the governor.	N/A.	Nine drugs and one insulin product each year based on drugs reported in OR's Prescription Drug Price Transparency Program. Excludes any drug designated by the FDA to treat a rare disease/condition.
Washington	WA SB 5532/Chapter 153-2022	Initial appropriation of $1.5 million over the first 3 years.	Yes. *For up to 12 drugs.*	4 FTE. The Board consists of 5 members appointed by the governor with expertise in health care economics or clinical medicine.	All consumers. *Exemption for state funded plans that choose to opt out.*	Drugs that have been on the market for 7+ years, are not designated by the FDA to treat a rare disease/condition, and meet the following criteria: - Brand name/biologics with a WAC of over $60,000 per year or course of treatment - Brand name/biologics that have a WAC increase of

						over 15% over 1 year or 50% over 3 years - Biosimilars that launch at a WAC that is not at least 15% less than the reference - Generics that have a WAC of over $100/30 days, a course of treatment, or have a price increase by 200%+ in the last year
Adapted from the NASHP Comparison of State Prescription Drug Affordability Review Initiatives and source legislation.						

9. MINIMUM REQUIREMENTS FOR MEDICATION FORMULARIES

Reference committee hearing: see report of Reference Committee A.

HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED
See Policy H-110.958, H-110.979 and H-320.949

At the 2024 Interim Meeting, the House of Delegates referred Resolution 809, which was introduced by the Mississippi Delegation, and asked that our American Medical Association (AMA) advocate for all payers to create, maintain, and enforce a minimum formulary for all beneficiaries that includes all "commonly prescribed, inexpensive, and generic" medications unless there are reasonable safety or economic concerns. The following report discusses the background and current state of formularies, impacts of their expansion, and AMA efforts on the topic. Additionally, the report recommends the adoption and reaffirmation of policies designed to balance formulary inclusion and economic concerns.

BACKGROUND

Formularies were initially simple lists of medications implemented by the military in the late 1700s during the American War of Independence.[1] In the mid-1900s, the concept of formularies became more widespread and took root in hospital pharmacies needing authorization to dispense interchangeable medications.[2] In 1965, with the inception of Medicare, formularies became well established as part of reimbursement eligibility requirements.[3] By the 1980s, formularies began to take a more contemporary shape, primarily due to the development of multi-brand categories of drugs with similar, but not identical, uses and prices. To encourage the use of their drugs, manufacturers began to offer rebates to purchasers. As a result, payers placed the more advantageous drugs, often due to higher rebates, in more favorable formulary positions.[4] Today's formularies continue to tout the goal of managing costs, ensuring patient access to therapies, and improving health outcomes.[4,5] While the actual outcomes delivered by formularies are diverse and occasionally questionable, they are highly influential in dictating what medications are accessible to patients.[4]

Contemporary formularies tend to follow similar rebate incentive structures as were developed in the 1980s, but with time have become increasingly complicated and, in many cases, opaque.[4,6] Formularies today are usually one of four types; open, closed, value-based, and tiered. Open structured formularies are those in which coverage for all prescription medications is granted.[6] While this may seem to be the most advantageous to patients, these types of formularies often see significantly higher cost to the patient and can actually block access due to high out-of-pocket (OOP) costs and/or high premiums.[4,6] Closed formularies are those that offer a narrower range of covered medications, but often at a lower cost to patients.[6] Within these formularies payers often select the medications that have higher rebates and, therefore, are financially advantageous to the payer.[4,6] Tiered formularies are more common and more complex in their execution. Within the tiers, payers incentivize the use of medications by placing them on lower tiers which, in turn, come with a lower OOP expense for the patient. While there is no limit on the number of tiers, it is most common for plans to have a three-tiered structure. Typically, tier one includes the most preferred medications, tier two includes preferred name brand drugs, and tier three includes non-preferred name brand drugs. Drugs are typically considered to be "preferred" by the payer when more attractive rebates are offered by the manufacturer or if the list price of the medication is lower.[4,6] Finally, value-based formularies are based on an assessment of the impact of a treatment on overall health care spending and long-term health compared to other structures which are based solely on the upfront cost of the drug. While value-based formularies vary in the specific criteria used to determine high versus low value drugs, most take clinical parameters, quality of life, and utilization of health care resources into account. Similar to tiered formularies, the use of preferred drugs, in this case defined as the higher value drugs, is encouraged by lower OOP costs.[4,6]

While it may seem that generic medications would often be placed on lower formulary tiers, that is not always the case. In practice, many payers place name-brand drugs on lower tiers due to greater price concessions offered by manufacturers. Therefore, drugs with higher list prices can often yield payers higher rebates, although these cost savings are often not passed on to the patient.[6] In some cases, patient OOP costs are determined by the list price, and as a result patients end up paying more than a generic option.[7] While the data for private plans are limited, anecdotal evidence and research based on Medicare Part D plans seem to confirm the underuse of generic drugs to reduce cost.

For example, one study found that 72 percent of Medicare Part D formularies had at least one branded product place on a lower tier than the comparable generic medication and 30 percent of branded multisource drugs had fewer utilization management requirements than the generic product.[8] Additionally, trends of generic drug usage in Medicare Part D seem to be declining as there was a 22 percent drop in generic medications placed on tiers between 2016 and 2025.[7,8]

Regardless of the formulary structure or drug type, the placement of medications is determined by a pharmacy and therapeutics (P&T) committee.[5] These committees are typically made up of physicians, other practitioners, legal experts, and administrators. P&T Committees will generally assess the safety, clinical efficacy, patient adherence, patient satisfaction, and economic factors of a drug in order to determine if it is placed on a formulary and/or the appropriate tier.[4,6] While payers are able to develop their own formularies, most choose to rely on pharmacy benefit managers (PBMs) to create and maintain formularies due to the high associated costs.[6] Typically, PBMs will create a number of formulary choices for payers to select from and, if desired, customize. While there are no federal legislative or regulatory guidelines for non-Medicare plans, Part D plans must follow guidelines and participate in annual reviews coordinated by the Centers for Medicare & Medicaid Services (CMS). These requirements were put in place by CMS in 2006 and are designed to regulate how private Part D plans create and manage formularies.[4,5,6,9]

FORMULARY REQUIREMENTS

Since its founding, Medicare has required payers to provide formularies in order to be approved for reimbursement. In 2003, the Medicare Prescription Drug Improvement and Modernization Act (MMA) was signed into law and included specific details as to minimum formulary requirements. MMA's goal was to not only update Medicare's prescription benefits, but to ensure that all associated carriers and their plans provide beneficiaries with high-quality and cost-effective drug benefits.[9,10] Since 2006, Medicare has required that at least two medications from each class are included in the plan formulary. However, there is some flexibility in this requirement should a medication class not include two or more medications. Additionally, in cases when there are therapeutic advantages of a specific medication for patients with certain diseases, more than two medications may be required to be included in the formulary.[9,11]

The Patient Protection and Affordable Care Act (ACA), signed into law in 2010, also includes minimum formulary requirements for associated plans.[12] Due to the structure of the ACA, specific formulary requirements vary significantly across states. However, prescription medication is considered one of the Essential Health Benefits (EHBs) that plans are required to cover. Specifically, states must ensure that plans either cover one drug in each of the United States Pharmacopeia (USP) class or at least the same number of drugs in each category and class of the EHB Benchmark plan for the respective state.[13] The 2025 USP list includes 50 medication categories, 175 medication classes, 207 Pharmacotherapeutic informational groups, and over 2,055 example drugs and how each example fits into each category, class, and group.[14] States have the ability to, within reason, establish their own EHB Benchmark plan, or the floor plan, for their state. As a result, some states, like Washington, require that plans cover at least one drug in every USP class, while other states, like Illinois and South Dakota, have more nuanced basic requirements. Each state is required to submit a plan to the Center for Consumer Information and Insurance Oversight (CCIIO) for approval.[13] Part of the role of CCIIO is to ensure that EHB Benchmark plans allow consumers access to high quality insurance plans while minimizing payer ability to discriminate between types of beneficiaries and to encourage marketplace competition.[13]

Although private health insurance plans operating outside of Medicare do not have blanket minimum drug formulary requirements, some states require plans to meet the ACA minimum. Additionally, many organizations, including the AMA, have offered guidance around formulary best practices. Specifically, the AMA, along with other relevant organizations, endorsed the Principles of a Sound Drug Formulary System.[15] While these principles do not specifically outline a minimum formulary requirement, they do delineate the need to ensure that formularies provide patients with medications necessary to address their diagnosis in a manner that is clinically appropriate and economically responsible.[15] Other organizations, including the American Academy of Family Physicians and American Society of Health-System Pharmacists, have outlined the need for formularies to be balanced based on efficacy, safety, cost, and patient outcomes.[16,17]

FORMULARY EXCEPTION PROCESS

An important aspect of formularies is the exception process. Since the vast majority of plans do not cover every medication on the market, patients and physicians may need to engage with exceptions to seek coverage of a medication. These exceptions occur when the covered medication is not an option for a patient. Commonly, this is due to allergies, a history of unsuccessful use of covered medications, covered medications not meeting therapeutic need, and/or concern that a covered medication would exacerbate an existing condition(s).[18] There may also be the need to submit an exception if a patient needs a quantity, dosage, or delivery method that is not typically covered. Importantly, exceptions are not limited to medications that are not covered at all by a payer. In some cases, if a medication is placed on a formulary tier that makes it unaffordable to the patient, an exception can be requested. This type of exception is called a tiering exception while the traditional exception process is called a formulary exception.[18,19]

While there is not one standardized process for exceptions, typically the process includes a request from the patient/patient representative paired with a physician statement. In some cases, the physician may directly request the exception and provide the statement for the patient.[19] When requesting a formulary exception, the physician statement typically includes information regarding the medical necessity of the alternative medication and potential consequences should the covered drug be used. When requesting a tiering exception, the physician statement will discuss the medical necessity of the medication and why it is unaffordable. In some cases, payers may require a statement of patient financial hardship.[18] Payers will typically respond to exception requests within 72 hours from the submission of the physician statement, although in urgent or emergency situations the payer should respond within 24 hours.[18,19]

As previously mentioned, there is not a requirement for payers to utilize a standard exception process, and as a result there is variance in the criteria utilized to review exception requests. Most plans will compare applicable scientific evidence on the efficacy and safety of the covered and requested drugs. Should an exception request be denied by the payer, the patient and/or physician may file an appeal to reverse the decision.[19] Similar to the original exception request, there is not a standardized process for appeals, however plans should have a defined method in place. For example, Medicare Part D plans provide a multistep appeals process starting with redetermination by the drug plan and escalating to an appeal in a federal court.[10,19]

IMPACTS OF FORMULARY EXPANSION

While it may seem beneficial for all medications to be included in drug formularies, research has shown that this may have unintended consequences. Specifically, economists have shown that, at least among ACA plans, those that cover more EHB drugs have significantly more utilization management requirements in place.[20] This seems to hold true when new drugs are added to formularies, as plans are increasingly likely to add utilization management requirements, often in the form of prior authorization. As discussed in a number of previous Council reports (CMS 6-A-24; CMS 8-A-17; CMS 7-A-16) prior authorization and other forms of utilization management are extremely burdensome for physicians/physician offices and potentially dangerous to patients. However, utilization management is not the only way that physicians are impacted by formulary placement and expansion. Many physicians report challenges with securing payment for high cost, but necessary physician-administered medications placed on higher tiers. Others have reported difficulties in receiving the full payment rate for administering vaccines, especially in private practice settings, from public payers.[21] A fuller discussion of the challenges faced by physicians in adequate vaccine payment can be found in CMS Report 3-I-20.

In addition to the potential challenges faced by physicians if formularies are expanded, patients may face adverse consequences. A main concern is that if payers incur additional costs, in this case due to formulary expansion, those costs may be passed on to the beneficiary through premium increases or higher OOP costs. Specifically, payers could simply require higher levels of patient cost sharing if they are required to include more medications on a formulary. Additionally, payers may react to forced formulary expansion by placing more medications on less desirable formulary tiers, leading to higher patient OOP costs and/or more utilization management requirements.[22] In conjunction with the potential negative impacts on patients with expanded formularies, research has demonstrated that overall, stricter formularies may not negatively impact patients. In some cases, research has shown that stricter formularies are actually associated with reported positive impacts, such as better medication adherence and clinical outcomes.[22] At the same time, other research seems to show that these policies also reduce costs in the majority of cases.[23] Together these

concerns and conclusions may suggest that more stringent formularies are not harmful to patients and may actually lower drug-related costs.

However, research has also demonstrated that when formularies are too restrictive, there can be negative outcomes like lower medication adherence and, in some cases, higher OOP costs for patients.[22,24] These two metrics go hand in hand as patients who face higher OOP costs are less likely to adhere to treatment plans, potentially incurring additional costs to treat the consequences from non-adherence down the line.[22,24] Additionally, the aforementioned utilization management does not just impact physicians but patients, as well. Patients who experience prior authorization have significantly increased wait times to access their medications and those who experience other forms of utilization management, like step therapy, can face long, uphill battles to obtain the necessary medication(s).[22,25] Therefore, it is important that formularies are balanced enough to allow patients to access necessary medications while also ensuring that utilization management and patient cost-sharing are not egregious.

AMA POLICY AND ADVOCACY

The AMA has established a number of policies that address the development and maintenance of drug formularies. Policy H-125.979 outlines the need for formulary information to be available to physicians and prescribers in real-time at the point of prescribing. This policy outlines efforts to ensure that formulary lists are also accessible to patients and that medications are not removed during the policy term. Policy H-110.979 outlines the AMA's advocacy efforts to ensure that both PBMs and payers are not just transparent in the creation of formularies, but also that rebates and refunds received will be shared with patients. Policy H-125.991 details the AMA standards for the makeup of P&T committees, the approval of their decisions by medical staff within hospital or institutional settings, and suggested guidelines for the creation and maintenance of a formulary system. Finally, Policy H-125.985 encourages all entities who design formularies or benefit packages, including managed care organizations and PBMs, to follow the principles outlined in the aforementioned Principles of a Sound Drug Formulary System.

The AMA also has several policies outlining the ideal formulary exception process for payers. Policy H-285.965 outlines the steps that physicians should take to ensure that patients have awareness of the most advantageous course of treatment, even when engaging with a formulary exception process is necessary. Policy H-320.949 outlines efforts to ensure that payers are required to provide exception processes that have clear response times and appeal processes. This policy also dictates support for legislative and regulatory efforts to ensure that these standards are implemented. Policy H-185.942 details the basic criteria that should be followed by payers and physicians in relation to utilization management criteria and when it can be appropriately utilized. In addition to these policies, the second principle of the AMA Prior Authorization and Utilization Management Reform Principles outlines the flexibility that should be provided by payers to ensure that patients have the ability receive effective and individualized care. In addition to policies related to the formulary exception process, Policies H-320.939 and D-320.982 detail the AMA's fight to make sure physicians are not experiencing undue burdens related to prior authorization and to mitigate the number of prior authorizations required. Additionally, the AMA has a longstanding grassroots campaign (Fix Prior Auth) working to educate about how prior authorization impacts patients and physicians as well as working to fix the system.

Finally, the AMA has many policies outlining the need for prescription medications to be affordable and accessible to patients. Specifically, Policy H-110.997 outlines support for programs that work to lower the cost of prescription drugs while also maintain quality of care and physician autonomy. Policy H-100.964 builds on the previously mentioned policy and expands the support for efforts to ensure that medications are covered in a manner that allows patients to access medications affordably. Policy H-125.984 reiterates support for generic medications when deemed appropriate and cost effective for the patient. This policy also supports programs that are designed to bolster generic development and federal approvals. Among other strategies to improve the affordability of prescription medications, Policy H-110.987 outlines AMA support for legislation and regulation that works to reduce drug prices, anticompetitive behaviors, and price gouging in an effort to increase drug affordability. In addition to the AMA body of policy on drug pricing, there have been extensive advocacy efforts over the last few years to bring awareness and offer solutions to high drug prices through letters to regulators (CMS 2023, CMS 2024), legislators (Senate 2024), and payers (NAIC 2023), along with testimony provided to the House of Representatives (House 2023, House 2023(a)). Additionally, the AMA grassroots campaign, TruthinRx, works to gather and disseminate physician and patient stories as well as to advocate for lower drug prices and increased process transparency.

DISCUSSION

While formularies have been around, in some form, for centuries, the current iteration is exceptionally complicated and, in many cases, opaque. As a result, the effectiveness of formularies increasingly has been called into question. Formularies are developed by P&T committees and, at least among private payers, are typically maintained by PBMs. Medication placement on these coverage lists is often heavily dictated by the rebates given to payers by drug manufacturers. Rebates, and other financial incentives are not required to be passed to the patient and, as a result, patients rarely see a share of the financial incentives that payers receive. Current formulary minimums vary greatly by payer type and state. While there is not a national minimum formulary requirement for private payers, public payers do have minimum standards that generally require a certain number of medications in each class to be included in each plan's formulary.

Patients must have access to medications deemed as most appropriate by their physicians and such access must be affordable in order to be effective. Formularies are one method designed to decrease medication costs. In some situations, more limited formularies have resulted in their intended outcomes: lower costs and greater patient access. Yet, when formularies are too restrictive, they may have the opposite effect: higher costs and lower access. In order to ensure that patients have access to affordable coverage and medications, the Council believes that formularies must find a middle ground between being too limited or too expansive, balancing the need for coverage with the potential for OOP or premium cost increases. It is essential to acknowledge that PBMs have significant negotiation power in formulary creation and drug placement and thus yield substantial power in the process. The complications of the negotiation process and the potential economic tradeoffs indicate the need for a nuanced approach to formulary minimum requirements. As such, support for a mandate to cover all medications could have serious adverse consequences on patients and physicians.

Therefore, the Council recommends the adoption of new AMA policy that supports a more nuanced approach, supporting all payers in setting a minimum formulary that covers all drugs in each of the protected classes and at least two medications in each of the non-protected classes. The Council believes that this minimum formulary requirement balances the intent of Resolution
809-I-24 while ensuring that patients and physicians will not face significant increases in OOP cost or utilization management requirements. Additionally, to ensure that patients have access to medications that are prescribed by their physician in an affordable manner, formularies exhibit transparency, and cost-savings are passed to the patient, the Council recommends that Policy
H-110.979 be reaffirmed. While affordability and formulary composition are exceptionally important, it is also vital that patients and physicians have an avenue to request coverage when a medication is not included in a formulary. In order to protect and simplify this process the Council also recommends reaffirmation of Policy H-320.949, which details the AMA principles to ensure that utilization management, including formulary exception processes, are clear, not overly burdensome, and have a defined appeals process.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 809-I-24, and the remainder of the report be filed:

1. Our American Medical Association (AMA) support all public and private payers in maintaining a formulary that includes at least:
    a. Coverage for substantially all drugs in the six protected classes; immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics; and
    b. Coverage for at least two medications in each non-protected therapeutic category. (New HOD Policy)

2. That our AMA reaffirm Policy H-110.979, which outlines AMA efforts to advocate for transparency in formularies and that patients can access medications (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy H-320.949, which details AMA principles regarding requirements for the formulary exception process (Reaffirm HOD Policy)

Fiscal Note: Less than $500.

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Council on Medical Service Report 9-A-25
Minimum Requirements for Medication Formularies
Policy Appendix

Private Health Insurance Formulary Transparency, H-125.979

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

(Sub. Res. 724, A-14; Appended: Res. 701, A-16; Appended: Alt. Res. 806, I-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: BOT Rep. 20, A-19; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 2, A-21; Reaffirmed: CMS Rep. 06, A-24)

Value-Based Management of Drug Formularies, H-110.979

Our American Medical Association: (1) will advocate that pharmacy benefit managers (PBMs) and health plans use a transparent process in formulary development and administration, and include practicing network physicians from the appropriate medical specialty when making determinations regarding formulary inclusion or placement for a particular drug class; (2) will advocate that any refunds or rebates received by a health plan or PBM from a pharmaceutical manufacturer under an outcomes-based contract be shared with impacted patients; and (3) opposes indication-based formularies in order to protect the ability of patients to access and afford the prescription drugs they need, and physicians to make the best prescribing decisions for their patients.
(CMS Rep. 6, I-20)

Drug Formularies and Therapeutic Interchanges, H-125.991

It is the policy of the American Medical Association (AMA):
(1) That the following terms be defined as indicated:
(a) Formulary: a compilation of drugs or drug products in a drug inventory list; open (unrestricted) formularies place no limits on which drugs are included whereas closed (restrictive) formularies allow only certain drugs on the list;
(b) Formulary system: a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care;
(c) Pharmacy & Therapeutics (P&T) Committee: an advisory committee of the medical staff that represents the official, organizational line of communication and liaison between the medical staff and the pharmacy department; its recommendations are subject to medical staff approval;

(d) Therapeutic alternates: drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;
(e) Therapeutic interchange: authorized exchange of therapeutic alternates in accordance with previously established and approved written guidelines or protocols within a formulary system; and
(f) Therapeutic substitution: the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber.
(2) That our AMA reaffirms its opposition to therapeutic substitution (dispensing a therapeutic alternate without prior authorization) in any patient care setting.
(3) That drug formulary systems, including the practice of therapeutic interchange, are acceptable in inpatient hospital and other institutional settings that have an organized medical staff and a functioning Pharmacy and Therapeutics (P&T) Committee, provided they satisfy the following standards:
(a) The formulary system must:
(i) have the concurrence of the organized medical staff;
(ii) openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;
(iii) have policies for the development, maintenance, approval and dissemination of the drug formulary and for continuous and comprehensive review of formulary drugs;
(iv) provide protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;
(v) provide active surveillance mechanisms to regularly monitor both compliance with these standards and clinical outcomes where substitution has occurred, and to intercede where indicated;
(vi) have enough qualified medical staff, pharmacists, and other professionals to carry out these activities;
(vii)provide a mechanism to inform the prescriber in a timely manner of any substitutions, and that allows the prescriber to override the system when necessary for an individual patient without inappropriate administrative burden;
(viii) provide a mechanism to assure that patients/guardians are informed of any change from an existing outpatient prescription to a formulary substitute while hospitalized, and whether the prior medication or the substitute should be continued upon discharge from the hospital;
(ix) include policies that state that practitioners will not be penalized for prescribing non-formulary drug products that are medically necessary; and
(x) be in compliance with applicable state and federal statutes and/or state medical board requirements.
(b) The P&T Committee must:
(i) objectively evaluate the medical usefulness and cost of all available pharmaceuticals (reliance on practice guidelines developed by physician organizations is encouraged);
(ii) recommend for the formulary those drug products which are the most useful and cost-effective in patient care;
(iii) conduct drug utilization review (DUR) activities;
(iv) provide pharmaceutical information and education to the organization's (e.g., hospital) staff;
(v) analyze adverse results of drug therapy;
(vi) make recommendations to ensure safe drug use and storage; and
(vii) provide protocols for the timely procurement of non-formulary drug products when prescribed by a physician for the individualized care of a specific patient, when that decision is based on sound scientific evidence or expert medical judgment.
(c) The P&T Committee's recommendations must be approved by the medical staff;
(d) Within the drug formulary system, the P & T Committee shall recommend, and the medical staff must approve, all drugs that are subject to therapeutic interchange, as well as all processes or protocols for informing individual prescribing physicians; and
(e) The act of providing a therapeutic alternate that has not been recommended by the P&T Committee and approved by the medical staff is considered unauthorized therapeutic substitution and requires immediate prior consent by the prescriber; i.e., authorization for a new prescription.
(4) That drug formulary systems in any outpatient setting shall operate under a P&T Committee whose recommendations must have the approval of the medical staff or equivalent body, and must meet standards comparable to those listed above. In addition:
(a) That our AMA continues to insist that managed care and other health plans identify participating physicians as their "medical staff" and that they use such staff to oversee and approve plan formularies, as well as to oversee and participate on properly elected P&T Committees that develop and maintain plan formularies;

(b) That our AMA continues to insist that managed care and other health plans have well-defined processes for physicians to prescribe non-formulary drugs when medically indicated, that this process impose minimal administrative burdens, and that it include access to a formal appeals process for physicians and their patients; and (c) That our AMA strongly recommends that the switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen be discouraged.
(5) That our AMA encourages mechanisms, such as incentive-based formularies with tiered co-pays, to allow greater choice and economic responsibility in drug selection, but urges managed care plans and other third party payers to not excessively shift costs to patients so they cannot afford necessary drug therapies.
(BOT Rep. 45, I-93; Reaffirmed by Sub. Res. 501, A-95; Appended: BOT Rep. 7, I-99; Modified: Sub. Res. 524 and Reaffirmed: Res. 123, A-00; Reaffirmed: Res. 515, I-00; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: Res. 533, A-03; Modified: CMS Rep. 6, A-03; Modified: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmed: CMS Rep. 2, I-05; Reaffirmation A-06; Reaffirmation A-08; Reaffirmed: CMS Rep. 2, A-10; Reaffirmed: CMS Rep. 01, A-20)

Expanded Use of the AMA's Principles of a Sound Drug Formulary, H-125.985
Our American Medical Association (AMA) urges managed care organizations, pharmacy benefit managers, and others who design benefit packages and/or make pharmacy benefit decisions, to utilize the Principles of a Sound Drug Formulary System (as described in BOT Rep. 28, I-00) as they develop their pharmaceutical benefit plan(s) and that the Principles of a Sound Drug Formulary System be readily available on the AMA web site.
(Res. 520, A-01; Amended: Res. 514, A-02; Reaffirmed: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmation A-06; Reaffirmed: CSAPH Rep. 01, A-16)

Prior Authorization and Utilization Management Reform, H-320.939
1. Our American Medical Association (AMA) will continue its widespread prior authorization (PA) advocacy and outreach, including promotion and/or adoption of the Prior Authorization and Utilization Management Reform Principles, AMA model legislation, Prior Authorization Physician Survey and other PA research, and the AMA Prior Authorization Toolkit, which is aimed at reducing PA administrative burdens and improving patient access to care.
2. Our AMA will oppose health plan determinations on physician appeals based solely on medical coding and advocate for such decisions to be based on the direct review of a physician of the same medical specialty/subspecialty as the prescribing/ordering physician.
3. Our AMA 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.
4. Our AMA will advocate for health plans to minimize the burden on patients, physicians, and medical centers when updates must be made to previously approved and/or pending prior authorization requests.

(CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18; Appended: Res. 812, I-18; Reaffirmed in lieu of: Res. 713, A-19; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: Res. 811, I-19; Reaffirmed: CMS Rep. 4, A-21; Appended: CMS Rep. 5, A-21; Reaffirmation: A-22)

Prior Authorization Reform, D-320.982
Our American Medical Association will explore emerging technologies to automate the prior authorization process for medical services and evaluate their efficiency and scalability, while advocating for reduction in the overall volume of prior authorization requirements to ensure timely access to medically necessary care for patients and reduce practice administrative burdens.
(Res. 704, A-19; Reaffirmation: A-22)

Cost of Prescription Drugs, H-110.997
Our American Medical Association (AMA):
(1) supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied: (a) physicians must have significant input into the development and maintenance of such programs; (b) such programs must encourage optimum prescribing practices and quality of care; (c) all patients must have access to all prescription drugs necessary to treat their illnesses; (d) physicians must have the freedom to prescribe the most appropriate drug(s) and method of delivery for the individual patient; and (e) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs;

(2) reaffirms the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourages physicians to supplement medical judgments with cost considerations in making these choices;
(3) encourages physicians to stay informed about the availability and therapeutic efficacy of generic drugs and will assist physicians in this regard by regularly publishing a summary list of the patient expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products;
(4) encourages expanded third party coverage of prescription pharmaceuticals as cost effective and necessary medical therapies;
(5) will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the AMA House of Delegates informed about the findings of these studies;
(6) encourages physicians to consider prescribing the least expensive drug product (brand name or FDA A-rated generic); and
(7) encourages all physicians to become familiar with the price in their community of the medications they prescribe and to consider this along with the therapeutic benefits of the medications they select for their patients.
(BOT Rep. O, A-90; Sub. Res. 126 and Sub. Res. 503, A-95; Reaffirmed: Res. 502, A-98; Reaffirmed: Res. 520, A-99; Reaffirmed: CMS Rep. 9, I-99; Reaffirmed: CMS Rep.3, I-00; Reaffirmed: Res. 707, I-02; Reaffirmation A-04; Reaffirmed: CMS Rep. 3, I-04; Reaffirmation A-06; Reaffirmed in lieu of Res. 814, I-09; Reaffirmed in lieu of Res. 201, I-11; Reaffirmed in lieu of: Res. 207, A-17; Reaffirmed: BOT Rep. 14, A-18)

Pharmaceutical Costs, H-110.987

1. Our American Medical Association (AMA) encourages Federal Trade Commission (FTC) actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives.
2. Our AMA encourages Congress, the FTC and the Department of Health and Human Services to monitor and evaluate the utilization and impact of controlled distribution channels for prescription pharmaceuticals on patient access and market competition.
3. Our AMA will monitor the impact of mergers and acquisitions in the pharmaceutical industry.
4. Our AMA will continue to monitor and support an appropriate balance between incentives based on appropriate safeguards for innovation on the one hand and efforts to reduce regulatory and statutory barriers to competition as part of the patent system.
5. Our AMA encourages prescription drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies.
6. Our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation.
7. Our AMA supports legislation to shorten the exclusivity period for biologics.
8. Our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
9. Our AMA will generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients.
10. Our AMA supports:
    a. drug price transparency legislation that requires pharmaceutical manufacturers to provide public notice before increasing the price of any drug (generic, brand, or specialty) by 10 percent or more each year or per course of treatment and provide justification for the price increase;
    b. legislation that authorizes the Attorney General and/or the Federal Trade Commission to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients; and
    c. the expedited review of generic drug applications and prioritizing review of such applications when there is a drug shortage, no available comparable generic drug, or a price increase of 10 percent or more each year or per course of treatment.
11. Our AMA advocates for policies that prohibit price gouging on prescription medications when there are no justifiable factors or data to support the price increase.
12. Our AMA will provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.

13. Our AMA supports legislation to shorten the exclusivity period for FDA pharmaceutical products where manufacturers engage in anti-competitive behaviors or unwarranted price escalations.
14. Our AMA supports legislation that limits Medicare annual drug price increases to the rate of inflation.

(CMS Rep. 2, I-15; Reaffirmed in lieu of: Res. 817, I-16; Appended: Res. 201, A-17; Reaffirmed in lieu of: Res. 207, A-17; Modified: Speakers Rep. 01, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Appended: BOT Rep. 14, A-19; Reaffirmed: Res. 105, A-19; Appended: Res. 113, I-21; Reaffirmed in lieu of: Res. 810, I-22; Reaffirmed: Res. 801, I-23; Reaffirmed: Res. 801, I-23)

Generic Drugs, H-125.984

Our American Medical Association (AMA) believes that: (1) Physicians should be free to use either the generic or brand name in prescribing drugs for their patients, and physicians should supplement medical judgments with cost considerations in making this choice.

(2) It should be recognized that generic drugs frequently can be less costly alternatives to brand-name products.

(3) Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products (i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician.

(4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA's MedWatch program.

(5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products.

(6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength).

(7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process.

(CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmation A-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 525, A-10; Reaffirmed in lieu of Res. 224, I-14; Reaffirmed in lieu of: Res. 922, I-18)

Managed Care Cost Containment Involving Prescription Drugs H-285.965

(1) Physicians who participate in managed care plans should maintain awareness of plan decisions about drug selection by staying informed about pharmacy and therapeutics (P&T) committee actions and by ongoing personal review of formulary composition. P&T committee members should include independent physician representatives. Mechanisms should be established for ongoing peer review of formulary policy. Physicians who perceive inappropriate influence on formulary development from pharmaceutical industry consolidation should notify the proper regulatory authorities.

(2) Physicians should be particularly vigilant to ensure that formulary decisions adequately reflect the needs of individual patients and that individual needs are not unfairly sacrificed by decisions based on the needs of the average patient. Physicians are ethically required to advocate for additions to the formulary when they think patients would benefit materially and for exceptions to the formulary on a case-by-case basis when justified by the health care needs of particular patients. Mechanisms to appeal formulary exclusions should be established. Other cost-containment mechanisms, including prescription caps and prior authorization, should not unduly burden physicians or patients in accessing optimal drug therapy.

(3) Limits should be placed on the extent to which managed care plans use incentives or pressures to lower prescription drug costs. Financial incentives are permissible when they promote cost-effectiveness, not when they require withholding medically necessary care. Physicians must not be made to feel that they jeopardize their compensation or participation in a managed care plan if they prescribe drugs that are necessary for their patients but that may also be costly. There should be limits on the magnitude of financial incentives, incentives should be calculated according to the practices of a sizable group of physicians rather than on an individual basis, and incentives based on quality of care rather than cost of care should be used. Physician penalties for non-compliance with a managed care formulary in the form of deductions from withholds or direct charges are inappropriate and unduly coercive. Prescriptions should not be changed without physicians having a change to discuss the change with the patient.

(4) Managed care plans should develop and implement educational programs on cost-effective prescribing practices. Such initiatives are preferable to financial incentives or pressures by HMOs or hospitals, which can be ethically problematic.

(5) Patients must fully understand the methods used by their managed care plans to limit prescription drug costs. During enrollment, the plan must disclose the existence of formularies, the provisions for cases in which the physician

prescribes a drug that is not included in the formulary and the incentives or other mechanisms used to encourage physicians to consider costs when prescribing drugs. In addition, plans should disclose any relationships with pharmaceutical benefit management companies or pharmaceutical companies that could influence the composition of the formulary. If physicians exhaust all avenues to secure a formulary exception for a significantly advantageous drug, they are still obligated to disclose the option of the more beneficial, more costly drug to the patient, so that the patient can decide whether to pay out-of-pocket.
(6) Research should be conducted to assess the impact of formulary constraints and other approaches to containing prescription drug costs on patient welfare.
(7) Our AMA urges pharmacists to contact the prescribing physician if a prescription written by the physician violates the managed care drug formulary under which the patient is covered, so that the physician has an opportunity to prescribe an alternative drug, which may be on the formulary.
(8) When pharmacists, insurance companies, or pharmaceutical benefit management companies communicate directly with physicians or patients regarding prescriptions, the reason for the intervention should be clearly identified as being either educational or economic in nature.
(9) Our AMA will develop model legislation which prohibits managed care entities, and other insurers, from retaliating against a physician by disciplining, or withholding otherwise allowable payment because they have prescribed drugs to patients which are not on the insurer's formulary, or have appealed a plan's denial of coverage for the prescribed drug.
(10) Our AMA urges health plans including managed care organizations to provide physicians and patients with their medication formularies through multiple media, including Internet posting
(11) In the case where Internet posting of the formulary is not available and the formulary is changed, coverage should be maintained until a new formulary is distributed
(12) For physicians who do not have electronic access, hard copies must be available.
(CEJA Rep. 2, A-95; Res. 734, A-97; Appended by Res. 524 and Sub. Res.714, A-98; Reaffirmed: Res. 511, A-99; Modified: Res. 501, Reaffirmed: Res. 123 and 524, A-00; Modified: Res. 509, I-00; Reaffirmed: CMS Rep. 6, A-03; Reaffirmation I-04; Reaffirmed: Sub. Res. 529, A-05; Reaffirmation A-08; Reaffirmation A-10; Reaffirmed in lieu of Res. 822, I-11; Reaffirmation A-14; Reaffirmed: CMS Rep. 05, A-19; Reaffirmed: CMS Rep. 6, I-2)

Clinical Practice Guidelines and Clinical Quality Improvement Activities H-320.949
Our American Medical Association (AMA) adopts the following principles for the development and application of utilization management guidelines:

1. The criteria or guidelines used for utilization management shall be based upon sound clinical evidence and consider, among other factors, the safety and effectiveness of diagnosis or treatment, and must be age appropriate.
2. These utilization management guidelines and the criteria for their application shall be developed with the participation of practicing physicians.
3. Appropriate data, clinical evidence, and review criteria shall be available on request.
4. When used by health plans or health care organizations, such criteria must allow variation and take into account individual patient differences and the resources available in the particular health care system or setting to provide recommended care. The guidelines should also include a statement of their limitations and restrictions.
5. Patients and physicians shall be able to appeal decisions based on the application of utilization management guidelines.
6. The competence of non-physician reviewers and the availability of same-specialty peer review must be delineated and assured.
7. Maintaining the best interests of the patient uppermost, the final decision to discharge a patient, or any other patient management decision, remains the prerogative of the physician.

(BOT Rep. 6, A-99; Reaffirmed: Res. 820, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmed: Res. 708, A-16; Reaffirmed: CMS Rep. 08, A-17; Reaffirmed: CMS Rep. 4, A-21)

Third Party Payer Quantity Limits H-185.942

1. Our American Medical Association (AMA) supports the protection of the patient-physician relationship from interference by payers and Pharmacy Benefit Managers (PBMs) via various utilization control mechanisms, including medication and testing and treatment supply quantity limits.
2. Our AMA will work with third party payers and PBMs to ensure that if they use quantity limits for prescription drugs or testing and treatment supplies, an exceptions process must be in place to ensure that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if

medically necessary, and that any such process should place a minimum burden upon patients, physicians and their staff.

3. Our AMA supports interested states legislative efforts and federal action and will develop model state legislation to ensure that third party payers or PBMs that institute quantity limits for prescription drugs or testing and treatment supplies include an exceptions process so that patients can access higher or lower quantities of prescription drugs or testing and treatment supplies if medically necessary, including provisions such as the following:
    - physicians can specify limited supplies of medications during initial trials of a medication, or if a larger quantity of medication would expose an at-risk patient to potential harm (e.g., opioids, benzodiazepines, or psychostimulants)
    - physicians can appeal adverse determinations regarding quantity limitations;
    - payers must provide an easily accessible list of all medications and testing and treatment supplies with quantity limits and the requirements for the exception process on the payer's Web site;
    - payers must indicate, what, if any, clinical criteria (e.g., evidence-based guidelines, FDA label, scientific literature) support the plan's quantity limitations;
    - physicians with specialized qualifications may not be subject to quantity limits;
    - payers cannot charge patients for an additional co-pay if an exception request for a higher medication or testing and treatment supply quantity has been approved based on medical necessity;
    - payer decisions on exception, and subsequent appeal requests, of quantity limits must be made within two working days in non urgent situations and one working day in urgent cases; and
    - physicians or patients can submit any denied appeals to an independent review body for a final, binding decision.

(BOT Rep. 12, A-12; Reaffirmation: I-17; Modified: CMS Rep. 05, A-23)

Drug Issues in Health System Reform H-100.964

1. Our American Medical Association (AMA) consistent with AMA Policy H-165.925, supports coverage of prescription drugs, including insulin, in the AMA standard benefits package.
2. Our AMA supports consumer choice of at least two options for their pharmaceutical benefits program. This must include a fee-for-service option where restrictions on patient access and physician autonomy to prescribe any FDA-approved medication are prohibited.
3. Our AMA reaffirms AMA Policy H-110.997, supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encourage physicians to supplement medical judgments with cost considerations in making these choices.
4. Our AMA supports a managed pharmaceutical benefits option with market-driven mechanisms to control costs, provided cost control strategies satisfy AMA criteria defined in AMA Policy H-110.997 and that drug formulary systems employed are consistent with standards defined in AMA Policy H-125.991.
5. Our AMA supports prospective and retrospective drug utilization review (DUR) as a quality assurance component of pharmaceutical benefits programs, provided the DUR program is consistent with Principles of Drug Use Review defined in AMA Policy H-120.978.
6. Our AMA encourages physicians to counsel their patients about their prescription medicines and when appropriate, to supplement with written information; and supports the physician's role as the "learned intermediary" about prescription drugs.
    a. Our AMA encourages physicians to incorporate medication reviews, including discussions about drug interactions and side effects, as part of routine office-based practice, which may include the use of medication cards to facilitate this process. Medication cards should be regarded as a supplement, and not a replacement, for other information provided by the physician to the patient via oral counseling and, as appropriate, other written information.
7. Our AMA reaffirms AMA Policy H-120.991, supporting the voluntary time-honored practice of physicians providing drug samples to selected patients at no charge, and to oppose legislation or regulation whose intent is to ban drug sampling.
8. Our AMA supports CEJA's opinion that physicians have an ethical obligation to report adverse drug or device events; supports the FDA's MedWatch voluntary adverse event reporting program; and supports FDA efforts to prevent public disclosure of patient and reporter identities.
9. Our AMA opposes legislation that would mandate reporting of adverse drug and device events by physicians that would result in public disclosure of patient or reporter identities.

10. Our AMA reaffirms AMA Policy H-120.988, supporting physician prescribing of FDA-approved drugs for unlabeled indications when such use is based upon sound scientific evidence and sound medical opinion, and supporting third party payer reimbursement for drugs prescribed for medically accepted unlabeled uses.
11. Our AMA reaffirms AMA Policy H-100.989, supporting the present classification of drugs as either prescription or over-the-counter items and opposing the establishment of a pharmacist-only third (transitional) class of drugs.

(BOT Rep. 53, A-94; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CSA Rep. 3, A-97; Amended: CSA Rep. 2, I-98; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-10; Reaffirmed in lieu of Res. 201, I-11; Modified: CMS Rep. 1, A-21)