October 22, 2018

Memo to: Delegates, Alternate Delegates
Executive Directors
State Medical Associations, National Medical Specialty Societies, Professional Interest Medical Associations, Other Societies, Sections and Special Groups

Subject: 2018 Interim Meeting Handbook Addendum

We are pleased to provide the following items received in addition to those included in the advance Delegate's Handbook.

Reports

- CEJA Opinion 03 - Mergers of Secular and Religiously Affiliated Health Care Institutions – CORRECTED (Info. Report)
- CEJA Report 01 - Competence, Self-Assessment and Self-Awareness (Amendments to C&B)
- CEJA Report 02 - Study Aid-in-Dying as End-of-Life Option / The Need to Distinguish "Physician-Assisted Suicide" and "Aid-in-Dying" (Amendments to C&B)
- CEJA Report 03 - Amendment to E-2.2.1, "Pediatric Decision Making" (Amendments to C&B)
- CEJA Report 04 - CEJA Role in Implementing H-140.837, "Anti-Harassment Policy" (Amendments to C&B)
- CEJA Report 05 - Physicians' Freedom of Speech (Amendments to C&B)
- CME Report 05 - Reconciliation of AMA Policy on Medical Student Debt (C)
- CMS Report 03 - Sustain Patient-Centered Medical Home Practices (J)
- CSAPH Report 01 Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals (K)
- CSAPH Report 02 - FDA Expedited Review Programs and Processes (K)
- Report of the House of Delegates Committee on Compensation of the Officers
- Joint Report CMS-CSAPH 01 - Aligning Clinical and Financial Incentives for High-Value Care (J)

Resolutions Recommended for Consideration

- 002 - Protecting the Integrity of Public Health Data Collection
- 003 - Mental Health Issues and Use of Psychotropic Drugs for Undocumented Immigrant Children
- 215 - Extending the Medical Home to Meet Families Wherever They Go
- 216 - Medicare Part B Competitive Acquisition Program (CAP)
- 217 - Opposition to Medicare Part B to Part D Changes
- 218 - Alternatives to Tort for Medical Liability
- 219 - Promotion and Education of Breastfeeding
- 220 - Supporting Mental Health Training Programs for Corrections Officers and Crisis Intervention Teams for Law Enforcement
- 221 - Regulatory Relief from Burdensome CMS "HPI" EHR Requirements
- 222 - Patient Privacy Invasion by the Submission of Fully Identified Quality Measure Data to CMS
- 223 - Permanent Reauthorization of the State Children's Health Insurance Program
- 224 - Fairness in the Centers for Medicare and Medicaid Services Authorized Quality Improvement Organization's (QIO) Medical Care Review Process
- 225 - Surprise Out of Network Bills
- 226 - Support for Interoperability of Clinical Data

- 227 - CMS Proposal to Consolidate Evaluation and Management Services
- 603 - Support of AAIP's Desired Qualifications for Indian Health Service Director
- 806 - Telemedicine Models and Access to Care in Post-Acute and Long-Term Care
- 807 - Emergency Department Copayments for Medicaid Beneficiaries
- 808 - The Improper Use of Beers or Similar Criteria and Third-Party Payer Compliance Activities (H-185.940)
- 809 - Medicaid Clinical Trials Coverage
- 810 - Medicare Advantage Step Therapy
- 811 - Infertility Benefits for Active-Duty Military Personnel
- 812 - ICD Code for Patient Harm from Payer Interference
- 813 - Direct Primary Care Health Savings Account Clarification
- 814 - Prior Authorization Relief in Medicare Advantage Plans
- 815 - Uncompensated Physician Labor
- 816 - Medicare Advantage Plan Inadequacies
- 817 - Increase Reimbursement for Psychiatric Services
- 818 - Drug Pricing Transparency
- 819 - Medicare Reimbursement Formula for Oncologists Administering Drugs
- 820 - Ensuring Quality Health Care for Our Veterans
- 821 - Direct Primary Care and Concierge Medicine Based Practices
- 915 - Mandatory Reporting
- 916 - Ban on Tobacco Flavoring Agents with Respiratory Toxicity
- 917 - Protect and Maintain the Clean Air Act
- 918 - Allergen Labeling on Food Packaging
- 919 - Opioid Mitigation
- 920 - Continued Support for Federal Vaccination Funding
- 921 - Food Environments and Challenges Accessing Healthy Food
- 958 - National Health Service Corps Eligibility
- 959 - Physician and Medical Student Mental Health and Suicide
- 960 - Inadequate Residency Slots
- 961 - Protect Physician-Led Medical Education
- 962 - Improve Physician Health Programs

Resolutions Not for Consideration

- 602 - AMA Policy Statement with Editorials

Finally, your Speakers wish to inform you that the charts listing actions taken in follow-up to resolutions and report recommendations from the 2017 Interim and 2018 Annual Meetings will be posted on the Interim Meeting website (www.*ama-assn.org/interim-meeting*).

Sincerely,

Susan R. Bailey, MD
Speaker, House of Delegates

Bruce A. Scott, MD
Vice Speaker, House of Delegates

CORRECTED

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Opinion 3-I-18

Subject: Mergers of Secular and Religiously Affiliated Health Care Institutions

Presented by: James E. Sabin, MD, Chair

INTRODUCTION

At the 2018 Annual Meeting, the American Medical Association (AMA) House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 2-A-18, "Mergers of Secular and Religiously Affiliated Health Care Institutions." The Council issues this Opinion, which will appear in the next version of AMA PolicyFinder and the next print edition of the *Code of Medical Ethics*.

E-11.2.6 – Mergers of Secular and Religiously Affiliated Health Care Institutions

The merger of secular health care institutions and those affiliated with a faith tradition can benefit patients and communities by sustaining the ability to provide a continuum of care locally in the face of financial and other pressures. Yet consolidation among health care institutions with diverging value commitments and missions may also result in limiting what services are available. Consolidation can be a source of tension for the physicians and other health care professionals who are employed by or affiliated with the consolidated health care entity.

Protecting the community that the institution serves as well as the integrity of the institution, the physicians and other professionals who practice in association with it, is an essential, but challenging responsibility.

Physician-leaders within institutions that have or are contemplating a merger of secular and faith-based institutions should:

(a) Seek input from stakeholders to inform decisions to help ensure that after a consolidation the same breadth of services and care previously offered will continue to be available to the community.

(b) Be transparent about the values and mission that will guide the consolidated entity and proactively communicate to stakeholders, including prospective patients, physicians, staff, and civic leaders, how this will affect patient care and access to services.

* Opinions of the Council on Ethical and Judicial Affairs will be placed on the Consent Calendar for informational reports, but may be withdrawn from the Consent Calendar on motion of any member of the House of Delegates and referred to a Reference Committee. The members of the House may discuss an Opinion fully in Reference Committee and on the floor of the House. After concluding its discussion, the House shall file the Opinion. The House may adopt a resolution requesting the Council on Ethical and Judicial Affairs to reconsider or withdraw the Opinion.

(c) Negotiate contractual issues of governance, management, financing, and personnel that will respect the diversity of values within the community and at minimum that the same breadth of services and care remain available to the community.

(d) Recognize that physicians' primary obligation is to their patients. Physician-leaders in consolidated health systems should provide avenues for meaningful appeal and advocacy to enable associated physicians to respond to the unique needs of individual patients.

(e) Establish mechanisms to monitor the effect of new institutional arrangements on patient care and well-being and the opportunity of participating clinicians to uphold professional norms, both to identify and address adverse consequences and to identify and disseminate positive outcomes.

Individual physicians associated with secular and faith-based institutions that have or propose to consolidate should:

(f) Work to hold leaders accountable to meeting conditions for professionalism within the institution.

(g) Advocate for solutions when there is ongoing disagreement about services or arrangements for care. (VII, VIII, IX)

REPORT 1 OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS (1-I-18)
Competence, Self-Assessment and Self-Awareness
(Reference Committee on Amendments to Constitution and Bylaws)

EXECUTIVE SUMMARY

The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society.

The ethical responsibility of competence encompasses more than knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient's well-being.

To fulfill their ethical responsibility of competence, physicians at all stages in their professional lives should cultivate and exercise skills of self-awareness and active self-observation; take advantage of tools for self-assessment that are appropriate to their practice settings and patient populations; and be attentive to environmental and other factors that may compromise their ability to bring their best skills to the care of individual patients. As a profession, medicine should provide meaningful opportunity for physicians to hone their ability to be self-reflective.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-I-18

Subject: Competence, Self-Assessment and Self-Awareness

Presented by: James E. Sabin, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Todd M. Hertzberg, MD, Chair)

The expectation that physicians will provide competent care is central to medicine. This expectation shaped the founding mission of the American Medical Association (AMA) and runs throughout the AMA *Code of Medical Ethics* [1-4]. It undergirds professional autonomy and the privilege of self-regulation granted to medicine by society [5]. The profession promises that practitioners will have the knowledge, skills, and characteristics to practice safely and that the profession as a whole and its individual members will hold themselves accountable to identify and address lapses [6-9].

Yet despite the centrality of competence to professionalism, the *Code* has not hitherto examined what the commitment to competence means as an ethical responsibility for individual physicians in day-to-day practice. This report by the Council on Ethical and Judicial Affairs (CEJA) explores this topic to develop ethics guidance for physicians.

DEFINING COMPETENCE

A caveat is in order. Various bodies in medicine undertake point-in-time, cross-sectional assessments of physicians' technical knowledge and skills. However, this report is not concerned with matters of technical proficiency assessed by medical schools and residency programs, specialty boards (for purposes of certification), or hospital and other health care organizations (e.g., for privileging and credentialing). Such matters lie outside the Council's purview.

The ethical responsibility of competence encompasses more than knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual patients, competence is fluid and dependent on context. Importantly, the ethical responsibility of competence requires that physicians at all stages of their professional lives be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole. For purposes of this analysis, competence is understood as "the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and the community being served" and as "developmental, impermanent, and context dependent" [10].

Moreover, the Council is keenly aware that technical proficiency evolves over time—what is expected of physicians just entering practice is not exactly the same as what is expected of mid-

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

career physicians or physicians who are changing or re-entering practice or transitioning out of active practice to other roles. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues.

The concept that informs this report differs as well from the narrower definition of competence as the knowledge and skills an individual has to do a job. Rather, this report explores a broader notion of competence that encompasses deeper aspects of wisdom, judgment and practice that enable physicians to assure patients, the public, and the profession that they provide safe, high quality care moment to moment over the course of a professional lifetime.

FROM SELF-ASSESSMENT TO "INFORMED" SELF-ASSESSMENT

Health care institutions and the medical profession as a whole take responsibility to regulate physicians through credentialing and privileging, routinely testing knowledge (maintenance of certification, requirements for continuing education, etc.) and, when needed, taking disciplinary action against physicians who fail to meet expectations for competent, professional practice. However, the better part of the responsibility to maintain competence rests with physicians' "individual capacity, as clinicians, to self-assess [their] strengths, deficiencies, and learning needs to maintain a level of competence commensurate with [their] clinical roles" [11].

Self-assessment has thus become "integral to many appraisal systems and has been espoused as an important aspect of personal professional behavior by several regulatory bodies and those developing learning outcomes for students" [12]. Undergraduate and graduate medical education programs regularly use self-assessment along with third-party evaluations to ensure that trainees are acquiring the knowledge and skills necessary for competent practice [5,10,13-16].

Yet how accurately physicians assess their own performance is open to question. Research to date suggests that there is poor correlation between how physicians rate themselves and how others rate them [5,12,13]. Various studies among health professionals have concluded that clinicians and trainees tend to assess their peers' performance more accurately than they do their own; several have found that poor performers (e.g., those in the bottom quartile) tend to over-estimate their abilities while high performers (e.g., those in the top quartile), tend to under-estimate themselves [5,12,17].

The available findings suggest that self-assessment involves an interplay of factors that can be complicated by lack of insight or of metacognitive skill, that is, ability to be self-observant in the moment. Similarly, personal characteristics (e.g., gender, ethnicity, or cultural background) and the impact of external factors (e.g., the purpose of self-assessment or whether it is designed to assess practical skills or theoretical knowledge) can all affect self-assessment [12,18]. The published literature also indicates that interventions intended to enhance self-assessment may seek different goals—improving the accuracy of self-assessors' perceptions of their learning needs, promoting appropriate change in learning activities, or improving clinical practice or patient outcomes [12].

Self-assessment tools alone are not sufficient measures of physicians' ability to provide safe, high quality care. Feedback from third parties is essential—or as one researcher has observed, "The road to self-knowledge may run through other people" [19]. However, physicians are often wary of assessment. They have indicated that while they want feedback, they are not sure how to use information that is not congruent with their self-appraisals [20]. Physicians can be hesitant to seek feedback for fear of looking incompetent or exposing possible deficiencies or out of concern that soliciting feedback could adversely affect their relationships with those whom they approach [20].

They may also question the accuracy and credibility of the assessment process and the data it generates [21].

To be effective, feedback must be valued both by those being assessed and by those offering assessment [14]. When there is tension between the stated goals of assessment and the implicit culture of the health care organization or institution, assessment programs can too readily devolve into an activity undertaken primarily to satisfy administrators that rarely improves patient care [20]. Feedback mechanisms should be appropriate to the skills being assessed—multi-source reviews ("360° reviews"), for example, are generally better suited to providing feedback on communication and interpersonal skills than on technical knowledge or skills—and easy for evaluators to understand and use [14]. High quality feedback will come from multiple sources; be specific and focus on key elements of the ability being assessed; address behaviors rather than personality or personal characteristics; and "provide both positive comments to reinforce good behavior and constructive comments with action items to address deficiencies" [22]. Beyond such formal mechanisms, physicians should welcome and seek out informal input from colleagues. They should be willing to offer timely comments to colleagues as well.

One study among physicians and physicians in training found that participants used a dynamic, multidimensional process to assess their own abilities. Under this process of what researchers identified as "informed self-assessment," participants interpreted and responded to multiple types of information, such as cognitive and affective data, from both formal and informal sources [23]. Participants described "critically reflecting 'in action,' that is, during an activity or throughout the day:"

> I think we do a lot of it without thinking of it as reflection. We do it every day when we look at a patient's chart. You look back and see the last visit, "What did I do, or should I have done something different?" I mean that's reflection, but yet I wouldn't have thought of that as self-assessment or self-reflection, but we do it dozens of times a day [23].

EXPERTISE & EXPERT JUDGMENT

On this broad understanding of competence, physicians' thought processes are as important as their knowledge base or technical skills. Thus, understanding competence requires understanding something of the nature of expertise and processes of expert reasoning, themselves topics of ongoing exploration [24,25,26,27]. Prevailing theory distinguishes "fast" from "slow" thinking; that is, reflexive, intuitive processes that require minimal cognitive resources versus deliberate, analytical processes that require more conscious effort [26]. Some scholars take expertise to involve "fast" processes, and specifically decision making that involves automatic, nonanalytic resources acquired through experience [24]. Others argue that expertise consists in using "slow," effortful, analytic processes to address problems [24]. A more integrative view argues that expertise resides in being able to transition between intuitive and analytical processes as circumstances require. On this account, experts use automatic resources to free up cognitive capacity so that they maintain awareness of the environment ("situational awareness") and can determine when to shift to effortful processes [24].

Expert judgment is the ability "to respond effectively in the moment to the limits of [one's] automatic resources and to transition appropriately to a greater reliance on effortful processes when needed" [24], a practice described as "slowing down." Knowing when to slow down and be reflective has been demonstrated to improve diagnostic accuracy and other outcomes [26]. To respond to the unexpected events that often arise in a clinical situation, the physician must "vigilantly monitor relevant environmental cues" and use these as signals to slow down, to

transition into a more effortful state [25]. This can happen, for example, when a surgeon confronts an unexpected tumor or anatomical anomaly during a procedure. “Slowing down when you should” serves as a critical marker for intraoperative surgical judgment [24].

INFLUENCES ON CLINICAL REASONING

Clinical reasoning is a complex endeavor. Physicians’ capabilities develop through education, training, and experiences that provide tools with which to shape their clinical reasoning. Every physician arrives at a diagnosis and treatment plan for an individual in ways that may align with or differ from the analytical and investigative processes of their colleagues in innumerable ways. When something goes wrong in the clinic, it can be difficult to discern why. Nonetheless, all physicians are open to certain common pitfalls in reasoning, including relying unduly on heuristics and habits of perception, and succumbing to overconfidence.

Heuristics

Physicians often use various heuristics—i.e., cognitive short cuts—to aid decision making. While heuristics can be useful tools to help physicians identify and categorize relevant information, these time-saving devices can also derail decision making. For example, a physician may mistakenly assume that “something that seems similar to other things in a certain category is itself a member of that category” (the representative heuristic) [28], and fail to diagnose a serious health problem. Imagine a case in which a patient presents with symptoms of a possible heart attack or a stroke that the physician proceeds to discount as stress or intoxication once the physician learns that the patient is going through a divorce or smells alcohol on the patient’s breath. Or a physician may miscalculate the likelihood of a disease or injury occurring by placing too much weight “on examples of things that come to mind easily, . . . because they are easily remembered or recently encountered” (the availability heuristic) [28]. For example, amidst heavy media coverage of an outbreak of highly infectious disease thousands of miles away in a remote part of the world, a physician seeing a patient with symptoms of what is actually a more commonplace illness may misdiagnose (or over diagnose) the exotic condition because that is what is top of mind.

Clinical reasoning can be derailed by other common cognitive missteps as well. These can include misperceiving a coincidental relationship as a causal relationship (illusory bias), or the tendency to remember information transferred at the beginning (or end) of an exchange but not information transferred in the middle (primary or recency bias) [28,29,30].

Habits of Perception

Like every other person, physicians can also find themselves prone to explicit (conscious) or implicit (unconscious) habits of perception or biases. Physicians may allow unquestioned assumptions based on a patient’s race or ethnicity, gender, socioeconomic status, or health behavior, among other features, to shape how they perceive the patient and how they engage with, evaluate and treat the individual. Basing one’s interactions with a patient on pre-existing expectations or stereotypes demeans the patient, undermines the patient’s relationship with the physician and the health care system, and can result in significant health disparities across entire communities [31]. This is of particular concern for patients who are members of minority and historically disadvantaged populations [31]. Physicians may fall victim to the tendency to seek out information that confirms established expectations or dismiss contradicting information that does not fit into predetermined beliefs (confirmatory bias) [28]. These often inadvertent thought processes can result in a physician pursuing an incorrect line of questioning or testing that then leads to a misdiagnosis or the wrong treatment.

No matter how well a patient may seem to fit a stereotype, it is imperative that the physician look beyond categories and assumptions to investigate openly the health issues experienced by the patient. Although all human beings exhibit both conscious and unconscious habits of perception, physicians must remain vigilant in not allowing preconceived or unexamined assumptions to influence their medical practice.

Overconfidence

Finally, another obstacle to strong clinical reasoning that physicians may encounter is overconfidence. Despite their extensive training, physicians, like all people, are poor at identifying the gaps in their knowledge [28,30]. Physicians may consider their skills to be excellent, when, in fact, their peers have identified areas for improvement [30]. Overconfidence in one's abilities can lead to suboptimal care for a patient, be it through mismanaging resources, failing to consider the advice of others, or not acknowledging one's limits [28,30].

To avoid falling into such traps, physicians must recognize that many factors can and will influence their clinical decisions [28]. They need to be aware of the information they do and do not have and they need to acknowledge that many factors can and will influence their judgment. They should keep in mind the likelihood of diseases and conditions and take the time to distinguish information that is truly essential to sound clinical judgment from the wealth of possibly relevant information available about a patient. They should consider reasons their decisions may be wrong and seek alternatives, as well as seek to disprove rather than confirm their hypotheses [28]. And they should be sensitive to the ways in which assumptions may color their reasoning and not allow expectations to govern their interactions with patients.

Shortcomings can be an opportunity for growth in medicine, as in any other field. By becoming aware of areas in which their skills are not at their strongest and seeking additional education or consulting with colleagues, physicians can enhance their practice and best serve their patients.

Physicians' ability to practice safely can be affected by their own health, of course. The *Code of Medical Ethics* addresses such situations in guidance on physicians' health and wellness (E-9.3.1) and their responsibilities to impaired colleagues (E-9.3.2).

FROM INFORMED SELF-ASSESSMENT TO SELF-AWARENESS

Recognizing that many factors affect clinical reasoning and that self-assessment as traditionally conceived has significant shortcomings, several scholars have argued that a different understanding of self-assessment is needed, along with a different conceptualization of its role in a self-regulating profession [32]. Self-assessment, it is suggested, is a mechanism for identifying both one's weaknesses and one's strengths. One should be aware of one's weaknesses in order to self-limit practice in areas in which one has limited competence, to help set appropriate learning goals, and to identify areas that "should be accepted as forever outside one's scope of competent practice" [32]. Knowing one's strengths, meanwhile, allows a physician both to "act with appropriate confidence" and to "set appropriately challenging learning goals" that push the boundaries of the physician's knowledge [32].

If self-assessment is to fulfill these functions, physicians need to reflect on past performance to evaluate not only their general abilities but also specific completed performances. At the same time, they must use self-assessment predictively to assess how likely they are to be able to manage new challenges and new situations. More important, physicians should understand self-assessment as an ongoing process of monitoring tasks during performance [3]. The ability to monitor oneself in

the moment is critical to physicians' ethical responsibility to practice safely, at the top of their expertise but not beyond it.

Expert practitioners rely on pattern recognition and other automatic resources to be able to think and act intuitively. As noted above, an important component of expert judgment is transitioning effectively from automatic modes of thinking to more effortful modes as the situation requires. Self-awareness, in the form of attentive self-observation (metacognitive monitoring), alerts physicians when they need to direct additional cognitive resources to the immediate task. For example, among surgeons, knowing when to "slow down" during a procedure is critical to competent professional performance, whether that means actually stopping the procedure, withdrawing attention from the surrounding environment to focus more intently on the task at hand, or removing distractions from the operating environment [25].

Physicians should also be sensitive to the ways that interruptions and distractions, which are common in health care settings, can affect competence in the moment [34,35], by disrupting memory processes, particularly the "prospective memory"—i.e., "a memory performance in which a person must recall an intention or plan in the future without an agent telling them to do so"—important for resuming interrupted tasks [35,36]. Systems-level interventions have been shown to help reduce the number or type of interruptions and distractions and mitigate their impact on medical errors [37].

A key aspect of competence is demonstrating situation-specific awareness in the moment of being at the boundaries of one's knowledge and responding accordingly [33]. Slowing down, looking things up, consulting a colleague, or deferring from taking on a case can all be appropriate responses when physicians' self-awareness tells them they are at the limits of their abilities. The capacity for ongoing, attentive self-observation, for "mindful" practice, is an essential marker of competence broadly understood:

> Safe practice in a health professional's day-to-day performance requires an awareness of when one lacks the specific knowledge or skill to make a good decision regarding a particular patient . . . . This decision making in context is importantly different from being able to accurately rate one's own strengths and weaknesses in an acontextual manner. . . . Safe practice requires that self-assessment be conceptualized as repeatedly enacted, situationally relevant assessments of self-efficacy and ongoing 'reflection-in-practice,' addressing emergent problems and continuously monitoring one's ability to effectively solve the current problem [32].

Self-aware physicians discern when they are no longer comfortable handling a particular type of case and know when they need to obtain more information or need additional resources to supplement their own skills [32]. Self-aware physicians are also alert to how external stressors—the death of a loved one or other family crisis, or the reorganization of their practice, for example—may be affecting their ability to provide care appropriately at a given time. They recognize when they should ask themselves whether they should postpone care, arrange to have a colleague provide care, or otherwise find ways to protect the patient's well-being.

MAINTAINING COMPETENCE ACROSS A PRACTICE LIFETIME

For physicians, the ideal is not simply to be "good" practitioners, but to excel throughout their professional careers. This ideal holds not just over the course of a sustained clinical practice, but equally when physicians re-enter practice after a hiatus, transition from active patient care to roles as educators or administrators, or take on other functions in health care. Self-assessment and self-awareness are central to achieving that goal.

A variety of strategies are available to physicians to support effective self-assessment and help physicians cultivate the kind of self-awareness that enables them to "know when to slow down" in day-to-day practice. One such strategy might be to create a portfolio of materials for reflection in the form of written descriptions, audio or video recording, or photos of encounters with patients that can provide evidence of learning, achievement and accomplishment [16] or of opportunities to improve practice. A strength of portfolios as a tool for assessing one's practice is that, unlike standardized examinations, they are drawn from one's actual work and require self-reflection [15].

As noted above, to be effective, self-assessment must be joined with input from others. Well-designed multi-source feedback can be useful in this regard, particularly for providing information about interpersonal behaviors [14]. Research has shown that a four-domain tool with a simple response that elicits feedback about how well one maintains trust and professional relationships with patients, one's communication and teamwork skills, and accessibility offers a valid, reliable tool that can have practical value in helping to correct poor behavior and, just as important, consolidate good behavior [14]. Informal arrangements among colleagues to provide thoughtful feedback will not have the rigor of a validated tool but can accomplish similar ends.

Reflective practice, that is, the habit of using critical reflection to learn from experience, is essential to developing and maintaining competence across a physician's practice lifetime [38]. It enables physicians to "integrate personal beliefs, attitudes, and values in the context of professional culture," and to bridge new and existing knowledge. Studies suggest that reflective thinking can be assessed, and that it can be developed, but also that the habit can be lost over time with increasing years in practice [38].

"Mindful practice," that is, being fully present in everyday experience and aware of one's own mental processes (including those that cloud decision making) [39], sustains the attitudes and skills that are central to self-awareness. Medical training, with its fatigue, dogmatism, and emphasis on behavior over consciousness, erects barriers to mindful practice, while an individual's unexamined negative emotions, failure of imagination, and literal-mindedness can do likewise. Mindfulness can be self-taught, but for most it is most effectively learned in relationship with a mentor or guide. Nonetheless, despite challenges, there are myriad ways physicians can cultivate mindfulness. Meditation, which may come first to mind, is one, but so is keeping a journal, reviewing videos of encounters with patients, or seeking insight from critical incident reports [39].

"Exemplary physicians," one scholar notes, "seem to have a capacity for self-critical reflection that pervades all aspects of practice, including being present with the patient, solving problems, eliciting and transmitting information, making evidence-based decisions, performing technical skills, and defining their own values" [39].

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

> The expectation that physicians will provide competent care is central to medicine. It undergirds professional autonomy and the privilege of self-regulation granted by society. To this end, medical schools, residency and fellowship programs, specialty boards, and other health care organizations regularly assess physicians' technical knowledge and skills.
>
> However, as an ethical responsibility competence encompasses more than medical knowledge and skill. It requires physicians to understand that as a practical matter in the care of actual

patients, competence is fluid and dependent on context. Each phase of a medical career, from medical school through retirement, carries its own implications for what a physician should know and be able to do to practice safely and to maintain effective relationships with patients and with colleagues. Physicians at all stages of their professional lives need to be able to recognize when they are and when they are not able to provide appropriate care for the patient in front of them or the patients in their practice as a whole.

To fulfill the ethical responsibility of competence, individual physicians and physicians in training should strive to:

(a) Cultivate continuous self-awareness and self-observation.

(b) Recognize that different points of transition in professional life can make different demands on competence.

(c) Take advantage of well-designed tools for self-assessment appropriate to their practice settings and patient populations.

(d) Seek feedback from peers and others.

(e) Be attentive to environmental and other factors that may compromise their ability to bring appropriate skills to the care of individual patients and act in the patient's best interest.

(f) Intervene in a timely and appropriate manner when a colleague's ability to practice safely is compromised by impairment, in keeping with ethics guidance.

Medicine as a profession should continue to refine mechanisms for assessing knowledge and skill and should develop meaningful opportunities for physicians and physicians in training to hone their ability to be self-reflective and attentive in the moment.

(New HOD/CEJA Policy)

Fiscal Note: Less than $500.

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 2-I-18

Subject:	Study Aid-in-Dying as End-of-Life Option (Resolution 15-A-16) The Need to Distinguish "Physician-Assisted Suicide" and "Aid in Dying" (Resolution 14-A-17)
Presented by:	James E. Sabin, MD, Chair
Referred to:	Reference Committee on Amendments to Constitution and Bylaws (Todd M. Hertzberg, MD, Chair)

At the 2016 Annual Meeting, the House of Delegates referred Resolution 15-A-16, "Study Aid-in-Dying as End-of-Life Option," presented by the Oregon Delegation, which asked:

> That our American Medical Association (AMA) and its Council on Judicial and Ethical Affairs (CEJA), study the issue of medical aid-in-dying with consideration of (1) data collected from the states that currently authorize aid-in-dying, and (2) input from some of the physicians who have provided medical aid-in-dying to qualified patients, and report back to the HOD at the 2017 Annual Meeting with recommendation regarding the AMA taking a neutral stance on physician "aid-in-dying."

At the following Annual Meeting in June 2017, the House of Delegates similarly referred Resolution 14-A-17, "The Need to Distinguish between 'Physician-Assisted Suicide' and 'Aid in Dying'" (presented by M. Zuhdi Jasser, MD), which asked that our AMA:

> (1) as a matter of organizational policy, when referring to what it currently defines as '*Physician Assisted Suicide'* avoid any replacement with the phrase '*Aid in Dying*' when describing what has long been understood by the AMA to specifically be '*Physician Assisted Suicide'*; (2) develop definitions and a clear distinction between what is meant when the AMA uses the phrase '*Physician Assisted Suicide'* and the phrase *'Aid in Dying'*; and (3) fully utilize these definitions and distinctions in organizational policy, discussions, and position statements regarding both '*Physician Assisted Suicide*' and *'Aid in Dying.'*

This report by the Council on Ethical and Judicial Affairs addresses the concerns expressed in Resolutions 15-A-16 and 14-A-17. In carrying out its review of issues in this area, CEJA reviewed the philosophical and empirical literature, sought input from the House of Delegates through an I-16 educational program on physician-assisted suicide, an informal "open house" at A-17, and its I-17 Open Forum. The council wishes to express its sincere appreciation for participants' contributions during these sessions and for additional written communications received from multiple stakeholders, which have enhanced its deliberations.

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The council observes that the ethical arguments advanced today supporting and opposing "physician-assisted suicide" or "aid in dying" are fundamentally unchanged from those examined in CEJA's 1991 report on this topic [1]. The present report does not rehearse these arguments again as such. Rather, it considers the implications of the legalization of assisted suicide in the United States since the adoption of Opinion E-5.7, "Physician-Assisted Suicide," in 1994.

"ASSISTED SUICIDE," "AID IN DYING," OR "DEATH WITH DIGNITY"?

Not surprisingly, the terms stakeholders use to refer the practice of physicians prescribing lethal medication to be self-administered by patients in many ways reflect the different ethical perspectives that inform ongoing societal debate. Proponents of physician participation often use language that casts the practice in a positive light. "Death with dignity" foregrounds patients' values and goals, while "aid in dying" invokes physicians' commitment to succor and support. Such connotations are visible in the titles of relevant legislation in states that have legalized the practice: "Death with Dignity" (Oregon, Washington, District of Columbia), "Patient Choice and Control at the End of Life" (Vermont), "End of Life Options" (California, Colorado), "Our Care Our Choice Act" (Hawaii), and in Canada's "Medical Aid in Dying."

Correspondingly, those who oppose physician provision of lethal medications refer to the practice as "physician-assisted suicide," with its negative connotations regarding patients' psychological state and its suggestion that physicians are complicit in something that, in other contexts, they would seek to prevent. The language of dignity and aid, critics contend, are euphemisms [2]; their use obscures or sanitizes the activity. In their view such language characterizes physicians' role in a way that risks construing an act that is ethically unacceptable as good medical practice [3]. Still others, meanwhile, argue that the choice by terminally ill patients to take action to end their own lives with the assistance of their physician is distinct from what is traditionally understood as "suicide" [4].

The council recognizes that choosing one term of art over others can carry multiple, and not always intended messages. However, in the absence of a perfect option, CEJA believes ethical deliberation and debate is best served by using plainly descriptive language. In the council's view, despite its negative connotations [5], the term "physician assisted suicide" describes the practice with the greatest precision. Most importantly, it clearly distinguishes the practice from euthanasia [1]. The terms "aid in dying" or "death with dignity" could be used to describe either euthanasia or palliative/hospice care at the end of life and this degree of ambiguity is unacceptable for providing ethical guidance.

COMMON GROUND

Beneath the seemingly incommensurate perspectives that feature prominently in public and professional debate about writing a prescription to provide patients with the means to end life if they so choose, CEJA perceives a deeply and broadly shared vision of what matters at the end of life. A vision that is characterized by hope for a death that preserves dignity, a sense of the sacredness of ministering to a patient at the end of life, recognition of the relief of suffering as the deepest aim of medicine, and fully voluntary participation on the part of both patient and physician in decisions about how to approach the end of life.

Differences lie in the forms these deep commitments take in concrete decisions and actions. CEJA believes that thoughtful, morally admirable individuals hold diverging, yet equally deeply held, and well-considered perspectives about physician-assisted suicide that govern how these shared commitments are ultimately expressed. For one patient, dying "with dignity" may mean accepting

the end of life however it comes as gracefully as one can; for another, it may mean being able to exercise some measure of control over the circumstances in which death occurs. For some physicians, the sacredness of ministering to a terminally ill or dying patient and the duty not to abandon the patient preclude the possibility of supporting patients in hastening their death. For others, not to provide a prescription for lethal medication in response to a patient's sincere request violates that same commitment and duty. Both groups of physicians base their view of ethical practice on the guidance of Principle I of the AMA *Principles of Medical Ethics*: "A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights."

So too, how physicians understand and act on the goals of relieving suffering, respecting autonomy, and maintaining dignity at the end of life is directed by identity-conferring beliefs and values that may not be commensurate. Where one physician understands providing the means to hasten death to be an abrogation of the physician's fundamental role as healer that forecloses any possibility of offering care that respects dignity, another in equally good faith understands supporting a patient's request for aid in hastening a foreseen death to be an expression of care and compassion.

IRREDUCIBLE DIFFERENCES IN MORAL PERSPECTIVES ON PHYSICIAN-ASSISTED SUICIDE

How to respond when coherent, consistent, and deeply held beliefs yield irreducibly different judgments about what is an ethically permissible course of action is profoundly challenging. With respect to physician-assisted suicide, some professional organizations—for example, the American Academy of Hospice and Palliative Medicine [6]—have adopted a position of "studied neutrality." Positions of studied neutrality neither endorse nor oppose the contested practice, but instead are intended to respect that there are irreducible differences among the deeply held beliefs and values that inform public and professional perspectives [6,7], and to leave space open for ongoing discussion. Nonetheless, as a policy position, studied neutrality has been criticized as neither neutral or appropriate for organized medicine [8], and as being open to unintended consequences, including stifling the very debate it purports to encourage or being read as little more than acquiescence with the contested practice [9].

CEJA approaches the condition of irreducible difference from a different direction. In its 2014 report on exercise of conscience, the Council noted that "health care professionals may hold very different core beliefs and thus reach very different decisions based on those core beliefs, yet equally act according to the dictates of conscience. For example, a physician who chooses to provide abortions on the basis of a deeply held belief in protecting women's autonomy makes the same kind of moral claim to conscience as does a physician who refuses to provide abortion on the basis of respect for the sanctity of life of the fetus" [10].

Importantly, decisions taken in conscience are not simply idiosyncratic; they do not rest on intuition or emotion. Rather, such decisions are based on "substantive, coherent, and reasonably stable" values and principles [10]. Physicians must be able to articulate how those values and principles justify the action in question.

The ethical arguments offered for more than two decades by those who support and those who oppose physician participation in assisted suicide reflect the diverging "substantive, coherent, and reasonably stable" values and principles within the profession and the wider moral community. While supporters and opponents of physician-assisted suicide share a common commitment to "compassion and respect for human dignity and rights" (AMA Principles of Medical Ethics, I),

they draw different moral conclusions from the underlying principle they share. As psychiatrist Harvey Chochinov observed with respect to the stakeholders interviewed by Canadian Supreme Court's advisory panel on physician-assisted death, "neither those who are strongly supportive nor those who are opposed hold a monopoly on integrity and a genuine concern for the well-being of people contemplating end of life. Equally true: neither side is immune from impulses shaped more by ideology than a deep and nuanced understanding of how to best honor and address the needs of people who are suffering" [11].

THE RISK OF UNINTENDED CONSEQUENCES

From the earliest days of the debate, a prominent argument raised against permitting physician-assisted suicide has been that doing so will have adverse consequences for individual patients, the medical profession, and society at large. Scholars have cited the prospect that boundaries will be eroded and practice will be extended beyond competent, terminally ill adult patients; to patients with psychiatric disorders, children; or that criteria will be broadened beyond physical suffering to encompass existential suffering; or that stigmatized or socioeconomically disadvantaged patients will be coerced or encouraged to end their lives. Concerns have also been expressed that permitting the practice will compromise the integrity of the profession, undermine trust, and harm the physicians and other health care professionals who participate; and that forces outside medicine will unduly influence decisions.

The question whether safeguards—which in the U.S. jurisdictions that permit assisted suicide, restrict the practice to terminally ill adult patients who have decision-making capacity and who voluntarily request assisted suicide, along with procedural and reporting requirements—can actually protect patients and sustain the integrity of medicine remains deeply contested. Some studies have "found no evidence to justify the grave and important concern often expressed about the potential for abuse—namely, the fear that legalized physician-assisted dying will target the vulnerable or pose the greatest risk to people in vulnerable groups" [12], others question whether the available data can in fact support any such conclusions, finding the evidence cited variously flawed [13], inadequate [14], or distorted [15].

Although cross-cultural comparisons are problematic [16], current evidence from Europe does tell a cautionary tale. Recent findings from studies in Belgium and the Netherlands, both countries that permit euthanasia as well as physician-assisted suicide, mitigate some fears but underscore others [17]. For example, research in the Netherlands has found that "requests characterized by psychological as opposed to physical suffering were more likely to be rejected, as were requests by individuals who lived alone," mitigating fears that "solitary, depressed individuals with potentially reversible conditions might successfully end their lives." At the same time, however, among patients who obtained euthanasia or assisted suicide, nearly 4 percent "reported only psychological suffering." At the level of anecdote, a description of a case of euthanasia in Belgium elicited widespread concern about the emergence of a "slippery slope" [18].

Studies have also raised questions about how effective retrospective review of decisions to provide euthanasia/assisted suicide is in policing practice [19,20]. A qualitative analysis of cases that Dutch regional euthanasia committees determined had not met legal "due care criteria" found that such reviews focus on procedural considerations and do not "directly assess the actual eligibility" of the patients who obtained euthanasia [19]. A separate study of cases in which psychiatric patients obtained euthanasia found that physicians' reports "stated that psychosis or depression did or did not affect capacity but provided little explanation regarding their judgments" and that review committees "generally accepted the judgment of the physician performing EAS [euthanasia or physician-assisted suicide]" [20]. It remains an open question whether reviews that are not able to

assess physicians' reasoning truly offer the protection they are intended to provide. To the extent that reporting and data collection in states that permit physician-assisted suicide have similar limitations, oversight of practice may not be adequate.

Medicine must learn from this experience. Where physician-assisted suicide is legalized, safeguards can and should be improved—e.g., "[t]o increase safeguards, states could consider introducing multidisciplinary panels to support patients through the entire process, including verifying consent and capacity, ensuring appropriate psychosocial counseling, and discussing all palliative and end-of-life options" [21]. Both the state and the medical profession have a responsibility to monitor ongoing practice in a meaningful way and to address promptly compromises in safeguards should any be discovered. It is equally important that strong practices be identified and encouraged across all jurisdictions that permit physicians to assist suicide. Health care organizations in California and Canada, for example, have shared richly descriptive reports of practices adopted in response to the recent legalization of "aid in dying" in those jurisdictions that seek to address concerns about quality of practice and data collection [22,23].

Medicine must also acknowledge, however, that evidence (no matter how robust) that there have not yet been adverse consequences cannot guarantee that such consequences would not occur in the future. As a recent commentary noted, "[p]art of the problem with the slippery slope is you never know when you are on it" [17].

SAFEGUARDING DECISIONS AT THE END OF LIFE

CEJA has found that just as there are shared commitments behind deep differences regarding physician-assisted suicide**,** there are also shared concerns about how to understand the available evidence. For example, in the council's recent Open Forum, both proponents and opponents of physician-assisted suicide observed that in the U.S., debate occurs against the backdrop of a health care system in which patients have uneven access to care, including access to high quality end-of-life care. They also noted that patients and physicians too often still do not have the conversations they should about death and dying, and that too few patients are aware of the range of options for end-of-life care, raising concern that many patients may be led to request assisted suicide because they don't understand the degree of relief of suffering state-of-the-art palliative care can offer. Participants who in other respects held very different views concurred as well that patients may be vulnerable to coercion, particularly patients who are in other ways disadvantaged; and expressed concern in common that forces external to medicine could adversely influence practice.

These are much the same concerns the Institute of Medicine identified in its 2015 report, *Dying in America* [24]. They are concerns echoed in a February 2018 workshop on physician-assisted death convened by the National Academies of Science, Engineering and Medicine [25]. They underscore how important it is to understand *why* a patient requests assisted suicide as a starting point for care [26].

Patient requests for assisted suicide invite physicians to have the kind of difficult conversations that are too often avoided. They open opportunities to explore the patient's goals and concerns, to learn what about the situation the individual finds intolerable and to respond creatively to the patient's needs other than providing the means to end life—by such means as better managing symptoms, arranging for psychosocial or spiritual support, treating depression, and helping the patient to understand more clearly how the future is likely to unfold [5,27]. Medicine as a profession must ensure that physicians are skillful in engaging in these difficult conversations and knowledgeable about the options available to terminally ill patients [28]. The profession also has a responsibility to advocate for adequate resources for end-of-life care [16,28], particularly for patients from

disadvantaged groups. The availability of assisted suicide where it is legal must not be allowed to interfere with excellent care at the end of life.

CONCLUSION

At the core of public and professional debate, the council believes, is the aspiration that every patient come to the end of life as free as possible from suffering that does not serve the patient's deepest self-defining beliefs and in the presence of trusted companions, including where feasible and when the patient desires, the presence of a trusted physician. As Timothy Quill noted more than 20 years ago, "dying patients do not have the luxury of choosing not to undertake the journey, or of separating their person from their disease" [27]. Decisions about how to approach the end of life are among the most intimate that patients, families, and their physicians make. Respecting the intimacy and the authenticity of those relationships is essential if our common ideal is to be achieved.

While supporters and opponents of physician-assisted suicide share a common commitment to "compassion and respect for human dignity and rights" (AMA Principles of Medical Ethics, I), they draw different moral conclusions from the underlying principle they share. Where one physician understands providing the means to hasten death to be an abrogation of the physician's fundamental role as healer that forecloses any possibility of offering care that respects dignity, another in equally good faith understands supporting a patient's request for aid in hastening a foreseen death to be an expression of care and compassion.

RECOMMENDATION

The Council on Ethical and Judicial Affairs has reviewed the literature and received thoughtful input from numerous individuals and organizations to inform its deliberations, and is deeply grateful to all who shared their insights. CEJA engaged in extensive, often passionate discussion about how to interpret the *Code of Medical Ethics* in light of ongoing debate and the irreducible differences in moral perspectives identified above. The council recognized that supporters and opponents share a fundamental commitment to values of care, compassion, respect, and dignity, but diverge in drawing different moral conclusions from those underlying values in equally good faith. The council further recognized that medicine must learn from experience of physician-assisted suicide, and must ensure that, where the practice is legal, safeguards are improved.

After careful consideration, CEJA concludes that in existing opinions on physician-assisted suicide and the exercise of conscience, the *Code* offers guidance to support physicians and the patients they serve in making well-considered, mutually respectful decisions about legally available options for care at the end of life in the intimacy of a patient-physician relationship.

The Council on Ethical and Judicial Affairs therefore recommends that the *Code of Medical Ethics* not be amended, that Resolutions 15-A-16 and 14-A-17 not be adopted and that the remainder of the report be filed.

Fiscal Note: None.

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REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3-I-18

Subject:	Amendment to E-2.2.1, "Pediatric Decision Making" (Resolution 3-A-16, "Supporting Autonomy for Patients with Differences of Sex Development [DSD]") (Resolution 13-A-18, "Opposing Surgical Sex Assignment of Infants with Differences of Sex Development")
Presented by:	James E. Sabin, MD, Chair
Referred to:	Reference Committee on Amendments to Constitution and Bylaws (Todd M. Hertzberg, MD, Chair)

At the 2016 Interim Meeting, the American Medical Association (AMA) House of Delegates referred Board of Trustees Report 7-I-16, "Supporting Autonomy for Patients with Differences of Sex Development (DSD)," responding to Resolution 3-A-16 of the same title introduced by the Medical Student Section, which asked:

> That our AMA affirm that medically unnecessary surgeries in individuals born with differences of sex development are unethical and should be avoided until the patient can actively participate in decision-making.

Testimony regarding BOT 7-I-16 expressed concern about lack of expert insight into the medical complexities in treating differences of sex development in pediatric patients in its analysis and possible unintended consequences of its recommendations.

Resolution 13-A-18, "Opposing Surgical Sex Assignment of Infants with Differences of Sex Development," brought by the Michigan Delegation, asked

> That our American Medical Association oppose the assignment of gender binary sex to infants with differences in sex development through surgical intervention outside of the necessity of physical functioning for an infant and believes children should have meaningful input into any gender assignment surgery.

Noting that the issue was under study by the Council on Ethical and Judicial Affairs (CEJA), the House of Delegates referred this resolution so that the council could address it during its ongoing deliberations in this area.

This CEJA report provides ethics guidance for physicians in relation to the concerns expressed in Resolutions 3-A-16 and 13-A-18. The council is grateful for participants' contributions during reference committee hearings and for additional written communications received from multiple stakeholders, which have greatly enhanced its deliberations.

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CLARIFYING THE QUESTION

Resolutions 3-A-16 and 13-A-18 speak to clinical decisions that have enormous significance for individual patients and families, decisions that also implicate socially and culturally sensitive issues of embodiment, gender, and sexuality. Each asks AMA to endorse specific broadly framed statements intentionally limiting the range of decisions physicians, patients, and families should reach. Yet as multiple stakeholders have pointed out, the label "differences [or disorders] of sex development" is problematic in that it encompasses a very broad range of conditions that carry quite variable implications for patients' immediate and longer-term health, making for an extremely complex clinical picture overall [e.g., 1,2,3].

It is, moreover, a clinical picture in which the body of evidence available to inform decisions remains both limited and contested in important ways. In part, this reflects the difficulty in collecting data, given the relative rarity of these conditions and the sheer range of conditions currently labeled "differences of sex development" [e.g., 4]. Importantly, it reflects divergence among understandings of children's physical and psychosocial development on which stakeholders' perspectives rest [e.g., 4,5,6,7,8,9].

Literature reviews that stakeholders have provided to help inform CEJA's deliberations indicate ongoing, significant differences in how the published evidence is interpreted [e.g., 1,10]. Concerns have been expressed about not just the quantity, but also the quality of the data available to inform clinical decisions, with questions raised about whether studies have asked the "right" question and about how well the framing of key research questions and the methodology, sample size, and data analysis support the conclusions drawn in a given study [e.g., 11]. Stakeholders concur on the need for systematic, well-designed research to provide robust evidence on the long-term outcomes that are meaningful to patients of different clinical approaches.

CEJA appreciates the challenge this state of affairs poses for families and physicians who strive to make clinically well-informed decisions for individual children. Thoughtful stakeholders differ in good faith, at times profoundly, about whether and at what developmental stage in the child's life intervention should be considered medically essential, preferred, or acceptable for children born with differences of sex development. Despite these differences, stakeholders clearly share a deep professional commitment to serving the best interest of pediatric patients.

However, to the extent that Resolutions 3-A-16 and 13-A-18 call on the council to address the lack of clinical consensus, they seek guidance that is not within CEJA's purview to offer. It is not the council's role to adjudicate clinical disagreement or to prescribe what manner of decision is "correct" or "best," but rather to clarify the values at issue and identify what factors must be considered to arrive at an *ethically sound* decision in any given patient's unique situation.

MAKING DECISIONS FOR PEDIATRIC PATIENTS

Health care decisions for pediatric patients necessarily have a different character than decisions for adult patients. Decisions for children are made in the context of a three-way relationship among patient, parents (or guardians), and physician rather than the patient-physician dyad typical of decision making for most adult patients. Further, except for emancipated minors, who are authorized to make their own health care decisions, or certain decisions that other minor patients are permitted to make independently (e.g., E-2.3.3, Confidential Care for Minors), decisions for pediatric patients are made, not by the patient, but by parents/guardians acting on the patient's behalf. Finally, the substituted judgment standard for surrogate decision making on behalf of adult patients is for the most part unavailable to those who make decisions for minors, insofar as

children, especially very young children, are unlikely to have formed settled views and preferences upon which substituted judgment could be based.

The Patient's "Best Interests"

Ethically, and legally, then, parents are expected to make health care decisions in their children's best interests. As the persons best positioned to understand their child's unique needs and interests, parents/guardians are asked to fulfill the dual responsibility of both protecting their children and, at the same time, empowering them and promoting development of the child's capacity to become an independent decision maker. Parents/guardians are expected to safeguard their children's physical health and well-being *and* to nurture their children's developing personhood and autonomy.

Best interests, and thus goals for care, then, should be understood broadly, as encompassing more than simply medical considerations. Parents/guardians are indeed expected to weigh the clinical benefits and risks of treatment alternatives, including the option of no treatment or the timing of interventions, but to do so against the broader background of likely impact on the child's psychosocial well-being, relationships within the family, and family resources and values. As CEJA noted in its original report on decisions for pediatric patients (2007), because families provide a child's usual, often only, source of support and care, the family's needs and interests can also be relevant to treatment decisions. The council further observed that, "If none of the reasonable alternatives the health care team recommends can be reconciled with the family's circumstances, deciding on the best course of treatment may be 'an exercise in psychosocial, as well as technical medical, expertise'" [12].

The Committee on Bioethics of the American Academy of Pediatrics similarly holds that best interest should be understood broadly, to encompass more than purely clinical considerations. The committee urges decision makers to "acknowledge the pediatric patient's emotional, social, and medical concerns along with the interests of the child's family in the process of medical decision making" [13]. However, the committee argues, the concept of "harm" may be a "more realistic standard" for decisions on behalf of pediatric patients, noting that,

> The intent of the harm principle is not to identify a single course of action that is in the minor's interest or is the physician's preferred approach, but to identify a harm threshold below which parental decisions will not be tolerated … [13].

Using the harm principle to inform choices for individual patients, including pediatric patients, requires that decision makers take into account the kind, degree and duration of foreseeable harms, as well as the likelihood of their occurrence.

Engaging Children in Care Decisions

Absent reason to believe otherwise, parents/guardians are understood to be best able to take a child's long-term interests to heart in reaching a decision about care and in general their decisions should be respected. But that does not mean children should have no role in the decision-making process. In its original report CEJA noted that "the ethical principle of respect for persons also applies to children" and urged physicians to seek pediatric patients' assent to decisions made on their behalf [12,13]. Assent, the council observed, "weighs a child's ability to understand options and potential outcomes and to communicate preferences" [12].

CEJA recognized that "the notion of assent can be applied most readily to adolescent patients," but instructed physicians to evaluate younger patients' "cognitive capacities and judgment to determine

if they can understand the risks and benefits of treatment" and to engage them accordingly in the decision-making process. Not all information is cognitively and emotionally appropriate for every pediatric patient, nor is it necessary to communicate all information about a diagnosis and proposed care all at once. As for any patient, physicians should assess the amount of information the individual is capable of receiving at a given time and tailor disclosure to meet patients' needs, preferences, and ability to understand (E-2.1.3, Withholding Information from Patients).

Respecting children as (developing) persons also entails seeking to understand their reasons for disagreeing with treatment decisions. When an intervention is not immediately necessary to safeguard the child's welfare, CEJA has argued, physicians (and parents/guardians) should respect a child's refusal to assent to proposed treatment. Even when immediate treatment is essential to preserve well-being, physicians should explore the child's reason for dissent, when circumstances permit. The more mature a minor patient is, the better able to understand what a decision will mean, and the more clearly the child can communicate preferences, the stronger the ethical obligation to engage young patients in decisions about their own care. As CEJA noted in refining its guidance on decisions for pediatric patients in 2010, communicating even sensitive and potentially frightening information—about HIV status or a terminal diagnosis, for example—can improve a child's well-being [14].

Preserving Future Choices

In fulfilling their responsibility to nurture their children's developing capacity to make autonomous decisions, parents/guardians are expected to make health care decisions that will least impinge on children's opportunity to make important life choices themselves in the future. In general, decisions taken now on a child's behalf should be made with an eye not to foreclose decisions the child can reasonably be expected, in time, to want and be able to make independently, realizing that choosing *not* to have a treatment or procedure performed also forecloses a future choice. This "right to an open future" is not absolute, of course. Parents/guardians must balance their responsibility to preserve the child's opportunity for future exercise of self-determination with the need to protect the child's immediate well-being. Physicians should be prepared to support them in that process, providing the best available data to inform their decision and directing them to appropriate psychosocial and other resources.

Finally, the opportunity to meet with and learn from others who have faced similar decisions can provide valuable firsthand insight and support that clinicians themselves may not be able to offer. Physicians should familiarize themselves with local peer support groups as resources to help inform decision making by parents and their minor children.

A CONTINUUM OF DECISIONS

The degree of difficulty faced by parents/guardians in making well-considered, ethically justifiable decisions for young patients who are not able to make their own health care choices varies across a continuum. At one end of that continuum are decisions that involve interventions about which there is consensus in the professional community, whose benefits are significant, supported by robust evidence, and significantly outweigh the risks they pose (the likelihood and magnitude of which are themselves well understood). In those situations, physicians have a responsibility to persuade reluctant parents/guardians to accept the intervention on their child's behalf. Where the intervention would preserve life or avert serious harm and disagreement persists despite efforts to resolve the tension, physicians have legal and ethical obligations to seek court interventions against parental refusal of treatment.

At the other end are decisions that involve interventions that carry significant risk of harm or that currently available evidence would suggest offer little prospect of clinical benefit or cannot reasonably be expected to achieve the intended goal. In these cases, physicians have a responsibility to dissuade parents/guardians from pursuing the intervention, especially when it is irreversible, and should decline to provide the requested care when a patient's parents/guardian persist, in keeping with ethics guidance (e.g., E-5.5, Medically Ineffective Interventions).

Between are decisions that involve interventions about which physicians may in good faith reach diverging professional judgments, and for which evidence as to short- and long-term benefit and risk is limited, equivocal, or contested. In such situations, how physicians interpret available evidence and its implications for an individual patient is shaped in significant part by their understanding of how to balance the competing values of beneficence and respect in upholding medicine's foundational commitment to serve the patient's (best) interests. In this "grey zone" physicians are challenged to negotiate with decision makers a shared agreement about how to understand this patient's medical and psychosocial interests and what plan of care will best serve those interests in the individual's unique circumstances and in most cases should give great deference to parental preferences.

SHOULD DECISIONS ABOUT DSD BE DIFFERENT FROM OTHER DECISIONS?

Helping parents/guardians make decisions for young patients with differences of sex development is inescapably challenging given the range of conditions at issue and the physiological/clinical complexity of many of those conditions. The fact that DSDs are entangled with socially and culturally sensitive issues of bodies, genders, and sex compounds that challenge—the more so in an environment in which a binary understanding of sex and gender is increasingly contested.

Yet whether these decisions are more challenging than decisions for pediatric patients with other diagnoses—say, decisions about cochlear implants for congenitally deaf newborns—is far from clear. The specific interventions about which decisions must be made and the timing of those decisions will be sensitive to the child's clinical situation, of course, but the fundamental task facing parents/guardians and physicians will still be to agree on a path forward that balances safeguarding the child's well-being, short and longer term, and nurturing the child's development as an individual with capacity to make decisions autonomously.

Regardless of the specific decision at issue, it is important that parents/guardians and physicians appreciate the fact that a pediatric patient will of necessity live out the consequences of a choice made by others—one with which the individual may ultimately come to disagree. Moreover, when decisions implicate issues that are socially and culturally divisive, such as sex assignment and "normalizing" surgery for DSD patients, patients and their families can be thrust into the role of agent of social change or preserver of the status quo, knowingly, willingly, or otherwise [4]. Ensuring that parents/guardians have the information and—absent immediate, life-threatening emergency—the time to make well-considered decisions is essential.

For physicians, supporting thoughtful, ethically sound decision making for all pediatric patients, especially very young patients, requires that they consider several fundamental questions and tailor recommendations to the individual's specific circumstances:

- What is this child's likely developmental course without (immediate) intervention? How strong is the evidence to support this prognosis?
- What are these parents/guardians' (and this patient's) overall goals for care?

- To what extent is the clinical anomaly a significant threat to health, immediately and in the long term?
- Is providing the proposed intervention at this stage in the child's development supported by clear, high quality evidence?
- Could other interventions reasonably be staged developmentally to allow the patient and family time to gain experience living with the condition and to reflect on and perhaps adjust goals for care?
- To what extent would the proposed intervention (or lack of intervention) foreclose important life choices for the adolescent and adult the child will become? Are there reasonable alternatives that would address immediate clinical needs while preserving opportunity to make important future choices?
- What resources will the child and family need to support the child's healthy physical and psychosocial development? How can the physician assist in making those resources available to the patient and family?

COMING TO COMMON GROUND

Parents/guardians are expected to make health care decisions in children's "best interest." In doing so, they are expected both to protect children and, at the same time, to empower children and promote children's developing capacity to become independent decision makers. To nurture this developing capacity, health care decisions are preferable that will least impinge on children's opportunity to make important life choices themselves in the future.

Making decisions for children that involve socially or culturally sensitive issues—for example, whether or how to discuss a terminal diagnosis with a child, or whether, when, or how to intervene medically for conditions that involve differences of sex development—is always challenging. The greater the uncertainty or lack of robust evidence supporting alternative courses of action, the more difficult the task becomes.

In such circumstances, despite a common commitment to serving the best interest of pediatric patients, thoughtful stakeholders may, in good faith, differ about whether a particular intervention, at a particular time is medically essential, preferred, or acceptable. When no single approach can be said a priori to be "best." Ethically sound practice requires that decisions be carefully tailored for each patient in a process of shared decision making among parents/guardians, physician and the patient (in keeping with the child's capacity to participate). Decision makers should seek a shared understanding of goals for care in creating a treatment plan that respects the unique needs, values, and preferences of the individual patient and family.

RECOMMENDATION

In light of the foregoing analysis, the Council on Ethical and Judicial Affairs recommends that Opinion E-2.2.1, "Pediatric Decision Making," be amended by substitution as follows in lieu of Resolutions 3-A-16, "Supporting Autonomy for Patients with Differences of Sex Development (DSD),"and 13-A-18, "Opposing Surgical Sex Assignment of Infants with Differences of Sex Development," and the remainder of this report be filed:

> As the persons best positioned to understand their child's unique needs and interests, parents (or guardians) are asked to fill the dual responsibility of protecting their children and, at the same time, empowering them and promoting development of children's capacity to become independent decision makers. In giving or withholding permission for medical treatment for

their children, parents/guardians are expected to safeguard their children's physical health and well-being and to nurture their children's developing personhood and autonomy.

But parents' authority as decision makers does not mean children should have no role in the decision-making process. Respect and shared decision making remain important in the context of decisions for minors. Thus, physicians should evaluate minor patients to determine if they can understand the risks and benefits of proposed treatment and tailor disclosure accordingly. The more mature a minor patient is, the better able to understand what a decision will mean, and the more clearly the child can communicate preferences, the stronger the ethical obligation to seek minor patients' assent to treatment. Except when immediate intervention is essential to preserve life or avert serious, irreversible harm, physicians and parents/guardians should respect a child's refusal to assent, and when circumstances permit should explore the child's reason for dissent.

For health care decisions involving minor patients, physicians should:

(a) Provide compassionate, humane care to all pediatric patients.

(b) Negotiate with parents/guardians a shared understanding of the patient's medical and psychosocial needs and interests in the context of family relationships and resources.

(c) Develop an individualized plan of care that will best serve the patient, basing treatment recommendations on the best available evidence and in general preferring alternatives that will not foreclose important future choices by the adolescent and adult the patient will become. Where there are questions about the efficacy or long-term impact of treatment alternatives, physicians should encourage ongoing collection of data to help clarify value to patients of different approaches to care.

(d) Work with parents/guardians to simplify complex treatment regimens whenever possible and educate parents/guardians in ways to avoid behaviors that will put the child or others at risk.

(e) Provide a supportive environment and encourage parents/guardians to discuss the child's health status with the patient, offering to facilitate the parent-child conversation for reluctant parents. Physicians should offer education and support to minimize the psychosocial impact of socially or culturally sensitive care, including putting the patient and parents/guardians in contact with others who have dealt with similar decisions and have volunteered their support as peers.

(f) When decisions involve life-sustaining treatment for a terminally ill child, ensure that patients have an opportunity to be involved in decision making in keeping with their ability to understand decisions and their desire to participate. Physicians should ensure that the patient and parents/guardians understand the prognosis (with and without treatment). They should discuss the option of initiating therapy with the intention of evaluating its clinical effectiveness for the patient after a specified time to determine whether it has led to improvement and confirm that if the intervention has not achieved agreed-on goals it may be discontinued.

(g) When it is not clear whether a specific intervention promotes the patient's interests, respect the decision of the patient (if the patient has capacity and is able to express a preference) and parents/guardians.

(h) When there is ongoing disagreement about patient's best interest or treatment recommendations, seek consultation with an ethics committee or other institutional resource.

(Modify Current HOD/CEJA Policy)

Fiscal Note: Less than $500

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The appendices referenced in this report are available online; visit https://www.ama-assn.org/sites/default/files/media-browser/public/hod/i18-ceja-appendix-reduced.pdf

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 4-I-18

Subject:	CEJA Role in Implementing H-140.837, "Anti-Harassment Policy"
Presented by:	James E. Sabin, MD, Chair
Referred to:	Reference Committee on Amendments to Constitution & Bylaws (Todd M. Hertzberg, MD, Chair)

At the 2018 Annual Meeting the American Medical Association (AMA) House of Delegates (HOD) adopted with amendment the recommendations of Board of Trustees Report 20-A-18, "Anti-Harassment Policy." The HOD amended the Board's recommendations for a process to address allegations of harassment during meetings associated with the AMA to give the Council on Ethical and Judicial Affairs (CEJA) the authority and responsibility for taking disciplinary action (Policy H-140.837).

CEJA has discussed at length the recommendations of BOT Report 20-A-18 and believes that promoting safe engagement among physicians, students, staff, and other attendees during professional meetings affiliated with the AMA is an urgent organizational responsibility. However, while respecting the deliberations of the HOD, CEJA has concluded that the council is not in a position to carry out this new responsibility as defined in the recommendations as adopted.

CEJA concluded that the responsibility to adjudicate allegations of harassment is qualitatively different from its normal judicial function. In assessing individual physicians' fitness for membership in the AMA, CEJA does not have direct, primary responsibility for taking punitive action. Rather, CEJA's decisions rest on review of extensive case files compiled by state medical boards that have already taken disciplinary action and, with rare exceptions, an interview with the physician.

With respect to allegations of harassment, CEJA is deeply concerned that this new role will be much more analogous to that of a state medical board; it also foresees the need to engage with *both* parties before reaching a final determination. CEJA strongly believes that the task demands a different set of skills than its usual adjudications, and that therefore council members would need appropriate training (provided annually as new members join the council). CEJA is also uncertain that the range of disciplinary options available to it in its judicial function are appropriate with respect to allegations of harassment.

CEJA is further concerned that the council as a whole has neither the resources nor flexibility required to carry out this additional responsibility effectively. The council has a substantial ongoing workload in its normal judicial function, requiring at least one full day at each of its four in-person meetings every year. CEJA believes that allegations of harassment should be dealt with as close as possible to the time of the event by a body able to convene on an ad hoc basis. Moreover, the council has reason to anticipate a significant volume of cases, particularly in the current social climate.

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Amendments to Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

Finally, CEJA is concerned as well that in reaching decisions that parties (and their supporters) see as either excessive or inadequate may undermine confidence in the council, to the detriment of both its judicial and policy work.

For these reasons, CEJA respectfully requests that H-140.837(3), "Disciplinary Action," be reconsidered.

RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

1. That provision (3) of H-140.837, "Anti-Harassment Policy" be rescinded (Directive to Take Action); and

2. That the process for implementing AMA's anti-harassment policy be referred to the Board of Trustees for further study (Directive to Take Action)

Fiscal Note: Less than $500

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 5-I-18

Subject:	Physicians' Freedom of Speech (Resolution 6-I-17)
Presented by:	James E. Sabin, MD, Chair
Referred to:	Reference Committee on Amendments to Constitution & Bylaws (Todd M. Hertzberg, MD, Chair)

At the 2017 Interim Meeting the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 6-I-17, "Physicians' Freedom of Speech," brought forward by the Minority Affairs Section. Resolution 6-I-17 asked the AMA to "encourage the Council on Ethical and Judicial Affairs (CEJA) to amend Ethical Opinion E-1.2.10, 'Political Action by Physicians'," by addition to read as follows:

> Like all Americans, physicians enjoy the right to advocate for change in law and policy, in the public arena, and within their institutions. Indeed, physicians have an ethical responsibility to seek change when they believe the requirements of law or policy are contrary to the best interests of patients and community health. However, they have a responsibility to do so in ways that are not disruptive to patient care.
>
> Physicians who participate in advocacy activities should:
>
> (a) Ensure that the health of patients is not jeopardized and that patient care is not compromised.
>
> (b) Avoid using disruptive means to press for reform. Strikes and other collection actions may reduce access to care, eliminate or delay needed care, and interfere with continuity of care and should not be used as a bargaining tactic. In rare circumstances, briefly limiting personal availability may be appropriate as a means of calling attention to the need for changes in patient care. Physicians should be aware that some actions may put them or their organizations at risk of violating antitrust laws or laws pertaining to medical licensure or malpractice.
>
> (c) Avoid forming workplace alliances, such as unions, with workers who do not share physicians' primary and overriding commitment to patients.
>
> (d) Refrain from using undue influence or pressure colleagues to participate in advocacy activities and should not punish colleagues, overtly or covertly, for deciding not to participate.

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Furthermore, physicians:

(e) Should indicate they are expressing their personal opinions, which are guaranteed under the First Amendment of the U.S. Constitution, and should refrain from implying or stating that they are speaking on behalf of their employers;

(f) Should be allowed to express their personal opinions publicly without being subjected to disciplinary actions or termination.

Testimony supported the spirit of this resolution; however, concerns were expressed regarding the appropriate wording of the additional clauses offered by the author.

AMA ETHICS POLICY

As Opinion E-1.2.10 indicates, the AMA *Code of Medical Ethics* recognizes that physicians have a right to advocate for change in law and policy, and indeed have a responsibility to do so when existing law or policy is contrary to patients' interests, a responsibility codified in Principle III of the AMA Principles of Medical Ethics, which states, "A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient."

The *Code* also recognizes that we have the right to communicate our personal political views to patients and patients' families, within the constraints set out in Opinion E-2.3.4, "Political Communication."

Similarly, the *Code* recognizes our right to due process in disciplinary actions and decisions regarding credentialing and privileging in Opinions E-9.4.1, "Peer Review and Due Process"; E-9.4.3, "Discipline and Medicine"; and E-9.4.4, "Physicians with Disruptive Behavior," all of which prohibit unwarranted or malicious action against physicians.

In Opinion E-2.3.2, "Professionalism in the Use of Social Media," the *Code* recognizes that "participating in social networking and other similar opportunities can support physicians' personal expression, enable individual physicians to have a professional presence online, foster collegiality and camaraderie within the profession, provide opportunities to widely disseminate public health messages and other health communication." However, E-2.3.2 also cautions physicians to be aware that "actions online and content posted may negatively affect their reputations among patients and colleagues, may have consequences for their medical careers (particularly for physicians-in-training and medical students) and can undermine public trust in medicine."

Although the *Code* does not, and indeed cannot, dictate the terms of physician employment as such, several additional opinions do address relationships between physicians and the institutions with which they are affiliated, as employees or otherwise. Thus Opinion E-8.7, "Routine, Universal Immunization of Physicians," provides that physicians who decline to be immunized must accept decisions of medical staff leadership or other authority to adjust practice activities. E-11.2.3, "Contracts to Deliver Health Care Services," calls on us to carefully review the terms of contracts and "negotiate modification or removal of any terms that unduly compromise physicians' ability to uphold ethical standards," while E-11.2.3.1, "Restrictive Covenants," holds that we should not enter into agreements that "unreasonably restrict" our right "to practice for a specified time or in a specific geographic area on termination of a contractual relationship."

ACTIONS AGAINST PHYSICIANS' LICENSES OR EMPLOYMENT

The Federation of State Medical Boards does not systematically track violations of online professionalism, but a 2012 survey indicated that medical and osteopathic boards have acted against physicians for violating patient privacy or professional boundaries, and other unprofessional or offensive conduct online [Greyson et al 2012]. Researchers found at the time that the total number of actions was small but observed that "this is likely to change as the use of social media continues to grow."

Information about termination or other actions taken against physicians by their employers is limited primarily to media accounts of individual cases [Advisory Board 2011, Canosa 2016, Anderson 2018]. Publicly reported incidents involve both patient-related issues, such as violation of confidentiality, and offensive personal conduct, such as racist speech [Canosa, Anderson].

FREEDOM OF SPEECH

Although constitutional protection for "freedom of speech" is often invoked as an argument against disciplinary action by employers, it is important to note that this concept does not apply to private places of employment. The First Amendment "limits only the government's ability to suppress speech" [Cox 2015].

Private employers generally have the power to terminate an employee because of the employee's speech. For example, Thomas Jefferson University Hospital noted in a statement regarding the hospital's decision to dismiss a nurse for a racially charged post,

> An employee's decision to post inflammatory comments on social media is an unfortunate choice and one that is not tolerated at Jefferson . . . . Whether we choose to acknowledge it or not, we must recognize that what we say on social media can directly affect how people perceive Jefferson — particularly when those comments put into question Jefferson's commitment to the care of our patients, treatment of our fellow colleagues and education of our students [Craig].

Protections for an employee regarding their speech in the private workplace, are possible, but come from outside of the sphere of constitutional law. Instead such protections may be found in contract and employment law. For example, common law analysis of the standard "employment-at-will" doctrine (where an employer can terminate an employee at any time for any reason), provide for exceptions, such that employers may not "contravene public policy" or that employers must act in accordance to an "implied convent of good faith and fair dealing" [McGinley 2012]. Or an employer may simply have an employment policy or agreement that outlines acceptable speech, providing an employee with contract remedies. These possible speech protections are sourced from contract and employment law, illustrating that "freedom of speech" in the private workplace is an employment law issue, not a constitutional rights issue.

CONCLUSION

In CEJA's view, the situation of physicians who express personal views on political and social issues online is importantly like that of physicians who participate professionally in the media. We should recognize that even when we speak personally, we are likely to be viewed by the public through the lens of our professional status and our relationships with health care institutions and should not conduct ourselves in ways that are likely to undermine trust in our profession or health care institutions. As Opinion E-8.12, "Ethical Physician Conduct in the

Media," observes, physicians in the public sphere "should be aware of their ethical obligations to patients, the public, and the medical profession; and that their conduct can affect their medical colleagues, other health care professionals, as well as institutions with which they are affiliated."

CEJA concludes, thus, that in its present form, the *Code of Medical Ethics* provides appropriate guidance with respect to physicians' rights to express ourselves on matters of social and political importance and underscores our right to due process when our conduct is subjected to disciplinary review.

RECOMMENDATION

For the foregoing reasons, the Council on Ethical and Judicial Affairs recommends that Resolution 6-I-17, "Physicians' Freedom of Speech," not be adopted and the remainder of this report be filed.

Fiscal Note: Less than $500

REFERENCES

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REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 5-I-18

Subject: Reconciliation of AMA Policy on Medical Student Debt

Presented by: Carol Berkowitz, MD, Chair

Referred to: Reference Committee C
(Peter C. Amadio, MD, Chair)

INTRODUCTION AND METHODS

The goal of this report is to review, reconcile, and consolidate existing American Medical Association (AMA) policy on medical student debt, eliminate duplication, and ensure that current policies are coherent and relevant. For each policy recommendation, a succinct but cogent justification is provided to support the proposed action. If a contradiction in policies was discovered, the most recent policy was deemed to supersede past AMA policies, and the language of each proposed policy was then edited so that it would be coherent and easily understood, without altering its meaning or intent.

POLICIES INCLUDED IN THIS REPORT

The following AMA policies are addressed in this report:

1. D-305.956, "AMA Participation in Reducing Medical Student Debt"
2. D-305.957, "Update on Financial Aid Programs"
3. D-305.962, "Tax Deductibility of Student Loan Payments"
4. D-305.966, "Reinstatement of Economic Hardship Loan Deferment"
5. D-305.970, "Proposed Revisions to AMA Policy on Medical Student Debt"
6. D-305.975, "Long-Term Solutions to Medical Student Debt"
7. D-305.977, "Deductibility of Medical Student Loan Interest"
8. D-305.978, "Mechanisms to Reduce Medical Student Debt"
9. D-305.979, "State and Local Advocacy on Medical Student Debt"
10. D-305.980, "Immediate Legislative Solutions to Medical Student Debt"
11. D-305.981, "Financing Federal Consolidation Loans"
12. D-305.993, "Medical School Financing, Tuition, and Student Debt"
13. D-405.986, "Student Loans and Medicare / Medicaid Participation"
14. H-305.926, "Supporting Legislation to Create Student Loan Savings Accounts"
15. H-305.928, "Proposed Revisions to AMA Policy on Medical Student Debt"
16. H-305.932, "State and Local Advocacy on Medical Student Debt"
17. H-305.948, "Direct Loan Consolidation Program"
18. H-305.954, "Repayment of Medical School Loans"
19. H-305.965, "Student Loans"
20. H-305.980, "Student Loan Repayment Grace Period"
21. H-305.991, "Repayment of Educational Loans"

SUMMARY AND RECOMMENDATIONS

This report encompasses a review of current AMA policies on medical student debt to ensure such policy is consistent, accurate and up-to-date. The new policy being proposed in recommendation 1, below (shown in Appendix A), incorporates relevant portions of the 21 existing policies that are recommended for rescission in recommendation 2. Appendix B shows a clean text version of the policy that is being proposed for adoption. Appendix C lists all 21 policies that are proposed for rescission. The (relatively few) segments of policy that are not being retained in the proposed new policy are listed in Appendix D.

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

1. That our American Medical Association (AMA) adopt as policy "Principles of and Actions to Address Medical Education Costs and Student Debt" the language shown in column 1 of Appendix A of this report. (New HOD Policy)

2. That our AMA rescind the following policies, as shown in Appendix C:

    1. D-305.956, "AMA Participation in Reducing Medical Student Debt"
    2. D-305.957, "Update on Financial Aid Programs"
    3. D-305.962, "Tax Deductibility of Student Loan Payments"
    4. D-305.966, "Reinstatement of Economic Hardship Loan Deferment"
    5. D-305.970, "Proposed Revisions to AMA Policy on Medical Student Debt"
    6. D-305.975, "Long-Term Solutions to Medical Student Debt"
    7. D-305.977, "Deductibility of Medical Student Loan Interest"
    8. D-305.978, "Mechanisms to Reduce Medical Student Debt"
    9. D-305.979, "State and Local Advocacy on Medical Student Debt"
    10. D-305.980, "Immediate Legislative Solutions to Medical Student Debt"
    11. D-305.981, "Financing Federal Consolidation Loans"
    12. D-305.993, "Medical School Financing, Tuition, and Student Debt"
    13. D-405.986, "Student Loans and Medicare / Medicaid Participation"
    14. H-305.926, "Supporting Legislation to Create Student Loan Savings Accounts"
    15. H-305.928, "Proposed Revisions to AMA Policy on Medical Student Debt"
    16. H-305.932, "State and Local Advocacy on Medical Student Debt"
    17. H-305.948, "Direct Loan Consolidation Program"
    18. H-305.954, "Repayment of Medical School Loans"
    19. H-305.965, "Student Loans"
    20. H-305.980, "Student Loan Repayment Grace Period"
    21. H-305.991, "Repayment of Educational Loans" (Rescind HOD Policy)

Fiscal note: $1,000.

APPENDIX A: PROPOSED AMA POLICY: "PRINCIPLES OF AND ACTIONS TO ADDRESS MEDICAL EDUCATION COSTS AND STUDENT DEBT" (WORKSHEET VERSION)

Note: The left column shows the proposed language for adoption; the right column shows the original language that is being modified and its policy number, if any.

Proposed language for adoption	**Original language**
The costs of medical education should never be a barrier to pursuit of a career in medicine nor to the decision to practice in a given specialty.	3. Financial aid opportunities, including scholarship and loan repayment programs, should be available so that individuals are not denied an opportunity to pursue medical education because of financial constraints. H-305.928
	4. A sufficient breadth of financial aid opportunities should be available so that student specialty choice is not constrained based on the need for financial assistance. H-305.928
To help address this issue, our American Medical Association (AMA) will: 1. Collaborate with members of the Federation and the medical education community, and with other interested organizations, to address the cost of medical education and medical student debt through public- and private-sector advocacy.	Our AMA will: 1. Collaborate, based on AMA policy, with members of the Federation and the medical education community, and with other interested organizations, to achieve the following immediate public- and private-sector advocacy goals: D-305.970
	1. Our AMA will make reducing medical student debt a high priority for legislative and other action and will collaborate with other organizations to study how costs to students of medical education can be reduced. H-305.928
2. Vigorously advocate for and support expansion of and adequate funding for federal scholarship and loan repayment programs—such as those from the National Health Service Corps, Indian Health Service, Armed Forces, and Department of Veterans Affairs, and for comparable programs from states and the private sector—to promote practice in underserved areas, the military, and academic medicine or clinical research.	(a) Support expansion of and adequate funding for federal scholarship and loan repayment programs, such as those from the National Health Service Corps, the Indian Health Service, the Armed Forces, and the Department of Veterans Affairs, and for comparable programs at the state level. D-305.970
	2. Our AMA will vigorously advocate for ongoing, adequate funding for federal and state programs that provide scholarship or loan repayment funds in return for service, including funding in return for practice in underserved areas, participation in the military, and participation in academic medicine or clinical research. Obtaining adequate support for the National Health Service Corps and similar programs, tied to the demand for participation in the programs, should be a focus for AMA advocacy efforts. D-305.993
	5. Our AMA supports the creation of new and the expansion of existing medical education

Proposed language for adoption	Original language
	financial assistance programs from the federal government, the states, and the private sector. H-305.928
3. Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.	(b) Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research. D-305.970
4. Advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas.	(2) advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas; D-305.975
5. Encourage the National Health Service Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.	(5) encourage the National Health Services Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas. D-305.975
6. Work to reinstate the economic hardship deferment qualification criterion known as the "20/220 pathway," and support alternate mechanisms that better address the financial needs of trainees with educational debt.	Our AMA will actively work to reinstate the economic hardship deferment qualification criterion known as the "20/220 pathway," and support alternate mechanisms that better address the financial needs of post-graduate trainees with educational debt. D-305.966
7. Advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans.	Our AMA will advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans. H-305.926
8. Work with other concerned organizations to advocate for legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit 100% tax deductibility of interest on student loans and elimination of taxes on aid from service-based programs.	8. Our AMA will work with other concerned organizations to promote legislation and regulations with the aims of …eliminating taxes on aid from service-based programs, and restoring tax deductibility of interest on educational loans. D-305.993
	(d) Ensure that the Higher Education Act and other legislation allow interest from medical

Proposed language for adoption	Original language
	student loans to be fully tax deductible. D-305.970
	Our AMA will draft legislation allowing 100% tax deductibility of student loan interest. D-305.962
	Our AMA will work toward 100% tax deductibility of medical student loan interest on federal and state income tax returns. D-305.977
	7. Our AMA supports legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit the full deductibility of interest on student loans. H-305.928
9. Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).	(f) Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs). D-305.970
10. Support stable funding for medical education programs to limit excessive tuition increases, and collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided.	(g) Support stable funding for medical education programs to limit excessive tuition increases. D-305.970
	(4) collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided; and D-305.975
11. Work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment.	(3) work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment; D-305.975
12. Encourage medical schools to (a) Study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, and combined baccalaureate/MD or DO programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education;	2. Encourage medical schools to study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, combined baccalaureate/MD programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education. D-305.970
(b) Engage in fundraising activities to increase the availability of	(e) Encourage medical schools, with the support of the Federation, to engage in fundraising

Proposed language for adoption	Original language
scholarship support, with the support of the Federation, medical schools, and state and specialty medical societies, and develop or enhance financial aid opportunities for medical students, such as self-managed, low-interest loan programs;	activities devoted to increasing the availability of scholarship support. D-305.970
	(3) encourage members of the Federation to develop or enhance financial aid opportunities for medical students; D-305.978
	(5) continue to collect and disseminate information to assist members of the Federation (state medical societies and specialty societies) and medical schools to establish or expand financial aid programs; and D-305.978
	Our AMA will: (1) encourage medical schools and state medical societies to consider the creation of self-managed, low-interest loan programs for medical students, and collect and disseminate information on such programs; D-305.975
	(2) urge state medical societies to actively solicit funds (either directly or through their Foundations) for the establishment and expansion of medical student scholarships, and that our AMA develop a set of guidelines and suggestions to assist states in carrying out such initiatives. D-305.979
(c) Cooperate with postsecondary institutions to establish collaborative debt counseling for entering first-year medical students;	(3) encourages medical schools to cooperate with undergraduate institutions to establish collaborative debt counseling for entering first-year medical students. H-305.932
(d) Allow for flexible scheduling for medical students who encounter financial difficulties that can be remedied only by employment, and consider creating opportunities for paid employment for medical students;	8. Medical students should not be forced to jeopardize their education by the need to seek employment. Any decision on the part of the medical student to seek employment should take into account his/her academic situation. Medical schools should have policies and procedures in place that allow for flexible scheduling in the case that medical students encounter financial difficulties that can be remedied only by employment. Medical schools should consider creating opportunities for paid employment for medical students. H-305.928
(e) Counsel individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation;	(3) encourages medical school financial aid officers to counsel individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation. H-305.991

Proposed language for adoption	Original language
(f) Inform students of all government loan opportunities and disclose the reasons that preferred lenders were chosen;	5. Our AMA supports a requirement that medical schools inform students of all government loan opportunities and requires disclosure of reasons that preferred lenders were chosen. D-305.993
(g) Ensure that all medical student fees are earmarked for specific and well-defined purposes, and avoid charging any overly broad and ill-defined fees, such as but not limited to professional fees;	Our AMA: (1) opposes the charging of broad and ill-defined student fees by medical schools, such as but not limited to professional fees, encouraging in their place fees that are earmarked for specific and well-defined purposes; H-305.932
(h) Use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies;	(2) encourages medical schools to use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies; and H-305.932
(i) Work to ensure stable funding, to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue; mid-year and retroactive tuition increases should be opposed.	2. Our AMA supports stable funding for medical schools to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue and should oppose mid-year and retroactive tuition increases. H-305.928
13. Support and encourage state medical societies to support further expansion of state loan repayment programs, particularly those that encompass physicians in non-primary care specialties.	Our AMA will: (1) support and encourage our state medical societies to support further expansion of state loan repayment programs, and in particular expansion of those programs to cover physicians in non-primary care specialties; and D-305.979
14. Take an active advocacy role during reauthorization of the Higher Education Act and similar legislation, to achieve the following goals:	Our AMA will: (1) take an active advocacy role during the upcoming reauthorization of the Higher Education Act and other pending legislation, to achieve the following goals: D-305.978
	Our AMA will: (1) endorse and actively lobby for the Reauthorization of the Higher Education Act, including: D-305.980
(a) Eliminating the single holder rule;	(1) (a) eliminating the single holder rule, D-305.978
	(1) (a) Elimination of the “single-holder” rule; D-305.980
(b) Making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training;	(c) With each reauthorization of the Higher Education Act and at every other legislative opportunity, proactively pursue loan consolidation terms that favor students and ensure that loan deferment is available for the entire duration of residency and fellowship training. D-305.970

Proposed language for adoption	Original language
	(1) (b) making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training, D-305.978
	(1) (d) Broadening of the definition of economic hardship as used to determine eligibility for student loan deferment; D-305.980
	(1) (c) Expansion of the deferment period for loan repayment to cover the entire duration of residency and fellowship; D-305.980
	Our AMA: (1) reaffirms its support of legislation that would defer the repayment of loans for education until the completion of residency training; and H-305.965
	(2) will lobby for deferment of medical student loans for the full initial residency period. H-305.965
	8. Our AMA will work with other concerned organizations to promote legislation and regulations with the aims of increasing loan deferment through the period of residency…. D-305.993
(c) Retaining the option of loan forbearance for residents ineligible for loan deferment;	(1) (c) retaining the option of loan forbearance for residents ineligible for loan deferment, D-305.978
	(1) (e) Retention of the option of loan forbearance for residents who are ineligible for student loan deferment; D-305.980
(d) Including, explicitly, dependent care expenses in the definition of the "cost of attendance";	(1) (d) including, explicitly, dependent care expenses in the definition of the "cost of attendance," D-305.978
	(1) (f) Inclusion of dependent care expenses in the definition of "cost of attendance"; and D-305.980
(e) Including room and board expenses in the definition of tax-exempt scholarship income;	(1) (e) including room and board expenses in the definition of tax-exempt scholarship income, D-305.978
	(2) (c) Include room and board expenses in the definition of tax-exempt scholarship income; D-305.980
(f) Continuing the federal Direct Loan Consolidation program, including the ability to "lock in" a fixed	(1) (f) continuing the loan consolidation program, including the ability to "lock in" a fixed interest rate, and D-305.978

Proposed language for adoption	Original language
interest rate, and giving consideration to grace periods in renewals of federal loan programs;	The AMA supports the Individual Education Account/Direct Loan Consolidation Program. H-305.948
	(1) (b) Continuation of the consolidation loan program and a consolidator's ability to lock in a fixed interest rate; D-305.980
	The AMA supports giving consideration to grace periods in renewals of federal loan programs and attempting to secure the most favorable repayment terms. H-305.980
(g) Adding the ability to refinance Federal Consolidation Loans;	(1) (g) adding the ability to refinance Federal Consolidation Loans; D-305.978
	Our AMA will: (1) support the refinancing of Federal Consolidation Loans; and D-305.981
	Our AMA will: (2) actively advocate for modification of pending and future legislation which that provides the opportunity to refinance Federal Consolidation Loans. D-305.981
(h) Eliminating the cap on the student loan interest deduction;	(2) (a) Eliminate the cap on the student loan interest deduction; D-305.980
(i) Increasing the income limits for taking the interest deduction;	(2) (b) Increase the income limits for taking the interest deduction; D-305.980
(j) Making permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001;	(2) (d) Make permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001. D-305.980
(k) Ensuring that loan repayment programs do not place greater burdens upon married couples than for similarly situated couples who are cohabitating;	11. Our AMA opposes any stipulations in loan repayment programs that place greater burdens upon married couples than for similarly-situated couples who are cohabitating. H-305.928
(l) Increasing efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students.	(2) urges increased efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students; and H-305.991
15. Continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases.	(2) continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases; D-305.978
16. Continue to study medical education financing, so as to identify long-term	(6) continue to study medical education financing, so as to identify long-term strategies

Proposed language for adoption	Original language
strategies to mitigate the debt burden of medical students, and monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location.	to mitigate the debt burden of medical students. D-305.978 (b) continue to monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location. D-305.957
17. Collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition.	3. Our AMA will collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition. D-305.993
18. Continue to monitor the availability of and encourage medical schools and residency/fellowship programs to (a) provide financial aid opportunities and financial planning/debt management counseling to medical students and resident/fellow physicians; (b) work with key stakeholders to develop and disseminate standardized information on these topics for use by medical students, resident/fellow physicians, and young physicians; and (c) share innovative approaches with the medical education community.	4. Our AMA will encourage medical schools to provide yearly financial planning/debt management counseling to medical students. D-305.993 6. Our AMA will urge the Accreditation Council for Graduate Medical Education (ACGME) to revise its Institutional Requirements to include a requirement that financial planning/debt management counseling be provided for resident physicians. D-305.993 7. Our AMA will work with other organizations, including the Association of American Medical Colleges, residency program directors groups, and members of the Federation, to develop and disseminate standardized information, for example, computer-based modules, on financial planning/debt management for use by medical students, resident physicians, and young physicians. D-305.993 6. Medical schools should have programs in place to assist students to limit their debt. This includes making scholarship support available, counseling students about financial aid availability, and providing comprehensive debt management/financial planning counseling. H-305.928 (4) continue to monitor the availability of financial aid opportunities and financial planning/debt management counseling at medical schools, and share innovative approaches with the medical education community; D-305.978
19. Seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt. The AMA	Our AMA will seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt. D-405.986

Proposed language for adoption	Original language
believes that it is improper for physicians not to repay their educational loans, but assistance should be available to those physicians who are experiencing hardship in meeting their obligations.	The AMA (1) believes that it is improper for any physician not to repay his or her educational loans; H-305.991
	9. Financial obligations, such as repayment of loans, and service obligations made in exchange for financial assistance, should be fulfilled. There should be mechanisms to assist physicians who are experiencing hardship in meeting these obligations. H-305.928
20. Related to the Public Service Loan Forgiveness (PSLF) Program, our AMA supports increased medical student and physician benefits the program, and will:	10. Our AMA supports the expansion and increase of medical student and physician benefits under Public Service Loan Forgiveness. H-305.928
(a) Advocate that all resident/fellow physicians have access to PSLF during their training years;	Our AMA will: (a) through the advocacy process, explore the possibility of assuring that all resident physicians and fellows have access to the Public Service Loan Forgiveness Program for the time they are in residency and fellowship training; and D-305.957
(b) Advocate against a monetary cap on PSLF and other federal loan forgiveness programs;	9. Our AMA will advocate against putting a monetary cap on federal loan forgiveness programs. D-305.993
(c) Work with the United States Department of Education to ensure that any cap on loan forgiveness under PSLF be at least equal to the principal amount borrowed;	10. Our AMA will: (a) advocate for maintaining a variety of student loan repayment options to fit the diverse needs of graduates; (b) work with the United States Department of Education to ensure that any cap on loan forgiveness under the Public Service Loan Forgiveness program be at least equal to the principal amount borrowed; and (c) ask the United States Department of Education to include all terms of Public Service Loan Forgiveness in the contractual obligations of the Master Promissory Note. D-305.993
(d) Ask the United States Department of Education to include all terms of PSLF in the contractual obligations of the Master Promissory Note;	
(e) Encourage the Accreditation Council for Graduate Medical Education (ACGME) to require residency/fellowship programs to include within the terms, conditions, and benefits of program appointment information on the PSLF program qualifying status of the employer;	11. Our AMA encourages the Accreditation Council for Graduate Medical Education (ACGME) to require programs to include within the terms, conditions, and benefits of appointment to the program (which must be provided to applicants invited to interview, as per ACGME Institutional Requirements) information regarding the Public Service Loan Forgiveness (PSLF) program qualifying status of the employer. D-305.993

Proposed language for adoption	Original language
(f) Advocate that the profit status of a physician's training institution not be a factor for PSLF eligibility;	12. Our AMA will advocate that the profit status of a physician's training institution not be a factor for PSLF eligibility. D-305.993
(g) Encourage medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed;	13. Our AMA encourages medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed. D-305.993
(h) Encourage medical school financial advisors to increase medical student engagement in service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas;	14. Our AMA encourages medical school financial advisors to promote to medical students service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas. D-305.993
(i) Strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.	15. Our AMA will strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes. D-305.993

APPENDIX B: PROPOSED AMA POLICY: "PRINCIPLES OF AND ACTIONS TO ADDRESS MEDICAL EDUCATION COSTS AND STUDENT DEBT" (TEXT VERSION)

The costs of medical education should never be a barrier to the pursuit of a career in medicine nor to the decision to practice in a given specialty.

To help address this issue, our American Medical Association (AMA) will:

1. Collaborate with members of the Federation and the medical education community, and with other interested organizations, to address the cost of medical education and medical student debt through public- and private-sector advocacy.

2. Vigorously advocate for and support expansion of and adequate funding for federal scholarship and loan repayment programs—such as those from the National Health Service Corps, Indian Health Service, Armed Forces, and Department of Veterans Affairs, and for comparable programs from states and the private sector—to promote practice in underserved areas, the military, and academic medicine or clinical research.

3. Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.

4. Advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas.

5. Encourage the National Health Service Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.

6. Work to reinstate the economic hardship deferment qualification criterion known as the "20/220 pathway," and support alternate mechanisms that better address the financial needs of trainees with educational debt.

7. Advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans.

8. Work with other concerned organizations to advocate for legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit 100% tax deductibility of interest on student loans and elimination of taxes on aid from service-based programs.

9. Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).

10. Support stable funding for medical education programs to limit excessive tuition increases, and collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided.

11. Work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment.

12. Encourage medical schools to

    (a) Study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, and combined baccalaureate/MD or DO programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education;

    (b) Engage in fundraising activities to increase the availability of scholarship support, with the support of the Federation, medical schools, and state and specialty medical societies, and develop or enhance financial aid opportunities for medical students, such as self-managed, low-interest loan programs;

    (c) Cooperate with postsecondary institutions to establish collaborative debt counseling for entering first-year medical students;

    (d) Allow for flexible scheduling for medical students who encounter financial difficulties that can be remedied only by employment, and consider creating opportunities for paid employment for medical students;

    (e) Counsel individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation;

    (f) Inform students of all government loan opportunities and disclose the reasons that preferred lenders were chosen;

    (g) Ensure that all medical student fees are earmarked for specific and well-defined purposes, and avoid charging any overly broad and ill-defined fees, such as but not limited to professional fees;

    (h) Use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies;

    (i) Work to ensure stable funding, to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue; mid-year and retroactive tuition increases should be opposed.

13. Support and encourage state medical societies to support further expansion of state loan repayment programs, particularly those that encompass physicians in non-primary care specialties.

14. Take an active advocacy role during reauthorization of the Higher Education Act and similar legislation, to achieve the following goals:

    (a) Eliminating the single holder rule;

(b) Making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training;

(c) Retaining the option of loan forbearance for residents ineligible for loan deferment;

(d) Including, explicitly, dependent care expenses in the definition of the "cost of attendance";

(e) Including room and board expenses in the definition of tax-exempt scholarship income;

(f) Continuing the federal Direct Loan Consolidation program, including the ability to "lock in" a fixed interest rate, and giving consideration to grace periods in renewals of federal loan programs;

(g) Adding the ability to refinance Federal Consolidation Loans;

(h) Eliminating the cap on the student loan interest deduction;

(i) Increasing the income limits for taking the interest deduction;

(j) Making permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001;

(k) Ensuring that loan repayment programs do not place greater burdens upon married couples than for similarly situated couples who are cohabitating;

(l) Increasing efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students.

15. Continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases.

16. Continue to study medical education financing, so as to identify long-term strategies to mitigate the debt burden of medical students, and monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location.

17. Collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition.

18. Continue to monitor the availability of and encourage medical schools and residency/fellowship programs to (a) provide financial aid opportunities and financial planning/debt management counseling to medical students and resident/fellow physicians; (b) work with key stakeholders to develop and disseminate standardized information on these topics for use by medical students, resident/fellow physicians, and young physicians; and (c) share innovative approaches with the medical education community.

19. Seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt. The AMA believes that it is improper for physicians not to repay their educational loans, but assistance should be available to those physicians who are experiencing hardship in meeting their obligations.

20. Related to the Public Service Loan Forgiveness (PSLF) Program, our AMA supports increased medical student and physician benefits the program, and will:

    (a) Advocate that all resident/fellow physicians have access to PSLF during their training years;

    (b) Advocate against a monetary cap on PSLF and other federal loan forgiveness programs;

    (c) Work with the United States Department of Education to ensure that any cap on loan forgiveness under PSLF be at least equal to the principal amount borrowed;

    (d) Ask the United States Department of Education to include all terms of PSLF in the contractual obligations of the Master Promissory Note;

    (e) Encourage the Accreditation Council for Graduate Medical Education (ACGME) to require residency/fellowship programs to include within the terms, conditions, and benefits of program appointment information on the PSLF program qualifying status of the employer;

    (f) Advocate that the profit status of a physician's training institution not be a factor for PSLF eligibility;

    (g) Encourage medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed;

    (h) Encourage medical school financial advisors to increase medical student engagement in service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas;

    (i) Strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.

APPENDIX C: AMA POLICIES AND DIRECTIVES PROPOSED FOR RESCISSION

1. D-305.956, "AMA Participation in Reducing Medical Student Debt"

Our AMA will explore the feasibility of the development of an affinity program in which student, resident and fellow members of our AMA could obtain new educational loans and consolidate existing loans from one or more national banks or other financial intermediaries. Membership in our AMA would be required during the life of the loan (typically 10 years or more following medical school). Such activities or program would neither result in our AMA becoming subject to regulation as a financial institution nor impair our AMA's ability to continue to be treated as a not-for-profit entity.
Res. 609, A-14; Modified: Speakers Rep., I-15

2. D-305.957, "Update on Financial Aid Programs"

Our AMA will: (a) through the advocacy process, explore the possibility of assuring that all resident physicians and fellows have access to the Public Service Loan Forgiveness Program for the time they are in residency and fellowship training; and (b) continue to monitor the short-and long-term impact of the economic environment on the availability of institutional and external sources of financial aid for medical students, as well as on choice of specialty and practice location.
CME Rep. 1, I-10

3. D-305.962, "Tax Deductibility of Student Loan Payments"

Our AMA will draft legislation allowing 100% tax deductibility of student loan interest.
Res. 232, A-09; Reaffirmed in lieu of Res. 225, I-12

4. D-305.966, "Reinstatement of Economic Hardship Loan Deferment"

Our AMA will actively work to reinstate the economic hardship deferment qualification criterion known as the "20/220 pathway," and support alternate mechanisms that better address the financial needs of post-graduate trainees with educational debt.
Res. 930, I-07; Reaffirmed: BOT Rep. 22, A-17

5. D-305.970, "Proposed Revisions to AMA Policy on Medical Student Debt"

Our AMA will:

1. Collaborate, based on AMA policy, with members of the Federation and the medical education community, and with other interested organizations, to achieve the following immediate public- and private-sector advocacy goals:
   (a) Support expansion of and adequate funding for federal scholarship and loan repayment programs, such as those from the National Health Service Corps, the Indian Health Service, the Armed Forces, and the Department of Veterans Affairs, and for comparable programs at the state level.
   (b) Encourage the expansion of National Institutes of Health programs that provide loan repayment in exchange for a commitment to conduct targeted research.
   (c) With each reauthorization of the Higher Education Act and at every other legislative opportunity, proactively pursue loan consolidation terms that favor students and ensure that loan deferment is available for the entire duration of residency and fellowship training.

(d) Ensure that the Higher Education Act and other legislation allow interest from medical student loans to be fully tax deductible.
(e) Encourage medical schools, with the support of the Federation, to engage in fundraising activities devoted to increasing the availability of scholarship support.
(f) Encourage the creation of private-sector financial aid programs with favorable interest rates or service obligations (such as community- or institution-based loan repayment programs or state medical society loan programs).
(g) Support stable funding for medical education programs to limit excessive tuition increases.

2. Encourage medical schools to study the costs and benefits associated with non-traditional instructional formats (such as online and distance learning, combined baccalaureate/MD programs) to determine if cost savings to medical schools and to medical students could be realized without jeopardizing the quality of medical education.
CME Rep. 13, A-06; Reaffirmation I-08

6. D-305.975, "Long-Term Solutions to Medical Student Debt"

Our AMA will:
(1) encourage medical schools and state medical societies to consider the creation of self-managed, low-interest loan programs for medical students, and collect and disseminate information on such programs;
(2) advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas;
(3) work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment;
(4) collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided; and
(5) encourage the National Health Services Corps to have repayment policies that are consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.
CME Rep. 3, I-04; Reaffirmation I-06; Appended: Res. 321, A-12; Reaffirmation A-13; Modified: CCB/CLRPD Rep. 2, A-14; Reaffirmation I-14

7. D-305.977, "Deductibility of Medical Student Loan Interest"

Our AMA will work toward 100% tax deductibility of medical student loan interest on federal and state income tax returns.
Res. 705, I-04; Reaffirmed: CME Rep. 2, A-14

8. D-305.978, "Mechanisms to Reduce Medical Student Debt"

Our AMA will:
(1) take an active advocacy role during the upcoming reauthorization of the Higher Education Act and other pending legislation, to achieve the following goals:
(a) eliminating the single holder rule,
(b) making the availability of loan deferment more flexible, including broadening the definition of economic hardship and expanding the period for loan deferment to include the entire length of residency and fellowship training,

(c) retaining the option of loan forbearance for residents ineligible for loan deferment,
(d) including, explicitly, dependent care expenses in the definition of the "cost of attendance,"

(e) including room and board expenses in the definition of tax-exempt scholarship income,
(f) continuing the loan consolidation program, including the ability to "lock in" a fixed interest rate, and
(g) adding the ability to refinance Federal Consolidation Loans;
(2) continue to work with state and county medical societies to advocate for adequate levels of medical school funding and to oppose legislative or regulatory provisions that would result in significant or unplanned tuition increases;
(3) encourage members of the Federation to develop or enhance financial aid opportunities for medical students;
(4) continue to monitor the availability of financial aid opportunities and financial planning/debt management counseling at medical schools, and share innovative approaches with the medical education community;
(5) continue to collect and disseminate information to assist members of the Federation (state medical societies and specialty societies) and medical schools to establish or expand financial aid programs; and
(6) continue to study medical education financing, so as to identify long-term strategies to mitigate the debt burden of medical students.
CME Rep. 10, A-04; Reaffirmation I-08

9. D-305.979, "State and Local Advocacy on Medical Student Debt"

Our AMA will: (1) support and encourage our state medical societies to support further expansion of state loan repayment programs, and in particular expansion of those programs to cover physicians in non-primary care specialties; and
(2) urge state medical societies to actively solicit funds (either directly or through their Foundations) for the establishment and expansion of medical student scholarships, and that our AMA develop a set of guidelines and suggestions to assist states in carrying out such initiatives.
Res. 847, I-03; Reaffirmation A-13; Modified: CME Rep. 2, A-13

10. D-305.980, "Immediate Legislative Solutions to Medical Student Debt"

Our AMA will:
(1) endorse and actively lobby for the Reauthorization of the Higher Education Act, including:
(a) Elimination of the "single-holder" rule;
(b) Continuation of the consolidation loan program and a consolidator's ability to lock in a fixed interest rate;
(c) Expansion of the deferment period for loan repayment to cover the entire duration of residency and fellowship;
(d) Broadening of the definition of economic hardship as used to determine eligibility for student loan deferment;
(e) Retention of the option of loan forbearance for residents who are ineligible for student loan deferment; and
(f) Inclusion of dependent care expenses in the definition of "cost of attendance"; and
(2) lobby for passage of legislation that would:
(a) Eliminate the cap on the student loan interest deduction;
(b) Increase the income limits for taking the interest deduction;
(c) Include room and board expenses in the definition of tax-exempt scholarship income; and

(d) Make permanent the education tax incentives that our AMA successfully lobbied for as part of Economic Growth and Tax Relief Reconciliation Act of 2001.

Res. 850, I-03; Reaffirmation I-08

11. D-305.981, "Financing Federal Consolidation Loans"

Our AMA will: (1) support the refinancing of Federal Consolidation Loans; and (2) actively advocate for modification of pending and future legislation which that provides the opportunity to refinance Federal Consolidation Loans.

Res. 849, I-03; Reaffirmed: BOT Rep. 28, A-13

12. D-305.993, "Medical School Financing, Tuition, and Student Debt"

1. The Board of Trustees of our AMA will pursue the introduction of member benefits to help medical students, resident physicians, and young physicians manage and reduce their debt burden. This should include consideration of the feasibility of developing web-based information on financial planning/debt management; introducing a loan consolidation program, automatic bill collection, loan repayment programs, and a rotating loan program; and creating an AMA scholarship program funded through philanthropy. The AMA also should collect and disseminate information on available opportunities for medical students and resident physicians to obtain financial aid for emergency and other purposes.
2. Our AMA will vigorously advocate for ongoing, adequate funding for federal and state programs that provide scholarship or loan repayment funds in return for service, including funding in return for practice in underserved areas, participation in the military, and participation in academic medicine or clinical research. Obtaining adequate support for the National Health Service Corps and similar programs, tied to the demand for participation in the programs, should be a focus for AMA advocacy efforts.
3. Our AMA will collect and disseminate information on successful strategies used by medical schools to cap or reduce tuition.
4. Our AMA will encourage medical schools to provide yearly financial planning/debt management counseling to medical students.
5. Our AMA supports a requirement that medical schools inform students of all government loan opportunities and requires disclosure of reasons that preferred lenders were chosen.
6. Our AMA will urge the Accreditation Council for Graduate Medical Education (ACGME) to revise its Institutional Requirements to include a requirement that financial planning/debt management counseling be provided for resident physicians.
7. Our AMA will work with other organizations, including the Association of American Medical Colleges, residency program directors groups, and members of the Federation, to develop and disseminate standardized information, for example, computer-based modules, on financial planning/debt management for use by medical students, resident physicians, and young physicians.
8. Our AMA will work with other concerned organizations to promote legislation and regulations with the aims of increasing loan deferment through the period of residency, promoting the expansion of subsidized loan programs, eliminating taxes on aid from service-based programs, and restoring tax deductibility of interest on educational loans.
9. Our AMA will advocate against putting a monetary cap on federal loan forgiveness programs.
10. Our AMA will: (a) advocate for maintaining a variety of student loan repayment options to fit the diverse needs of graduates; (b) work with the United States Department of Education to ensure that any cap on loan forgiveness under the Public Service Loan Forgiveness program be at least equal to the principal amount borrowed; and (c) ask the United States Department of Education to include all terms of Public Service Loan Forgiveness in the contractual obligations of the Master Promissory Note.

11. Our AMA encourages the Accreditation Council for Graduate Medical Education (ACGME) to require programs to include within the terms, conditions, and benefits of appointment to the program (which must be provided to applicants invited to interview, as per ACGME Institutional Requirements) information regarding the Public Service Loan Forgiveness (PSLF) program qualifying status of the employer.
12. Our AMA will advocate that the profit status of a physician's training institution not be a factor for PSLF eligibility.
13. Our AMA encourages medical school financial advisors to counsel wise borrowing by medical students, in the event that the PSLF program is eliminated or severely curtailed.
14. Our AMA encourages medical school financial advisors to promote to medical students service-based loan repayment options, and other federal and military programs, as an attractive alternative to the PSLF in terms of financial prospects as well as providing the opportunity to provide care in medically underserved areas.
15. Our AMA will strongly advocate that the terms of the PSLF that existed at the time of the agreement remain unchanged for any program participant in the event of any future restrictive changes.
CME Rep. 2, I-00; Reaffirmation I-03; Reaffirmation I-06; Reaffirmation A-13; Appended: Res. 323, A-14; Appended: Res. 324, A-15; Appended: Res. 318, A-16; Appended: CME Rep. 07, A-17; Modified: CME Rep. 01, A-18.

13. D-405.986, "Student Loans and Medicare / Medicaid Participation"

Our AMA will seek federal legislation or rule changes that would stop Medicare and Medicaid decertification of physicians due to unpaid student loan debt.
Res. 203, I-12

14. H-305.926, "Supporting Legislation to Create Student Loan Savings Accounts"

Our AMA will advocate for federal legislation to support the creation of student loan savings accounts that allow for pre-tax dollars to be used to pay for student loans.
Res. 202, A-16

15. H-305.928, "Proposed Revisions to AMA Policy on Medical Student Debt"

1. Our AMA will make reducing medical student debt a high priority for legislative and other action and will collaborate with other organizations to study how costs to students of medical education can be reduced.
2. Our AMA supports stable funding for medical schools to eliminate the need for increases in tuition and fees to compensate for unanticipated decreases in other sources of revenue and should oppose mid-year and retroactive tuition increases.
3. Financial aid opportunities, including scholarship and loan repayment programs, should be available so that individuals are not denied an opportunity to pursue medical education because of financial constraints.
4. A sufficient breadth of financial aid opportunities should be available so that student specialty choice is not constrained based on the need for financial assistance.
5. Our AMA supports the creation of new and the expansion of existing medical education financial assistance programs from the federal government, the states, and the private sector.
6. Medical schools should have programs in place to assist students to limit their debt. This includes making scholarship support available, counseling students about financial aid availability, and providing comprehensive debt management/financial planning counseling.

7. Our AMA supports legislation and regulation that would result in favorable terms and conditions for borrowing and for loan repayment, and would permit the full deductibility of interest on student loans.
8. Medical students should not be forced to jeopardize their education by the need to seek employment. Any decision on the part of the medical student to seek employment should take into account his/her academic situation. Medical schools should have policies and procedures in place that allow for flexible scheduling in the case that medical students encounter financial difficulties that can be remedied only by employment. Medical schools should consider creating opportunities for paid employment for medical students.
9. Financial obligations, such as repayment of loans, and service obligations made in exchange for financial assistance, should be fulfilled. There should be mechanisms to assist physicians who are experiencing hardship in meeting these obligations.
10. Our AMA supports the expansion and increase of medical student and physician benefits under Public Service Loan Forgiveness.
11. Our AMA opposes any stipulations in loan repayment programs that place greater burdens upon married couples than for similarly-situated couples who are cohabitating.
CME Rep. 13, A-06; Reaffirmation I-06; Reaffirmation I-07; Reaffirmation I-08; Reaffirmed: CME Rep. 8, A-12; Reaffirmation A-13; Appended: Res. 304, A-13; Appended: Res. 323, A-15; Reaffirmation I-15

16. H-305.932, "State and Local Advocacy on Medical Student Debt"

Our AMA:
(1) opposes the charging of broad and ill-defined student fees by medical schools, such as but not limited to professional fees, encouraging in their place fees that are earmarked for specific and well-defined purposes;
(2) encourages medical schools to use their collective purchasing power to obtain discounts for their students on necessary medical equipment, textbooks, and other educational supplies; and
(3) encourages medical schools to cooperate with undergraduate institutions to establish collaborative debt counseling for entering first-year medical students.
Res. 847, I-03; Reaffirmed: CME Rep. 2, A-13

17. H-305.948, "Direct Loan Consolidation Program"

The AMA supports the Individual Education Account/Direct Loan Consolidation Program.
Res. 312, I-95; Reaffirmed: CME Rep. 2, A-05; Reaffirmed: CME Rep. 1, A-15

18. H-305.954, "Repayment of Medical School Loans"

Our AMA will further develop and more aggressively publicize a low interest rate and extended payment loan program for young physician members of the AMA to assist them in retiring their educational debts.
CME Rep. O, A-93; Appended: Res. 610, I-98; Modified: CME Rep. 13, A-06; Modified: CME Rep. 01, A-16

19. H-305.965, "Student Loans"

Our AMA: (1) reaffirms its support of legislation that would defer the repayment of loans for education until the completion of residency training; and
(2) will lobby for deferment of medical student loans for the full initial residency period.
Sub. Res. 203, A-90; Appended Res. 306, I-99; Reaffirmation A-01; Reaffirmation I-06; Modified: CME Rep 01, A-16

20. H-305.980, "Student Loan Repayment Grace Period"

The AMA supports giving consideration to grace periods in renewals of federal loan programs and attempting to secure the most favorable repayment terms.
CME Rep. I, A-86; Reaffirmed: Sunset Report, I-96; Reaffirmed: CME Rep. 2, I-00; Reaffirmed: CME Rep. 2, A-10

21. H-305.991, "Repayment of Educational Loans"

The AMA (1) believes that it is improper for any physician not to repay his or her educational loans;
(2) urges increased efforts to collect overdue debts from the present medical student loan programs in a manner that would not interfere with the provision of future loan funds to medical students; and
(3) encourages medical school financial aid officers to counsel individual medical student borrowers on the status of their indebtedness and payment schedules prior to their graduation.
Sub. Res. 47, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CME Rep. 2, A-05; Reaffirmed: CME Rep. 1, A-15

APPENDIX D: PORTIONS OF AMA POLICIES AND DIRECTIVES THAT ARE NOT BEING RETAINED THROUGH THIS REPORT

Language	**Rationale for removal**
H-305.954: Our AMA will further develop and more aggressively publicize a low interest rate and extended payment loan program for young physician members of the AMA to assist them in retiring their educational debts.	Accomplished through AMA affinity partnership programs (Credible and Laurel Roads).
H-305.980: The AMA supports giving consideration to grace periods in renewals of federal loan programs and attempting to secure the most favorable repayment terms.	The first phrase, "giving consideration to grace periods in renewals of federal loan programs," has been integrated into the new policy. The second phrase, "attempting to secure the most favorable repayment terms," has been accomplished through the AMA affinity partnership programs (Credible and Laurel Roads).
D-305.993: 1. The Board of Trustees of our AMA will pursue the introduction of member benefits to help medical students, resident physicians, and young physicians manage and reduce their debt burden. This should include consideration of the feasibility of developing web-based information on financial planning/debt management; introducing a loan consolidation program, automatic bill collection, loan repayment programs, and a rotating loan program; and creating an AMA scholarship program funded through philanthropy. The AMA also should collect and disseminate information on available opportunities for medical students and resident physicians to obtain financial aid for emergency and other purposes.	• Through an AMA affinity program, AMA members can obtain discounts on refinancing student loans. https://www.ama-assn.org/content/ama-preferred-provider-offers-and-services-loans-and-financial-services • The AMA Career Planning Resource offers budget planning tools: https://www.ama-assn.org/life-career/career-planning-resource. Evaluation of the feasibility of further tools has been accomplished. • The AMA Foundation provides student scholarships, as well as the AMA Employee-funded scholarship
D-305.956: Our AMA will explore the feasibility of the development of an affinity program in which student, resident and fellow members of our AMA could obtain new educational loans and consolidate existing loans from one or more national banks or other financial intermediaries. Membership in our AMA would be required during the life of the loan (typically 10 years or more following medical school). Such activities or program would neither result in our AMA becoming subject to regulation as a financial institution nor impair our AMA's ability to continue to be treated as a not-for-profit entity.	Accomplished through AMA affinity partnership programs (Credible and Laurel Roads).

REPORT 3 OF THE COUNCIL ON MEDICAL SERVICE (I-18)
Sustain Patient-Centered Medical Home Practices
(Resolution 813-I-17)
(Reference Committee J)

EXECUTIVE SUMMARY

At the American Medical Association (AMA) 2017 Interim Meeting, the House of Delegates referred Resolution 813, "Sustain Patient-Centered Medical Home Practices," which was introduced by the Michigan delegation. The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2018 Interim Meeting. Resolution 813-I-17 asked (1) that our AMA amend Policy H-160.918 to urge the Centers for Medicare & Medicaid Services (CMS) to assist physician practices seeking to qualify for and sustain medical home status with financial and other resources; and (2) encourage CMS to subsidize the cost of sustaining Patient-Centered Medical Home (PCMH) designated practices.

The Council believes that primary care and the PCMH are bedrocks of high-quality, patient-centered health care. However, in order to make the transition to a PCMH, practices of all sizes and settings must have the support to confront the challenges of practice transformation. The Council notes that cultural and financial obstacles of becoming a PCMH are substantial and demand significant investment and buy-in. To that end, the Council recommends a set of recommendations recognizing that it is critical to not only have financial support during the initial stages of practice transformation, but also to maintain ongoing funding and continuous cultural and monetary support for PCMH activities.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-18

Subject: Sustain Patient-Centered Medical Home Practices (Resolution 813-I-17)

Presented by: James G. Hinsdale, MD, Chair

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

At the American Medical Association (AMA) 2017 Interim Meeting, the House of Delegates referred Resolution 813, "Sustain Patient-Centered Medical Home Practices," which was introduced by the Michigan delegation. The Board of Trustees referred this issue to the Council on Medical Service for a report back to the House at the 2018 Interim Meeting. Resolution 813-I-17 asked:

> (1) That our American Medical Association (AMA) amend Policy H-160.918, "The Patient-Centered Medical Home," by addition as follows:
>
> Our AMA:
>
> a. Will urge the Centers for Medicare & Medicaid Services (CMS) to work with our AMA and national medical specialty societies to design incentives to enhance care coordination among providers who provide medical care for patients outside the medical home;
> b. Will urge CMS to assist physician practices seeking to qualify for and sustain medical home status with financial and other resources;
> c. Will advocate that Medicare incentive payments associated with the medical home model be paid for through system-wide savings – such as reductions in hospital admissions and readmissions (Part A), more effective use of pharmacologic therapies (Part D), and elimination of government subsidies for Medicare Advantage plans (Part C) – and not be subject to a budget neutrality offset in the Medicare physician payment schedule; and
> d. Will advocate that all health plans and CMS use a single standard to determine whether a physician practice qualifies to be a patient-centered medical home; and
>
> (2) That our AMA work with and encourage CMS to subsidize the cost of sustaining Patient-Centered Medical Home designated practices for practicing physicians.

This report provides background on Patient-Centered Medical Homes (PCMHs), outlines the costs of sustaining a PCMH, discusses the various payment methodologies employed with the model, provides an example of a PCMH, outlines relevant AMA policy and AMA advocacy efforts, and proposes policy recommendations.

BACKGROUND

The PCMH is a team-based practice that is led by a personal physician who provides continuous and coordinated care throughout a patient's lifetime to maximize health outcomes.[1] The PCMH model emphasizes population management, team-based care, and care management, particularly for at-risk patients with the objective of having a centralized setting that facilitates partnerships between individual patients, their physicians, and, when appropriate, the patient's family.[2] The PCMH encompasses five functions and attributes: comprehensiveness, patient-centered, coordinated, accessibility, and quality and safety.[3] Evidence suggests that PCMHs improve quality, the patient experience and staff satisfaction, while reducing health care costs.[4]

While recognizing the utility of specialty care medical homes, the Council chose to limit the scope of this report to PCMHs. Improving and investing in primary care has become a major health policy objective, and, for many patients, primary care services are their entry point into the health care system.[5] As such, primary care is well positioned to help address the fragmentation in the health care system and optimize the delivery of health care. Moreover, the Council believes that primary care physicians are the touchstone of the physician-led health care team and are the gateway to health care.

Building a PCMH requires hard work from all stakeholders including physicians, practice teams, patients, and institutional partners. It requires time, money, dedication, sustained effort, and a cultural shift.[6]

COST OF SUSTAINING A PCMH

Identifying the costs of maintaining PCMH functions can contribute to effective payment reform and sustainability of transformation. The costs for a practice to implement these PCMH services vary depending on factors such as practice size, existing capabilities, characteristics of the patient population, and availability of low-cost or funded resources.[7]

Generally, the most significant cost to sustaining a PCMH is the ongoing cost of maintaining personnel. A recent study assessed the direct personnel costs to 20 primary care practices that differed in PCMH recognition status, ownership, payer mix, and patient populations. The study looked into the practice costs associated with the staffing necessary to deliver PCMH functions per the National Committee for Quality Assurance (NCQA) Standards. The NCQA is the most widely adopted PCMH recognition program.[8] The study looked at 20 differing primary care practices in Utah and Colorado and found that the incremental costs per full-time equivalent primary care clinician associated with PCMH functions varied across practices with an average of $7,691 per month in Utah practices and $9,658 in Colorado practices. Also, the study found that PCMH incremental costs per encounter were $32.71 in Utah and $36.68 in Colorado. The average estimated cost per member per month for an assumed panel of 2,000 patients was $3.85 in Utah and $4.83 in Colorado. In addition to finding that the staffing and care coordination requirements of a PCMH could have an average incremental cost of $8600 per month, the study found that smaller practices may be particularly susceptible to increased costs.[9]

Additional insight on practice transformation costs may be gleaned from the traditional cost of electronic health record implementation. According to an extensive study of EHR implementation in Texas-based primary care practices that were not PCMHs, it is estimated that the first-year cost of implementation is about $162,000 with about $86,000 in maintenance expenses for a five-physician practice.[10] This figure is likely a significant underestimate of the costs and challenges of

implementing a medical home.[11] Similar implementation and maintenance costs have been reported across the country including in Massachusetts and New York City.

Moreover, a recent RAND study found that overall PCMH transformation costs are likely anywhere between $83,829 and $346,603 per year and that practice transformation could take several years.[12] Further, the report found that the costs per clinician ranged from $18,585 to $93,856, with ongoing median costs at $147,573 per practice and nearly $65,000 per clinician.

PCMH PAYMENT

PCMHs are a care delivery concept rather than a defined payment model and do not have a defined payment structure. However, many PCMH payment models have similarities. For example, PCMHs often receive payment based on an established fee schedule and supplemental payments for care coordination. The structure of PCMH payment is intended to support and promote practice activities that traditionally do not qualify for payment such as e-mail and phone communications, care coordination, and workflow changes. Therefore, the supplemental payments may be adjustment payments for traditionally non-reimbursed care management services. Other models' supplemental payments are simply additional lump sum payments to incentivize care management. Other models use a capitation-based payment that may include enhanced payment to support medical home activities.[13] Additionally, many models participate in shared savings.

EXAMPLES OF A PCMH

Comprehensive Primary Care Initiative

The Comprehensive Primary Care (CPC) initiative is a four-year multi-payer CMS PCMH initiative intended to strengthen primary care.[14] In initiating CPC, CMS recognized concerns that primary care has been traditionally underfunded and that sufficient payment is critical for the practice-wide changes needed to transform primary care.[15] CPC launched in 2012, and in the ensuing years of the program CMS has partnered with commercial and state health insurance plans to offer population-based care management and shared savings opportunities to participating primary care practices to support the delivery of CPC functions.

A recent study that looked at the cumulative results of CPC over four years found that CPC practices reported improved primary care delivery, such as care management for high-risk patients, enhanced access, and improved coordination after care transitions.[16] Moreover, CPC slowed growth in emergency department visits by two percent and hospitalizations by two percent relative to the comparison group. Importantly, CPC fostered substantial local collaboration wherein payers and practices came together to collectively work on solutions.[17] This has signaled a paradigm shift wherein payers are now working together in communities to build primary care capacity, and some payers are funding community resources such as data aggregation to drive success. All CPC regions are sharing the lessons learned and best practices to drive further innovation.

In 2015, the CPC initiative generated $57.7 million in gross savings for Medicare Parts A and B. Moreover, over half of the participating CPC practices shared in savings of over $13 million. In addition to generating overall savings, practices in the CPC program exhibited improvement in quality measures including a lowering of hospital admissions and readmission rates. Stakeholders believe that CPC demonstrates the potential for primary care clinicians to redesign their practices to deliver better care to patients and improved outcomes to patients.

However, despite decreased utilization and improved outcomes, CPC did not reduce Medicare spending enough to cover care management fees or appreciably improve physician or beneficiary experience or practice performance on a limited set of Medicare claims-based quality measures.[18] Comprehensive Primary Care Plus (CPC+), which qualifies as an advanced alternative payment model (APM), was built on the CPC structure and is a five-year PCMH model that launched in 2017 in 14 regions across the country. While CPC practices had to achieve savings in total cost of care for their state, CPC+ practices have to achieve good performance on metrics such as reducing ambulatory care sensitive admissions. CPC+ has two tracks. One track is for practices building medical home capabilities, and the second track is for those practices that are already delivering advanced primary care.[19] Moreover, the Physician-Focused Payment Model Technical Advisory Committee (PTAC) recommended to the Secretary of Health & Human Services a proposal developed by the American Academy of Family Physicians (AAFP) for Advanced Primary Care, and the AMA supported this proposal. There is now a second round of CPC+ which expanded the program to more regions.

CPC+ provides primary care practices with up-front and improved payment in addition to technical assistance.[20] Its payment components de-emphasize fee-for-service (FFS) and increase payment to support practice improvement and delivery transformation. Both CPC+ tracks offer three payment components. The first component is a care management fee (CMF) paid per-beneficiary-per-month. The CMF is paid prospectively on a quarterly basis and is based on the complexity of the patient population. The second component is a performance-based incentive payment (PBIP) that is received as a prospective payment at the beginning of each program year in order to meet patient needs and build practice capacity. At the end of the year, if practices do not meet the quality and cost benchmarks, they will repay some or all of the PBIP. The third component is a payment under the Medicare fee schedule. Track 1 practices continue to receive FFS payments while Track 2 practices receive a hybrid payment with a prospective portion paid quarterly called the Comprehensive Primary Care Payment (CPCP) coupled with a reduced FFS payment. The CPCP and FFS payments taken together are larger than the practice's historical FFS payment.

CareFirst

In 2011, a PCMH program operated by CareFirst BlueCross BlueShield launched, which is the largest coordinated care program of its kind. The program is structured around groups of primary care providers organized into panels of between five to fifteen physicians. These physicians are grouped together to coordinate the care of CareFirst members with the most pressing health care needs, and how the panels operate is largely up to them.[21] As teams, panels are eligible to earn Outcome Incentive Awards that are paid as increases to their fee schedules based on the level of quality and the savings achieved against projected costs.

Recognizing that coordinated care often involves services that are not typically compensated under traditional insurance arrangements, CareFirst's PCMH provides for an across-the-board 12 percentage point increase in compensation for primary care services. Additionally, the insurer also pays physicians $200 per patient to develop care plans for high-risk patients and $100 for every time a care plan needs to be updated.[22]

Importantly, the program is designed to appeal to solo and small group practices. CareFirst understands that the needed investments, particularly IT investments, to create and maintain a PCMH are often cost-prohibitive to physicians in solo or small practice arrangements. Therefore, the program provides physicians with access to all necessary IT to participate in the PCMH. Additionally, CareFirst has dedicated more than 100 nurses across the region to help coordinate care and ensure that the program runs smoothly.[23]

Over the course of the program, it has lowered the expected cost of care for CareFirst members by nearly $1.2 billion.[24] In 2017 alone, the CareFirst PCMH helped save $223 million against the expected cost of care. The savings was largely driven by reductions in hospital admissions and the length of hospital stays. Since the program's inception, all CareFirst members experienced 21.3 percent fewer hospital admissions; 22.5 percent fewer emergency department visits; and 7.8 percent fewer days in the hospital.[25]

AMA POLICY

Relevant to the subject of this report, Policy H-160.918 addresses the financial aspects of the PCMH model. It urges CMS to work with the AMA and national medical specialty societies to enhance care coordination among providers who provide medical care for patients outside the medical home and urges CMS to assist physician practices seeking to qualify for medical home status with financial and other resources. Specifically, Policy H-160.918 calls for Medicare incentive payments associated with the medical home model to be paid for through system-wide savings – such as reductions in hospital admissions and readmissions (Part A), more effective use of pharmacologic therapies (Part D), and elimination of government subsidies for Medicare Advantage plans (Part C) – and not be subject to a budget neutrality offset in the Medicare physician payment schedule. Moreover, it calls for all health plans and CMS to use a single standard to determine whether a physician practice qualifies to be a patient-centered medical home.

Policy H-160.919 articulates principles of the PCMH and adopts the Joint Principles of Patient-Centered Medical Homes developed and endorsed by primary care societies including the American Academy of Pediatrics, American College of Physicians, American Osteopathic Association, and AAFP, among others. The organizations initially developed these principles to emphasize the patient-physician relationship, physician leadership of a care team and physician responsibility for care coordination, supported by other qualified providers. The policy states that payment should appropriately recognize the added value provided to patients who have a PCMH. The policy calls for the AMA to recognize the value of physician work associated with remote monitoring of patients and clinical data and states that PCMH payment models should allow for separate payments for face-to-face visits. Consequently, Policy H-160.919 supports physician payments that reflect the value of care management work outside of the face-to-face visit and calls for additional payments for achieving measurable and continuous quality improvements and supports a structure for shared savings. The policy promotes a voluntary recognition process for medical homes and supports integrated care across all elements of the health care system. It advocates for quality and safety, patient-centered outcomes, evidence-based decision making, physician engagement in achieving medical outcomes and utilization of information technology (IT). Further, the policy also advocates for access to care through systems such as open scheduling, expanded hours and new options for communicating with patients.

Policy H-450.931 supports the move to APMs and calls for the AMA to provide physician practices with support and guidance in the transition. Policy H-385.908 calls for the AMA to work with organizations to improve the availability and use of health IT, including continuing to expand technical assistance and developing IT systems that support and streamline clinical participation. Policy H-385.908 also urges CMS to limit financial risk to costs that physicians participating in APMs have the ability to influence or control.

AMA ACTIVITY

The AMA continues to work to assist physicians with the requirements and incentives contained in the Medicare Access & CHIP Reauthorization Act (MACRA), which includes the development and

successful implementation of PCMHs. The AMA has been active in educational activities including webinars and regional conferences for physicians and staff and will be continuing these activities. Recent AMA advocacy activity has called for improvements in the methodologies behind APMs to reduce practice barriers and enable more physicians to participate. The AMA has urged CMS to enhance proposals that provide credit for and promote medical homes and APMs. Therefore, the AMA has repeatedly advocated for CMS to extend the CPC+ model nationwide for all of Medicare. Further, the AMA has called for an increase in medical home flexibility and to expand medical home eligibility to specialty medical homes. Additionally, the AMA has called for the lower financial risk requirements available for patient-centered primary care medical homes to be extended to specialty medical homes. Moreover, the AMA continues to advocate for proper risk adjustment in APMs and has urged CMS to prevent stringent two-sided risk requirements from being extended to primary care medical homes serving vulnerable populations, such as children with Medicaid coverage.

Additionally, the AMA is advocating for PCMHs to earn more credit in the Merit-Based Incentive Payment System (MIPS). PCMHs can be recognized by a variety of organizations and have this recognition count as their Improvement Activity under MIPS. However, because the Improvement Activity score is only weighted at 15 percent of the total score so it does not count for a significant percentage of overall score. However, the AMA has advocated that practices that go to the effort of transforming to PCMHs should be able to utilize their PCMH status for more credit in MIPS.

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

In its advocacy efforts, the AMA has highlighted that some practices are effectively doing the work of the PCMH but are not being compensated for its activities or recognized because the certification process is arduous and expensive. To that end, the AMA has advocated for CMS to recognize programs that accredit medical homes based on the advanced primary care functions, including state-based, payer-sponsored, and regional medical home recognition programs. Moreover, the AMA has stated that physicians should not be required to pay a third party accrediting body to receive recognition as a PCMH. Recognition or certification by an accrediting body may not necessarily capture the actual advanced primary care functions.

DISCUSSION

The value of primary care is often underemphasized relative to other parts of the health care system.[26] However, payers and other stakeholders are increasingly recognizing the need to strengthen primary care and to help reduce overall health care costs and improve care quality. Accordingly, the Council recommends reaffirming Policy H-160.919 that contains principles of the PCMH including that payment should appropriately recognize the added value provided to patients who have a PCMH and the additional physician and team work associated with participating in a PCMH. The Council also recommends reaffirming Policy H-385.908 stating that physicians should only be held responsible for costs that they can reasonably control.

Additionally, recognizing that flexibility is integral to ensuring that PCMHs are designed in ways that improve care for patients and are feasible for physicians to implement, the Council recommends rescinding Part 4 of Policy H-160.918, which states that the AMA will advocate that

all health plans and CMS use a single standard to determine whether a physician practice qualifies to be a PCMH because the AMA has continued to support increased medical home flexibility. Rescinding this section of the policy would support flexibility in practices to implement medical home functions with methods best suited for their practice designs and patient populations.

As Resolution 813-I-17 recognizes, adequate compensation for ongoing and incremental costs is critical for practices to sustain PCMH functions. Not only are the costs of implementation and maintenance significant, but also, care innovations such as telemedicine that increase access and improve care quality also may be expensive. Therefore, the Council recommends advocating that all payers support medical home transformation and maintenance efforts recognizing that payer support is crucial to the long-term sustainability of delivery reform. Similarly, the Council believes many stakeholders have a role to play in assisting PCMHs and thus recommends encouraging health agencies, health systems, and other stakeholders to support and assist medical home transformation and maintenance efforts. The Council believes that these stakeholders have a critical role to play in supporting PCMHs financially, with technical assistance, and culturally by increasing awareness of the PCMH and improving patient education.

Primary care and the PCMH are acknowledged as bedrocks of high-quality, patient-centered health care. However, in order to make the transition to a PCMH, practices of all sizes and settings must have the support to confront the challenges of practice transformation. The cultural and financial obstacles of becoming a PCMH are substantial and demand significant investment and buy-in. It is critical to not only have financial support during the initial stages of practice transformation but also to maintain ongoing funding and continuous cultural and financial support for PCMH activities.

The Council recognizes that both PCMHs and specialty care medical homes play an increasingly important role in an evolving payment and delivery system. As such, the Council will continue to monitor primary care and specialty medical homes.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 813-I-17 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-160.919 that contains principles of the Patient-Centered Medical Home (PCMH) including that payment should appropriately recognize the added value provided to patients who have a PCMH and the additional physician and team work associated with participating in a PCMH. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-385.908 urging that financial risk should be limited to costs that physicians have the ability to influence or control. (Reaffirm HOD Policy)

3. That our AMA amend Policy, H-160.918, "The Patient-Centered Medical Home," by addition and deletion as follows:

   Our AMA:
   a. will urge the Centers for Medicare and Medicaid Services (CMS) to work with our AMA and national medical specialty societies to design incentives to enhance care coordination among providers who provide medical care for patients outside the medical home;

b. will urge CMS to assist physician practices seeking to qualify for and sustain medical home status with financial and other resources; and

c. will advocate that Medicare incentive payments associated with the medical home model be paid for through system-wide savings – such as reductions in hospital admissions and readmissions (Part A), more effective use of pharmacologic therapies (Part D), and elimination of government subsidies for Medicare Advantage plans (Part C) – and not be subject to a budget neutrality offset in the Medicare physician payment schedule.~~; and~~

d. ~~will advocate that all health plans and CMS use a single standard to determine whether a physician practice qualifies to be a patient-centered medical home.~~ (Modify Current HOD Policy)

4. That our AMA advocate that all payers support and assist PCMH transformation and maintenance efforts at levels that provide a stable platform for optimized patient-centered care recognizing that payer support is crucial to the long-term sustainability of delivery reform. (New HOD Policy)

5. That our AMA encourage health agencies, health systems, and other stakeholders to support and assist patient-centered medical home transformation and maintenance efforts at levels that provide a stable platform for optimized patient-centered care. (New HOD Policy)

Fiscal Note: Less than $500

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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-18

Subject:	Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals
Presented by:	Robyn F. Chatman, MD, MPH, Chair
Referred to:	Reference Committee K (Darlyne Menscer, MD, Chair)

INTRODUCTION

Policy D-515.980, "Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals," asks:

> That our American Medical Association study recent domestic violence data and the unique issues faced by the LGBTQ population.

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases from January 2008 to June 2018 using the search terms "gay," "lesbian," "bisexual," "transgender," "queer," "LGBT," and "LGBTQ" in conjunction with the terms "intimate partner violence," "domestic violence," and "partner abuse." Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by non-profit and advocacy organizations were also reviewed for relevant information.

CURRENT AMA POLICY

AMA Policy H-160.991, "Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations," recognizes that the physician's nonjudgmental recognition of patients' sexual orientation, sexual behaviors, and gender identities enhances their ability to render optimal patient care." Furthermore, this policy states that our AMA will collaborate with partner organizations to educate physicians on how individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence (IPV), and how sexual and gender minorities present with IPV differ from their cisgender, heterosexual peers and the fact they may have unique complicating factors. The AMA will also promote crisis resources for LGBTQ patients that cater to the specific needs of LGBTQ survivors of domestic violence (D-515.980, "Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals"). AMA Policy H-515.965, "Family and Intimate Partner Violence," broadly addresses the physician's role in IPV and is not specific to patients of a certain gender or sexual orientation. The AMA encourages physicians to routinely inquire about the IPV histories of their patients and upon identifying patients experiencing abuse or threats from intimates, assess and discuss safety issues, and refer patients to appropriate medical or health care professionals and/or community-based trauma-specific resources as soon as possible.

BACKGROUND

IPV describes physical violence, sexual violence, stalking and psychological aggression (including coercive acts) by a current or former intimate partner.[1] Examples of intimate partners include current or former spouses, boyfriends or girlfriends, dating partners, or sexual partners. While IPV can occur between heterosexual or same-sex couples and does not require sexual intimacy, much of the effort to address this public health problem has focused on heterosexual women even though other populations experience IPV at similar rates.

EPIDEMIOLOGY OF IPV IN THE LGBTQ POPULATION

Little is known about the national prevalence of IPV in the LGBTQ population in the United States.[2] While a number of small-scale studies have examined violence in the LGBTQ population, the research is difficult to interpret and generalize due to the variability of methodologies utilized, which include different measures of IPV and different time frames to which the violence corresponds (i.e., past year, lifetime).[2-5] In addition, researchers have had difficulty recruiting samples that are representative of the LGBTQ population, so the majority of studies have been conducted with small convenience samples.[2-4] A further complication with the research involves the failure to distinguish between sexual activity (behavior) and sexual identity.[3] These factors have resulted in inconsistent findings in terms of victimization rates among these groups.[4,5] For example, a systematic review on IPV in self-identified lesbians found that victimization prevalence in studies ranged between 10 to 51 percent.[3]

In 2010, the Centers for Disease Control and Prevention's (CDC) National Intimate Partner and Sexual Violence Survey (NISVS), provided the first national-level data on the prevalence of intimate partner violence, sexual violence, and stalking among the lesbian, gay, and bisexual (LGB) population by self-reported sexual orientation (transgender individuals were not included in this study).[2] The pattern of results suggests that individuals who self-identify as LGB experience an equal or greater likelihood of experiencing sexual violence, stalking, and intimate partner violence compared with self-identified heterosexuals. The survey found that 61 percent of bisexual women and 44 percent of lesbian women reported experiencing rape, physical violence, and/or stalking within the context of an intimate partner relationship at least once during their lifetime versus 35 percent of heterosexual women.[2] For men, the lifetime prevalence of intimate partner violence was 37 percent for bisexual men, 29 percent for heterosexual men, and 26 percent for gay men.[2]

Limited data is available regarding IPV in transgender and genderqueer people as researchers tend to offer only binary gender identify categories. However, the available evidence suggests these populations are even more vulnerable to LGBTQ-specific IPV tactics.[4] Findings of lifetime IPV among people who are transgender range from 31 percent to 50 percent.[6] One study directly compared the lifetime prevalence of IPV among transgender and cisgender people and found that 31 percent of transgender people and 20 percent of cisgender people had ever experienced IPV or dating violence.[7]

DISCUSSION

Risk Factors

A number of factors can put LGBTQ individuals at increased risk for IPV victimization and perpetration and many of these risk factors are similar to those among heterosexual individuals. Risk factors for IPV victimization include:

racial minority status, lower socioeconomic status, younger age, deaf or hard of hearing, substance use/abuse/dependence, low self-esteem, risky sexual behavior, victim blaming attitudes, lack of power in relationships, attachment anxiety, HIV positive status, child abuse, witnessing IPV as a child, victimization in peer networks, psychological and physical health problems, history of sex work, and history of incarceration.[5]

Risk factors for IPV perpetration include:

interpersonal problems, greater conformity to masculine norms, less secure attachments, greater psychological distress, more substance use/abuse/dependency, high need for control, low socioeconomic status, less education, racial minority status, low self-esteem, more stress, HIV positive status, unprotected sexual intercourse, child abuse, exposure to IPV as a child, disordered personality characteristics, and poor relationship quality.[5]

Identity Abuse Tactics

While some research on the abusive partners' use of physical and psychological abuse may be generalizable across communities, unique aspects to LGBTQ relationships are believed to exist. This includes identity abuse (IA), which are abuse tactics that leverage systematic oppression to harm an individual.[8] IA tactics of IPV leverage heterosexism and cissexism against LGBTQ survivors.[8] These tactics including threatening to disclose a partner's LGBTQ status without their consent. This can result in fear of loss of children, employment, housing, or relationships with family and friends.[4] Another IA tactic includes undermining, attacking, or denying a partner's identity as an LGBTQ person.[8] Examples include accusing a partner of being straight, questioning their authenticity, or being prevented from expressing their gender identity. Other IA tactics include using slurs or derogatory language regarding the partner's sexual orientation or gender identity and isolating survivors from the LGBTQ community.[8,9] These tactics are also used in threatening partners who seek help.

In examining the prevalence of IA in the LGBTQ community, nearly 17 percent of the sample (n=734) of sexual minority adults reported experiencing at least one form of IA in the last year and 40 percent reported experiencing IA at some point in adulthood.[8] In terms of gender, women (43 percent) experienced significantly more exposure to IA in adulthood than men (24 percent). Transgender or gender non-confirming participants (50 percent) reported higher rates of IA in adulthood than their cisgender counterparts.[8] In terms of sexual orientation, queer-identified participants (49 percent) and bisexual participants (48 percent) had the highest rates of IA in adulthood (nearly 50 percent) compared with their lesbian (35 percent) and gay (26 percent) counterparts.[8]

Health Outcomes

IPV is associated with poor physical and mental health outcomes. For example, in a study (n=817) of men who have sex with men there was a significant relationship between a range of health problems and IPV.[10] Abused men were more likely than non-abused men to report problems such as hypertension, heart disease, obesity, smoking-related illness and, to some extent, sexually transmitted infections.[10] Men in abusive relationships were more likely to report depression or other mental health problems, and to engage in unhealthy behaviors such as substance abuse, combining drugs with sex, or unprotected sex.[10] Another study of LGBT young adults (n=172) found that being a victim of IPV was associated with concurrent sexual risk taking and prospective mental health outcomes, but was not associated with substance abuse.[11]

BARRIERS TO SEEKING HELP

Screening

The medical community has been criticized for neglecting members of the LGBTQ population in their efforts to respond to the problem of IPV.[12] However, research is lacking on the best practices for identifying LGBTQ survivors of IPV.[13] It is unclear if existing tools are relevant to LGBTQ survivors, though limited research suggests that they are and that changes in wording and additional questions could improve their relevancy.[13]

U.S. Preventive Services Task Force (USPSTF). The USPSTF recommends that clinicians screen women of childbearing age for IPV, such as domestic violence, and provide or refer women who screen positive to intervention services (B recommendation).[14] In making this recommendation, the USPSTF examined the accuracy of available screening tests, the effectiveness of early detection through trials examining interventions, the potential harms of screening and interventions, and the estimated magnitude of the net benefit. The USPSTF, in discussing clinical considerations, recognized that a significant body of evidence is lacking for other populations, especially men. It was noted that research is needed in all areas related to screening and treatment in men, as well as reporting, safety, community linkages and supports, legal ramifications, and cultural aspects.[14] The USPSTF is in the process of updating this recommendation, but the draft statement that has been posted indicates that research gaps still exist. However, the draft recommendation does not specifically note the gaps in research related to the LGBTQ population.[15]

Futures Without Violence has collaborated with a number of organizations to develop materials that are specifically for LGBTQ people. The "Caring Relationships, Healthy You" safety cards and poster are survivor-centered tools that are useful conversation starters for health care providers who are doing universal education around healthy relationships and assessing for IPV.[16]

Interventions and Services

In addition to effective screening tools, more research is needed to determine the interventions that are effective in reducing the harms of IPV in the LGBTQ population. For women of childbearing age, effective interventions include ongoing support services focused on counseling and home visits, those that address multiple risk factors (not just IPV), or include parenting support for new mothers.[15] However, IPV interventions should be culturally relevant, tailored to specific groups, and evaluated within those groups.[17]

There is limited knowledge about LGBTQ IPV in the general community and limited resources are available to support LGBTQ survivors.[9] When LGBTQ individuals attempt to access IPV services their options are often severely limited.[12] When services are provided to LGBTQ IPV survivors, the lack of cultural competency and informed support can re-traumatize the victim.[12] Gaps in services include: limited LGBTQ-friendly health care services, lack of adequate training at agencies around LGBTQ issues, limited medical access, and intake forms that are not LGBTQ friendly.[9] A 2010 study by the National Coalition of Anti-Violence Programs surveyed domestic violence agencies, sexual assault centers, prosecutors' offices, law enforcement agencies, and child victim services (n=648). The survey found that 94 percent of respondents were not serving LGBTQ survivors of IPV.[18] For example, in 2011, more than 60 percent of LGBTQ IPV survivors who sought assistance at a shelter were turned away.[19]

Similar barriers exist in seeking support from law enforcement and the justice system.[4] LGBTQ individuals are hesitant to seek law enforcement assistance and this hesitation is likely due to fear

of discrimination or harassment.[4] Furthermore, state laws may not specifically grant protections to LGBTQ survivors. For example, state statutes on protection orders that do not include LGBTQ survivors are often decided on a case-by-case basis and are at the discretion of a judge.[4]

LEGISLATION

Violence Against Women Reauthorization Act of 2013

The Violence Against Women Act (VAWA) reauthorization of 2013 attempted to address the lack of services for LGBTQ survivors by including a non-discrimination clause. This clause provided that no person in the United States shall, based on actual or perceived race, color, religion, national origin, sex, gender identity, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity funded in whole or in part with funds made available under VAWA and any other program or activity funded in whole or in part with funds appropriated by the Office on Violence Against Women.[20] While there has not been an evaluation on the impact of this clause, it is worth nothing that VAWA is up for reauthorization in 2018 and there are concerns this provision may be removed.

CONCLUSION

The lifetime prevalence of IPV in the LGBTQ community is estimated to be comparable to or higher than that among heterosexual couples. Much of the work that has been done to address the public health problem of IPV has focused on heterosexual women. There is limited information available on the aspects of IPV that are unique to same-sex relationships and the effects on LGBTQ survivors' mental and physical health. Research is also lacking on the best practices for identifying LGBTQ survivors of IPV. It is unclear if existing screening tools are relevant to LGBTQ survivors. In addition to effective screening tools, research is needed to determine the interventions that are effective in reducing the harms of IPV in the LGBTQ population. Furthermore, community resources to support LGBTQ survivors of IPV are limited. While the 2013 reauthorization of VAWA specifically provided for non-discrimination against sexual and gender minorities, the implementation and enforcement of this provision is unclear.

Despite the limited research available on this topic, physicians should be alert to the possibility of IPV among their LGBTQ patients and should familiarize themselves with resources available in their communities for LGBTQ survivors of IPV.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and the remainder of the report be filed:

1. That Policy D-515.980, "Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals" be amended by addition and deletion to read as follows:

   Our AMA will: (1) ~~study recent domestic violence data and the unique issues faced by the LGBTQ population; and (2)~~ promote crisis resources for LGBTQ patients that cater to the specific needs of LGBTQ ~~victims~~ survivors of domestic violence, (2) encourage physicians to familiarize themselves with resources available in their communities for LGBTQ survivors of intimate partner violence, and (3) advocate for federal funding to support programs and services for survivors of intimate partner violence that do not discriminate against underserved

communities, including on the basis of sexual orientation and gender identity. (Modify Current HOD policy)

2. Our AMA encourages research on intimate partner violence in the LGBTQ community to include studies on the prevalence, the accuracy of screening tools, effectiveness of early detection and interventions, as well as the benefits and harms of screening. (New HOD Policy)

3. That Policy H-160.991, "Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations," be reaffirmed.

Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors. (Reaffirm HOD Policy)

Fiscal Note: Less than $1,000

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REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-18)
FDA Expedited Review Programs and Processes
(Resolution 201-I-17)
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. To examine expedited FDA drug approval programs or processes in place in the United States, including so-called fast track, accelerated approval, designated breakthrough therapies, and "priority review" for drugs and biologics, and whether the operation of such programs needs to be re-examined or modified.

Methods. English-language reports were selected from a PubMed and Google Scholar search from 1992 to August 2018, using the MeSh terms "*biomarkers," "*surrogate end points," "drug approval/*methods/*statistical outcomes/*legislation & jurisprudence, *validation," " United States Food and Drug Administration," product surveillance/*postmarketing" and "government regulation," combined with the text terms "clinical trials," "treatment outcome," "accelerated approval," "breakthrough therapy," "priority review," and "fast track." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA).

Results. Different programs have been put in place over the last 25 years by the FDA and Congress to expedite the review of promising new therapies and to approve drugs for initial marketing based on lower evidentiary standards, including the use of surrogate markers. The use of surrogate endpoints has assumed increasing importance as approximately 40% of pivotal clinical trials for drug approvals or new indications rely on them. More than 60% of fast track approvals are now characterized as specialty drugs. Priority review processes have been successful in reducing the average application review time. One overarching theme is the strength of evidence relied on by the FDA to support marketing of new drugs. While various analyses have been conducted over different time frames examining the impact of expedited review programs on drug safety and efficacy, the most comprehensive review found that, for the most part, the use of surrogate endpoints has been successful, and the majority of sponsors have approached the conduct of confirmatory studies in a timely manner, although some failures do exist.

Conclusion. Over the years, the FDA has implemented various approaches to expedite the review and approval of new drug and biologic applications, as well as new indications for existing products. Accelerated approval, fast track, prior review, and breakthrough therapy designations have been developed, but these expedited programs differ and should not be lumped together from a scientific, public health, or policy point of view. Key variables include the requirement for post-approval studies for drugs marketed under accelerated approval, whether a surrogate endpoint that has not been validated is used to support approval, and the need to confirm clinical benefit and the risk-benefit profile for drugs approved based on limited evidence, regardless of their review designation. While it is important for the agency to retain regulatory flexibility, and many positive aspects of expedited programs are apparent, some changes should be made to improve implementation, establish the value of surrogate endpoints, and provide more transparency for clinicians and their patients.

REPORT OF COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-18

Subject: FDA Expedited Review Programs and Processes (Resolution 201-I-17)

Presented by: Robyn F. Chatman, MD, MPH, Chair

Referred to: Reference Committee K (Darlyne Menscer, MD, Chair)

INTRODUCTION

Resolution 201-I-17, "Improving FDA Expedited Approval Pathways," introduced by the Resident and Fellow Section and referred by the House of Delegates asked:

> That our American Medical Association work with U.S. Food and Drug Administration (FDA) and other interested stakeholders to design and implement via legislative action (including ensuring appropriate FDA staffing) a process by which drugs which obtain FDA approval via the Fast Track, Accelerated Approval, or Breakthrough Therapy pathways be granted FDA approval on a temporary basis not to exceed 5 years, pending further evidence of safety and efficacy that is at the level set for the standard drug approval process; and,
>
> That our AMA work with the FDA and other interested stakeholders in improving the process by which drugs are selected for the expedited pathway to improve the prevalence of these drugs that are classified as "specialty drugs."

This report examines expedited FDA drug approval processes in place in the United States, including so-called fast track, accelerated approval, designated breakthrough therapies, and "priority review" for drugs and biologics. Such programs are "intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions" (especially when no satisfactory alternative therapies exist), and "be available to patients as soon as it can be concluded that the therapies' benefits justify the risks."[1-3] Accordingly, under the current regulatory structure for approval of new chemical entities or new indications (efficacy supplements), the specific drug development program, including eligibility for expedited programs, is determined by the seriousness and prevalence of the disease, availability of existing treatments, and evidence that the drug can offer significant improvement compared with available therapies.

Two specific topics, one referred to in the resolution (specialty drugs) and the other which also impacts the FDA's review of new drug applications (user fees) are not specifically evaluated in this report. The FDA does not define "specialty drugs" nor is it a term found in regulations or statute. The term specialty drug is generally used for complex, high-cost medications; they are often derived from a living source, characterizing them as biologics. Historically, they have been used to treat serious, chronic conditions such as rare diseases, cancer, rheumatoid arthritis, and multiple sclerosis. In recent years, specialty drugs have targeted more common conditions such as high cholesterol, asthma and hepatitis C, significantly increasing the potential pool of patients that

receive them. Specialty drugs are not stocked at most pharmacies, are often injectable medications, and may have unique storage or shipment requirements, such as refrigeration. These medications usually require additional patient education and support beyond traditional dispensing and counseling activities to maintain adherence and ensure patient safety. The growth in specialty drugs has been exponential. In the past four years nearly 100 new specialty drugs were launched, and in the same time there were 80 supplemental approvals establishing new indications for existing products.[4] Based on the number and high degree of success in getting such drugs approved, special attention to these types of drugs, with respect to drug development, is not warranted. Concerns also have been expressed that the high cost of many specialty drugs is not justified when compared with their clinical benefits. Cost is a variable that is not under the purview of the FDA.

The Prescription Drug User Fee Act (PDUFA), first enacted in 1992, established the current framework by which pharmaceutical manufacturers help fund the FDA by submitting a fee along with their application. Monies derived from so-called "user fees" have been used to expand FDA staffing dedicated to the review of new drug (NDA) and biological license applications (BLA) and efficacy supplements (sNDA); the latter are submitted when sponsors seek approval to add a new indication to prescription drug labeling. A comparable user fee process also is now in place for abbreviated new drug applications (ANDA) that govern generic drug approval. Because user fees support FDA drug reviews in general, and are not an expedited program or process *per se*, the impact of PDUFA review times on drug safety and patient benefits is not further evaluated in this report.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from 1992 to August 2018, using the MeSh terms "*biomarkers," "*surrogate end points," "drug approval/*methods/*statistical outcomes/*legislation & jurisprudence, *validation," " United States Food and Drug Administration," product surveillance/*postmarketing" and "government regulation," combined with the text terms "clinical trials," "treatment outcome," "accelerated approval," "breakthrough therapy," "priority review," and "fast track." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet site of the US Food and Drug Administration (FDA).

CURRENT AMA POLICY

AMA Policy H-100.992, "FDA," supports the concept that an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports *as provided by statute.* The statute regarding evidentiary standards for drug approval was modified in 1997 permitting FDA to approve a drug product "upon determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit." The evidence should be evaluated by the agency in consultation with its Advisory Committees and expert extramural advisory bodies, and any risk-benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.

Policy D-100.978, "FDA Drug Safety Policies," directs the AMA to monitor and respond, as appropriate, to implementation of the drug safety provisions of the FDA Amendments Act of 2007 (FDAAA; P.L. 110-85). This directive was related primarily to the fact that FDA authorities around Risk Evaluation and Mitigation Strategies were strengthened by the 2007 law.

DESCRIPTION OF EXPEDITED DRUG AND BIOLOGIC APPROVAL PROCESSES

Regular approval was the only FDA approval pathway until 1992. Largely in response to the HIV/AIDS epidemic in the mid-late 1980s, the FDA institutionalized approaches by which certain drugs, including antiretroviral products at the time, could be initially approved based on less rigorous data, including the use of surrogate endpoints.

Accelerated Approval

Conceptualized in the 1980s, initially implemented in 1992 and further refined in 2012, the accelerated approval pathway for drugs and biologics is described in 21CFR parts 314 (subpart H) and 602 (subpart E) and contained in Section 506(c) of the Food Drug and Cosmetic (FD&C) Act.[5-7] It has been primarily used in settings where the course of the disease is long and an extended period would be required to measure the intended clinical benefit (e.g., decreased mortality from HIV infection, increased overall survival from cancer). Qualifying criteria are a drug that treats a serious condition, generally provides a meaningful advantage over available therapies and demonstrates an effect on a "surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality." Furthermore, the surrogate endpoint is *reasonably likely* to predict an effect on "some other clinical benefit (i.e., an intermediate clinical endpoint), considering the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments." The accelerated approval designation requires post-approval testing to verify efficacy and confirm the anticipated risk-benefit profile. From 2000 to 2103, 37 new drugs were granted accelerated approval, or about 10% of new molecular entities (NMEs).[8]

A drug marketed under accelerated approval can be subject to expedited withdrawal if the surrogate endpoint(s) turns out to be faulty. The FDA maintains a list of drugs that have been withdrawn due to safety concerns or lack of efficacy.[9] Many of these products predate 1992. Since 1992 about 25 drugs have been withdrawn from the market, most of which had gone through regular approval. A limited number of drugs marketed under accelerated approval have had their approval for specific indications withdrawn (see below).

Surrogate Endpoints. A surrogate is "a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and is expected to predict the effect of the therapy."[10] Such measures are not intrinsically beneficial to patients, but are relied on to predict the benefits of treatment in the absence of data on patient-relevant final outcomes based on a "reasonably likely" standard. The use of surrogate endpoints allows for clinical trials with reduced sample size and shorter duration, thereby reducing expense and speeding patient access to new therapies. For most drugs marketed under accelerated approval, requiring the endpoint to be overall survival is not practical and may not be ethical.[11]

Approval of a drug based on a surrogate endpoint introduces uncertainty about the drug's true clinical benefit and this degree of uncertainty must be considered acceptable in order for the new drug or indication to be approved. Different scenarios exist in which a treatment may significantly affect a surrogate marker, but not the clinically significant endpoint. The strength of evidence for validating a surrogate marker is based on: (1) the biological plausibility of the relationship between the surrogate marker and patient outcomes; (2) epidemiologic evidence on the predictive value of the surrogate for the clinical outcome of interest; and (3) clinical trial level data confirming that the response of the surrogate marker to treatment corresponds to the effects of the treatment on the clinical outcome.[12] Optimally, the strength of the surrogate-survival correlation would already be

established; however, many surrogate endpoints used during the drug approval process are not validated at the time. To validate all surrogate endpoints ahead of time would require several trials to be conducted on a specific research question, essentially defeating the purpose of the accelerated approval pathway.

The Use of Surrogate Endpoints for Drug Approval. Surrogate endpoints have assumed increasing importance as approximately 40% of pivotal trials constituting the basis for approval of NMEs and/or new indications for existing drugs are based on surrogate endpoints, with a high percentage of these being for oncology drugs.[12,13]

Several studies have been published examining the use of surrogate endpoints and accelerated approval of oncology drugs over the past 25 years.[14-16] Two snapshots covered the periods from 1994-2004 and 2004-2011, with a few others covering different time periods.[16,17] A comprehensive review of oncology drugs approved as NMEs and for new indications via accelerated approval (n=93) was recently published covering the period from the inception of the program (1992) through May 2017 and is the focus of the following discussion.[16]

Twenty-eight percent of accelerated approvals were supported by randomized controlled trials (RCTs), with single arm trials accounting for the remainder; the median patient population for determining efficacy was 143. Seven RCTs used time to progression as the end point and four used disease-free survival; the remainder of both RCTs and single arm trials (87%) used response rate (i.e., tumor burden) as the endpoint. Approximately 55% of the approvals have fulfilled their post-marketing requirements and verified benefit in a median 3.4 years after approval, based on measurement of progression-free survival or time to progression (i.e., disease control) (39%), overall survival (29%), response rate (26%) or disease-free recurrence or progression (6%). Most of the success stories had ongoing confirmatory trials planned and underway at the time of accelerated approval. Forty percent of accelerated approvals are still in the process of completing confirmatory trials and verifying clinical benefit; FDA approval was subsequently withdrawn for five new indications. Most of the unfulfilled commitments represent recent approvals (median time on the market = 18 months), although some outliers exist; eight of such products have been on the market for more than 5 years, mostly in rare patient populations. While one criticism of the accelerated approval pathway is the smaller sample size, review of documentation supporting accelerated approval indicates that the safety database is usually larger, about double the efficacy database.[16] The safety database includes patients "treated with the drug regardless of age, condition, or volunteer status."[16] If the accelerated approval is for a new indication of an already-approved drug then more expansive safety information and postmarketing data are already available. Only one cancer drug approved under accelerated approval has been withdrawn from the market because of both efficacy and safety issues (gemtuzumab ozogamicin), and this drug was later reapproved for a narrower population.[19]

Several trial-level analyses have "quantified the association between surrogate endpoints and overall survival, with one study finding that nearly 50% of meta-analyses reported correlation between surrogate outcomes and overall survival exceeding 0.7. On average surrogate endpoints are positively correlated with survival."[20]

Fast Track Designation

The current fast track designation is defined in section 506(b) of the FD&C, as amended by the 1997 Food and Drug Modernization Act (section 112) and 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) (section 109). This designation was designed to facilitate the development, and expedite the review of drugs to *treat serious conditions and fill an unmet*

medical need. Some critics maintain that the term "unmet medical need" has been overused and is too imprecise.[21] This pathway also is available for drugs that have been designated as a qualified infectious disease product. Fast track allows for approval based on preliminary evidence such as Phase 2 clinical studies (rarely Phase 1). A request for fast track designation can be filed with the investigational new drug application (IND) or after, but ideally before the pre-NDA or BLA meeting; the timeline for an FDA decision is within 60 calendar days of receipt of the request.

Actions to expedite development and review include more frequent interactions with the review team to discuss, in part, study design, the extent of safety data required to support approval, dose-response concerns and use of biomarkers, and a "rolling review" where parts of the application can be acted on when they are ready, in sequence. Drugs with fast track designation also could be eligible for *priority review* (see below) if such a request is supported by sufficient data when the NDA, BLA, or efficacy supplement submission is submitted. Fast track designations can be rescinded if qualifying criteria are not met.

From 2000 to 2013, the FDA approved 82 drugs under the fast track designation, or approximately 22% of the NME's approved during the same time period.[8] More than 60% of the fast track approvals were characterized as specialty drugs by the authors of this study.

Breakthrough Therapy

Described in Section 506(a) of the FD&C Act, the breakthrough therapy designation was created by the 2012 FDASIA to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy. Qualifying criteria are that a drug is intended to treat a *serious condition* and *preliminary clinical evidence* indicates that the drug may demonstrate "substantial improvement on a clinically significant endpoint over available therapies." The timeline for FDA response is the same as fast track and priority designations. In contrast to the fast track designation which could include theoretical or non-clinical data, a breakthrough designation requires clinical evidence which is sufficient to demonstrate substantial improvement in safety or effectiveness over available therapies, but additional evidence is still required for final approval. Determining if the "substantial improvement" criterion is met is a matter of judgement, and the evidence that is relied on for approval of drugs with this designation is heterogenous.[22] This designation triggers intensive guidance on the drug development program beginning as early as Phase 1, FDA commitment involving senior FDA managers, a rolling review of the application and eligibility for *priority review* designation.

Priority Review

This process was established by the 1992 PDUFA to improve the efficiency of NDA reviews for NMEs. A priority review designation can be assigned to applications for drugs "that treat *serious conditions* and provide *significant improvements* in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions *compared to available therapies*."[3] A priority review designation is assigned at the time of the NDA, BLA or efficacy supplement filing. Priority review can be granted to applications for drugs with fast track or breakthrough therapy designation, or to applications submitted for review under accelerated approval. That decision is based on the information and data available at the time the application is submitted."[1]

The timeline for FDA response is the same as fast track designations with a shorter timeframe for reviewing the application versus standard review cycles (6 months compared with the 10-month target for the latter). From FY 2007 through FY 2016, the (average) median time to application approval was 11.4 months for standard review compared with 7.9 months for priority review.[23]

CLINICAL TRIAL EVIDENCE AND EXPEDITED REVIEW PROGRAMS

A Perspective on New Drug Safety-Related Issues

One study conducted on postmarket safety outcomes for all NMEs (n=278) approved from 2002-2014 demonstrated that safety updates to the product labeling were the rule rather than the exception.[24] At least one safety update was added to 195 (70.1%) of the products, most commonly between the 2nd and 8th year after marketing. Safety information was added earlier after marketing for drugs approved with a fast-track designation or under an accelerated approval using a surrogate end point; safety issues also were more likely to arise for drugs with a fast track designation.

Evidentiary Standards

Another perspective on drugs approved via expedited reviews is to examine the strength of evidence accompanying market approvals, which clearly has important implications for patients, physicians, and payers. Concern has been expressed about the potential lack of systematic monitoring for confirmation of effectiveness for drugs that have been approved based on limited evidence, compared with standard approvals.[25]

One recent review of cancer drugs approved from 2006-2016 found that when RCTs were lacking, approved indications were more likely to be based on accelerated approval, receive a breakthrough designation or have a companion diagnostic test. Indications not supported by RCTs had higher odds of post approval safety changes, but not major modifications in indications and dosage, warnings and precautions, boxed warnings, or contraindication sections of the labeling.[26]

Analysis of all drugs approved by the FDA from 2005-2012 revealed that most indications were supported by at least 1 RCT, although more than one-third of indications were approved based on a single pivotal efficacy trial. Substantial variation existed in terms of the comparators and end points, trial duration, number of participants, and completion rates.[12] Surrogate endpoints served as the primary outcome for 91 of 206 (44%) of the approved indications.

From 2005-2014, 295 supplemental NDAs for new indications were submitted. Thirty percent of these were supported by efficacy trials with an active comparator and 32% used a clinical endpoint. Among those expanding the patient population (almost all pediatric), only 11% used an active comparator, with 22% using a clinical endpoint.[27]

DISCUSSION

Over the years, the FDA has implemented various approaches to expedite the review and approval of new drug and biologic applications, as well as new indications for existing products. Under the current regulatory structure, the specific drug development program, including eligibility for expedited programs, is determined by the seriousness and prevalence (or rarity) of the disease, availability of existing treatments, and evidence that the new drug can offer significant improvement compared with available therapies and/or otherwise address an unmet medical need. Accelerated approval, fast track, priority review, and breakthrough therapy designations have been developed to consider and address these variables. These expedited programs differ and should not be lumped together from a scientific, public health, or policy point of view. Key variables include the requirement for post-approval studies for drugs marketed under accelerated approval, whether a surrogate endpoint that has not been validated is used to support approval, and the need to confirm clinical benefit and the risk-benefit profile for drugs approved based on limited evidence, regardless of their review designation.

It has been argued that the process of approving medications based on more limited evidence, including fewer patients and patient years of exposure, makes the process of reducing healthcare disparities costlier.[28] Earlier drug approval reduces the power of studies to detect difference in risk and benefit in relevant subgroups and could direct the burden of medical uncertainty toward groups of people who are often disadvantaged. It may be advisable for the FDA to encourage that confirmatory trials enable appropriate sub-group analyses that were not possible during initial, lower-powered studies. Accelerating drug approval shifts the burdens of uncertainty away from clinical trial participants (who have undergone informed consent) to others who are exposed to the treatment under different conditions, socializing the costs of uncertainty while pharmaceutical companies profit from new drug development. The relevant question is "whether earlier access to drugs, driven by changes in regulatory policy or growing reliance on surrogate endpoints, benefits or harms patients."[29]

Confirmatory studies are needed for drugs approved based on limited evidence to avoid exposing patients to potentially unsafe or ineffective therapies. Even the use of uncertain surrogate endpoints is not problematic if confirmatory studies reliably demonstrate meaningful clinical endpoints. A report from the Government Accountability Office, in referring to the FDA's activities in this area, concluded that "the agency needs to clarify the conditions under which it would use its authority to expedite the withdrawal of drugs granted accelerate approval," when confirmatory studies are not conducted in a timely manner or fail to confirm predicted benefits.[30]

Over the past 15 years, most accelerated approvals were for oncologic drugs, and that experience is instructive. The accelerated approval of bevacizumab for breast cancer has been held up as a prime example of harm, because it was approved based on the endpoint of progression-free survival, but eventually this drug was shown to not increase overall survival.[19] However, "clear and convincing evidence" has emerged from phase 2 (and some phase 1) trials leading to marketing approval of new chemical entities within 2-3 years accounting for "advances in treatment for molecular subsets of non-small cell lung cancer, melanoma, chronic leukemia, breast cancer, and acute myeloid leukemia," among others.[19]

Although critics have condemned a lack of "improved survival" as the optimal endpoint for clinical trials, there has been a "steady improvement in U.S. cancer mortality and survival over the past 2 decades."[19] in part because of new treatments, but also better screening and early detection. Nevertheless, more than half of oncologic drugs marketed under accelerated approvals relied on a surrogate endpoint that was chosen in the absence of any formal analysis of the strength of the surrogate-survival connection.[31] This observation reinforces the need for timely determination of the predicted clinical benefit and confirmation of the risk-benefit profile.

Comprehensive evaluation of oncologic drugs marketed under accelerated approval confirms that satisfactory progress has been made on confirmatory trials. By balancing risk, accounting for uncertainty, and operating under a paradigm of regulatory flexibility, existing FDA expedited pathways can ensure early access to, and appropriate use of new drugs and biologics, including specialty drugs. The Institute of Medicine recommended that the FDA should "implement a benefit and risk assessment and management plan that would summarize the FDA's evaluation of drug's risk-benefit profile in a single document and that would be continuously updated" during the life-cycle of the drug on the market.[32,33] While it is important for the agency to retain regulatory flexibility, and mostly positive aspects of expedited programs are apparent, some changes should be made to improve implementation, establish the value of surrogate endpoints, and provide more transparency for physicians and their patients on the level of evidence used for marketing approval.

RECOMMENDATION

The Council on Science and Public Health recommends that Policy H-100.992 be amended by addition and deletion to read as follows in lieu of Res-201-I-17, and the remainder of the report be filed:

(1) Our AMA ~~reaffirms its~~ supports ~~for~~ the principles that:

(a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute;
(b) the~~is~~ evidence for drug approval should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies;
(c) expedited programs for drug approval serve the public interest as long as sponsors for drugs that are approved based on surrogate endpoints or limited evidence conduct confirmatory trials in a timely fashion to establish the expected clinical benefit and predicted risk-benefit profile;
(d) confirmatory trials for drugs approved under expedited programs should be planned and underway at the time of expedited approval;
(e) the FDA should pursue having in place a systematic process to ensure that sponsors adhere to their obligations for confirmatory trials, and Congress should establish a firmer threshold to trigger expedited withdrawal when sponsors fail to fulfill their postmarketing study obligations;
(~~d~~ f) any risk-benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications; and,
(g) FDA should consider a simple system to assign a grade for each approval of prescription drugs occurring via expedited programs in order to signal, and provide in a transparent manner, the quality of clinical trial evidence used to establish safety and effectiveness, and whether confirmatory trials are required for labeled indications.

(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.

(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

Fiscal Note: Less than $500

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REPORT OF THE HOUSE OF DELEGATES COMMITTEE
ON THE COMPENSATION OF THE OFFICERS

Comp. Comte. Report I-18

Subject: Report of the House of Delegates Committee on Compensation of the Officers

Presented by: Marta J. Van Beek, MD, Chair

Referred to: Reference Committee F
(Greg Tarasidis, MD, Chair)

This report by the Committee at the 2018 Interim Meeting presents one recommendation. It also documents the compensation paid to Officers for the period July 1, 2017 thru June 30, 2018 and includes the 2017 calendar year IRS reported taxable value of benefits, perquisites, services, and in-kind payments for all Officers.

BACKGROUND

At the 1998 Interim Meeting, the House of Delegates (HOD) established a House Committee on Trustee Compensation, currently named the Committee on Compensation of the Officers, (the "Committee"). The Officers are defined in the American Medical Association's (AMA) Constitution and Bylaws. (Note: under changes to the Constitution previously approved by the HOD, Article V refers simply to "Officer," which includes all 21 members of the Board among whom are President, President-Elect, Immediate Past President, Secretary, Speaker of the HOD and Vice Speaker of the HOD, collectively referred to in this report as Officers.) The composition, appointment, tenure, vacancy process and reporting requirements for the Committee are covered under the AMA Bylaws. Bylaws 2.13.4.5 provides:

> The Committee shall present an annual report to the House of Delegates recommending the level of total compensation for the Officers for the following year. The recommendations of the report may be adopted, not adopted or referred back to the Committee, and may be amended for clarification only with the concurrence of the Committee.

At A-00, the Committee and the Board jointly adopted the American Compensation Association's definition of total compensation which was added to the Glossary of the AMA Constitution and Bylaws. Total compensation is defined as the complete reward/recognition package awarded to an individual for work performance including: (a) all forms of money or cash compensation; (b) benefits; (c) perquisites; (d) services; and (e) in-kind payments.

Since the inception of this Committee, its reports document the process the Committee follows to ensure that current or recommended Officer compensation is based on sound, fair, cost-effective compensation practices as derived from research and use of independent external consultants, expert in Board compensation. Reports beginning in December 2002 documented the principles the Committee followed in creating its recommendations for Officer compensation.

At A-08, the HOD approved changes that simplified compensation practices with increased transparency and consistency. At A-10, Reference Committee F requested that this Committee

recommend that the HOD affirm a codification of the current compensation principle, which occurred at I-10. At that time, the HOD affirmed that this Committee has and will continue to base its recommendations for Officer compensation on the principle of the value of the work performed, consistent with IRS guidance and best practices as recommended by the Committee's external independent consultant, who is expert in Board compensation.

At A-11, the HOD approved the alignment of Medical Student and Resident Officer compensation with that of all other Officers (excluding Presidents and Chair) because these positions perform comparable work.

Immediately following A-11, the Committee retained Mr. Don Delves, founder of the Delves Group, to update his 2007 research by providing the Committee with comprehensive advice and counsel on Officer compensation. The updated compensation structure was presented and approved by the HOD at I-11 with an effective date of July 1, 2012.

The Committee's I-13 report recommended and the HOD approved the Committee's recommendation to provide a travel allowance for each President to be used for upgrades because of the significant volume of travel in representing our AMA.

At I-16, based on results of a comprehensive compensation review conducted by Ms. Becky Glantz Huddleston, an expert in Board Compensation with Willis Towers Watson, the Committee recommended and the HOD approved modest increases to the Governance Honorarium and Per Diems for Officer Compensation, excluding the Presidents and Chair, effective July 1, 2017. A-17's report, approved by the HOD, modified the Governance Honorarium and Per Diem definition so that Internal Representation, in excess of eleven days, receives a per diem.

At A-18, based on a compensation review focused on the Presidents' and Chairs' compensation, the Committee recommended and the House approved a modest increase to their Honoraria, the first increase in ten years.

CASH COMPENSATION SUMMARY

The cash compensation of the Officers shown in the following table will not be the same as compensation reported annually on the AMA's IRS Form 990 because Form 990s are based on a calendar year. The total cash compensation in the summary is compensation for the days these Officers spent away from home on AMA business approved by the Board Chair. The total cash compensation in the summary includes work as defined by the Governance Honorarium and Per Diem for Representation including conference calls with groups outside of the AMA, totaling 2 hours or more per calendar day as approved by the Board Chair. Detailed definitions are in the Appendix.

The summary covers July 1, 2017 to June 30, 2018

AMA Officers	Position	Total Compensation	Total Days
Maya A Babu, MD, MBA	Resident Officer	$ 5,400	0
Susan R Bailey, MD	Speaker, House of Delegates	$ 96,850	50.5
David O Barbe, MD, MHA	President	$ 279,000	161
Willarda V Edwards, MD, MBA	Officer	$ 67,600	48
Jesse M Ehrenfeld, MD, MPH	Secretary & Young Physician Officer	$ 131,650	90
E Scott Ferguson, MD	Officer	$ -	2.5
Sandra A Fryhofer, MD	Officer	$ -	4
Andrew W Gurman, MD	Immediate Past President	$ 274,000	98
Gerald E Harmon, MD	Chair	$ 269,500	91.5
Patrice A Harris, MD, MA	Immediate Past Chair	$ 150,600	120.5
William E Kobler, MD	Officer	$ 92,950	63
Russell WH Kridel, MD	Officer	$ 70,200	47
Barbara L McAneny, MD	President-Elect	$ 274,000	135
William A McDade, MD, PhD	Officer	$ 74,100	60
Mario E Motta, MD	Officer	$ -	2
S Bobby Mukkamala, MD	Officer	$ 65,000	43.5
Albert J Osbahr, III, MD	Officer	$ 78,000	54.5
Stephen R Permut, MD, JD	Officer	$ 89,050	68
Jack Resneck, Jr, MD	Chair-Elect	$ 199,500	94.5
Ryan J Ribeira, MD, MPH	Resident Officer	$ 66,300	39
Karthik V Sarma, MS	Medical Student Officer	$ 102,050	85.5
Bruce A Scott, MD	Vice Speaker, House of Delegates	$ 78,650	55.5
Carl A Sirio, MD	Officer	$ 106,600	78.5
Georgia A Tuttle, MD	Officer	$ 85,800	60.5
Kevin W Williams, MSA	Public Board Member Officer	$ 65,000	43.5

President, President-Elect, Immediate Past President and Chair
In 2017-2018, each of these positions received an annual Governance Honorarium which was paid in monthly increments. These four positions spent a total of 485.5 days on approved Assignment and Travel, or 121.4 days each on average.

Chair-Elect
This position received a Governance Honorarium of approximately 75% of the Governance Honorarium provided to the Chair.

All other Officers
All other Officers received cash compensation, which included a Governance Honorarium of $65,000 paid in monthly installments. The remaining cash compensation is for Assignment and Travel Days that are approved by the Board Chair to externally represent the AMA. These days were compensated at a per diem rate of $1,300.

Assignment and Travel Days
The total Assignment and Travel Days for all Officers (excluding the President, President-Elect, Immediate Past President and Chair) were 1110.5; this includes reimbursement for telephonic representation meetings for external organizations that are 30 minutes or longer during a calendar day and total 2 or more hours. These are reimbursed at ½ of the current per diem rate. During this reporting period, there were 18 reimbursed calls, representing 9 per diem days.

EXPENSES

Total expenses paid for the period, July 1, 2017 – June 30, 2018, $798,212 compared to $844,506 for the previous period, representing a 5.5% decrease. This includes $1,907 in upgrades for Presidents' travel per the approved Presidential Upgrade Allowance of $2,500 per position per term.

BENEFITS, PERQUISITES, SERVICES AND IN-KIND PAYMENTS

Officers are able to request benefits, perquisites, services and in-kind payments, as defined in the "AMA Board of Trustees Standing Rules on Travel and Expenses." These non-taxable business expense items are provided to assist the Officers in performing their duties:

- AMA Standard laptop computer or iPad
- iPhone
- American Express card (for AMA business use)
- Combination fax/printer/scanner
- An annual membership to the airline club of choice offered each year during the Board member's tenure
- Personalized AMA stationery, business cards and biographical data for official use.

Additionally, all Officers are eligible for $305,000 term life insurance and are covered under the AMA's $500,000 travel accident policy and $10,000 individual policy for medical costs arising out of any accident while traveling on official business for the AMA. Life insurance premiums paid by the AMA are reported as taxable income. Also, travel assistance is available to all Officers when traveling more than 100 miles from home or internationally.

Secretarial support, other than that provided by AMA's Board office, is available up to defined annual limits as follows: President, during the Presidential year, $15,000; $5,000 each for the President-Elect, Chair, Chair-Elect and Immediate Past president per year. Secretarial expenses incurred by other Officers in connection with their official duties are paid up to $750 per year per Officer. This is reported as taxable income.

Travel expenses incurred by family members are <u>not</u> reimbursable, except for the family of the incoming President at the Annual Meeting of the HOD.

Calendar year taxable life insurance and taxable secretarial fees reported to the IRS totaled $28,791 and $28,750 respectively for 2017. An additional $5,750 was paid to third parties for secretarial services during 2017.

METHODOLOGY

Periodically, the issue of health insurance for the Presidents has been brought to this Committee's attention. Specifically, what our AMA can do to assist our President(s) when replacement health insurance is needed because he/she loses health insurance coverage at his/her practice, university or hospital (collectively referred to as "Employer") when they reduce their work schedule to fulfill their responsibilities as President, President-Elect or Immediate Past President. While this has occurred infrequently, the Committee wanted our AMA to be prepared going forward. In researching possible solutions, the Committee's objective was to arrive at a solution that was fiscally responsible to the AMA, require the President to have some responsibility for the premium

cost and provide flexibility to address each President's health insurance needs based on his/her family demographics. An annual stipend to assist the President(s) seemed to meet this goal.

To determine the amount of the stipend, premiums were obtained from the Health Insurance Marketplace ("Exchange") established under the Patient Protection and Affordable Care Act of 2010 to obtain the specific amounts of 2018 premiums. The Committee reviewed the Plan designs offered on the Exchange and determined that the Gold Plan would be the basis for the stipend. The Gold Plan's actuarial value is that the plan covers 80% of expenses. Gold Plan design can vary by state but the actuarial equivalent of the design must be to cover 80% of expenses. In addition, insurance carriers, plan availability, premium amounts and the scope of the network varies state to state down to county level within a state. Premiums are individually determined based on the home zip code of the family and the demographics of each covered family member.

Demographics of the full Board were used to obtain a broader cross-section of Gold Plan premiums across the country. Board members who qualify for Medicare were excluded from the analysis and would not be eligible for a stipend. With the assistance of AMA's external employee benefits broker, premiums were anonymously obtained based on each Board member's state of residence, and demographics.

The range of the premiums was significant which demonstrated the need for a "customized" stipend. The Committee determined that the stipend would reflect a "cost-sharing" of the premium for the President and covered family members. Premiums would also change annually. Medicare-eligible President(s) would not be eligible to receive a stipend.

President(s) who lose his/her employer insurance would substantiate his/her eligibility for an annual stipend by written notice to the Board Chair detailing the effective date of the loss and listing covered family members. The amount of the stipend will be reported as taxable income for the President each calendar year and will be included in this Committee's annual report to the House, which documents compensation paid to Officers and the IRS reported taxable value of benefits, perquisites, services and in-kind payments.

FINDINGS

The Committee notes that the President-Elect, President and Immediate Past President responsibilities require a significant time commitment in supporting our AMA in governance and representation functions. Our A-18 report noted that this level of responsibility results in a time commitment well above that required by other not-for-profit boards. The level of commitment needed in supporting our AMA may necessitate a President reduce his/her work schedule with his/her employer to a part-time status which may result in a President losing his/her eligibility for employer's health insurance coverage.

This Committee considers health insurance a necessity. As such, this Committee recommends that Presidents who are not Medicare-eligible receive a stipend based on 70% of the then current Gold Plan premium for the President and his/her covered family members once the President provides written notice to the Board Chair about the loss of coverage. The stipend would be reported as taxable income to the President(s).

RECOMMENDATIONS

The Committee on Compensation of the Officers recommends the following recommendations be adopted and the remainder of this report be filed:

1. That there be no change to the current Definitions effective July 1, 2018 as they appear in the Travel and Expenses Standing Rules for AMA Officers for the Governance Honorarium, Per Diem for External Representation and Telephonic Per Diem for External Representation.

2. Annual Health Insurance Stipend (Stipend)
   The purpose of this payment is to provide a Health Insurance Stipend (Stipend) to compensate the President, President-Elect and Immediate Past President under age 65, when the President(s) loses his/her employer-provided medical insurance coverage during his/her term. President(s) who lose his/her employer insurance will substantiate his/her eligibility for the Stipend by written notice to the Board Chair detailing the effective date of the loss of coverage and listing covered family members. The President receiving the Stipend will have the sole discretion to determine the appropriate health insurance coverage for the himself/herself and the family, and provide proof of purchasing such coverage to the Board Chair.

   The amount of the Stipend will be 70% of the then current Gold Plan premium in the President(s) state/county of residence for each covered family member. If there are multiple Gold Plans in the state/county, the Stipend will be based on the average of the then current Gold Plan premiums. The amount of the Stipend will be updated January 1 of each Plan year based on then Gold Plan premiums and covered family members. Should a President reach age 65 during his/her term(s), the Stipend will end the month Medicare coverage begins. In all cases the Stipend will end the sooner the President(s) obtains other health insurance coverage, reaches age 65 or the month following the end of his/her term as Immediate Past President. The Stipend will be paid monthly. The amount of the Stipend will be reported as taxable income for the President each calendar year and will be included in this Committee's annual report to the House which documents compensation paid to Officers and the IRS reported taxable value of benefits, perquisites, services and in-kind payments.

3. Except as noted above, there will be no other changes to the Officers' compensation for the period beginning January 1, 2019. (Directive to Take Action)

Fiscal Note: The maximum annual stipend is estimated at $87,000. This is based on 70% of the highest 2018 Gold Plan Premium based on current Board demographics and assumes all three Presidents and spouses/partners would receive the stipend in the same year.

APPENDIX

POSITION	GOVERNANCE HONORARIUM
President	$290,160
Immediate Past President & President-Elect	$284,960
Chair	$284,960
Chair-Elect	$280,280
Other Officers	$207,480

Definition of Governance Honorarium Effective July 1, 2017:
The purpose of this payment is to compensate Officers for all Chair-assigned internal AMA work and related travel. This payment is intended to cover all currently scheduled Board meetings, special Board or Board Committee meetings, task forces, subcommittees, Board orientation, development and media training, Board calls, sections, councils or other internal representation meetings or calls, and any associated review or preparatory work, and all travel days related to all meetings as noted up to eleven (11) Internal Representation day.

Definition of Per Diem for Representation effective July 1, 2017:

The purpose of this payment is to compensate for Board Chair-assigned representation day(s) and related travel. Representation is either external to the AMA, or for participation in a group or organization with which the AMA has a key role in creating/partnering/facilitating achievement of the respective organization goals such as the AMA Foundation, PCPI, etc. or for Internal Representation days above eleven (11). The Board Chair may also approve a per diem for special circumstances that cannot be anticipated such as weather-related travel delays. Per Diem for Chair-assigned representation and related travel is $1,300 per day.

Definition of Telephonic Per Diem for External Representation effective July 1, 2017:

Officers, excluding the Board Chair and the Presidents, who are assigned as the AMA representative to outside groups as one of their specific Board assignments or assigned Internal Representation days above eleven (11), receive a per diem rate for teleconference meetings when the total of all teleconference meetings of 30 minutes or longer during a calendar day equal 2 or more hours. Payment for these meetings would require approval of the Chair of the Board. The amount of the Telephonic Per Diem will be ½ of the full Per Diem or $650.

JOINT REPORT OF THE COUNCIL ON MEDICAL SERVICE
AND THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-18)
Aligning Clinical and Financial Incentives for High-Value Care
(Reference Committee J)

EXECUTIVE SUMMARY

The Council on Medical Service and the Council on Science and Public Health present this joint report to expand upon prior studies of access to and coverage for preventive services and other high-value health care services. A factor mitigating patient concerns about the cost of preventive care is the Affordable Care Act's (ACA) requirement that health plans cover select preventive services without any patient cost-sharing (zero-dollar). The ACA requirement of coverage for select preventive services without cost-sharing has been a popular and successful step in promoting access to preventive care, but more could and should be done to facilitate and incentivize high-value care. Value-Based Insurance Design (VBID) is a potential partial solution consistent with long-standing American Medical Association (AMA) policy. This report highlights the utilization of preventive services under ACA's mandated zero-dollar coverage, key challenges posed by the ACA mandated coverage, legal and regulatory obstacles, examples of how VBID has been used successfully to better align incentives for high-value care, and opportunities for expanded use of VBID.

The Councils recommend reaffirmation of existing AMA policy, as well as new policy to promote alignment of clinical and financial incentives for high-value care. Building on AMA policy regarding VBID, the Councils recommend that the AMA support: VBID plans designed in accordance with the tenets of "clinical nuance;" implementing innovative VBID programs in Medicare Advantage plans; and legislative and regulatory flexibility to accommodate VBID that (a) preserves health plan coverage without patient cost-sharing for evidence-based preventive services, and (b) allows innovations that expand access to affordable care, including changes needed to allow High Deductible Health Plans paired with Health Savings Accounts to provide pre-deductible coverage for preventive and chronic care management services. To enhance the effectiveness of VBID, the Councils recommend that the AMA support initiatives to align provider-facing financial incentives created through payment reform and patient-facing financial incentives created through benefit design reform. Additionally, recognizing the critical role that physicians of all specialties should play in shaping effective VBID programs, the Councils recommend that the AMA encourage national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services.

In addition, the Councils recommend three ways to protect and improve access to zero-dollar preventive care. First, the Councils recommend that the AMA continue to support requiring private health plans to provide coverage for evidence-based preventive services without imposing cost-sharing on patients. Second, the Councils recommend that the AMA develop coding guidance tools to help providers appropriately bill for zero-dollar preventive interventions and promote common understanding regarding what will be covered at given cost-sharing levels. Finally, the Councils recommend that the AMA develop physician educational tools that prepare physicians for conversations with their patients about the scope of preventive services provided without cost-sharing and instances where and when preventive services may result in financial obligations for the patient.

JOINT REPORT OF THE COUNCIL ON MEDICAL SERVICE
AND THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CMS/CSAPH Joint Report I-18

Subject:	Aligning Clinical and Financial Incentives for High-Value Care
Presented by:	James G. Hinsdale, MD, Chair, Council on Medical Service Robyn F. Chatman, MD, MPH, Chair, Council on Science and Public Health
Referred to:	Reference Committee J (Steven Chen, MD, Chair)

The Council on Medical Service and the Council on Science and Public Health present this joint report to expand upon prior studies of access to and coverage for preventive services and other high-value health care services. The Councils decided to pursue this report in light of: (a) the confusion among provider, patient, and payer communities in paying for preventive services; and (b) a common goal of improving affordable access to "high-value" services (as described below).

One factor mitigating patient concerns about the cost of preventive care is the Affordable Care Act's (ACA) requirement that health plans cover select preventive services without any patient cost-sharing (zero-dollar). The Councils previously considered preventive services in the Council on Medical Service and Council on Science and Public Health Joint Report at the 2017 Annual Meeting, "Value of Preventive Services." As detailed in the A-17 report, the ACA required all private, non-grandfathered health insurance plans to provide zero-dollar coverage for the preventive services recommended by four expert organizations: the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Women's Preventive Services Initiative, and Bright Futures. The report also described the varied methods used by those four organizations for developing preventive service guidelines. The report established Policy H-460.894, which encouraged those organizations to develop their recommendations with transparency, clarity and specificity. Given the significant challenges that have arisen as the health care industry strives to provide zero-dollar coverage for the expert organizations' recommendations, further study was warranted to explore additional policy options for promoting access to preventive interventions.

The ACA requirement of coverage for select preventive services without cost-sharing has been a popular and successful step in promoting access to preventive care, but more could and should be done to facilitate and incentivize high-value care. Value-Based Insurance Design (VBID) is a potential partial solution consistent with long-standing American Medical Association (AMA) policy. This report highlights the utilization of preventive services under ACA's mandated zero-dollar coverage, key challenges posed by the ACA-mandated coverage, legal and regulatory obstacles, examples of how VBID has been used successfully to better align incentives for high-value care, and opportunities for expanded use of VBID. Finally, this report makes several policy recommendations.

BACKGROUND

Health care affordability is determined not just by the cost of insurance coverage (e.g., the premium), but also by the amount of cost-sharing required (e.g., deductibles, co-payments, and coinsurance). The median level of liquid assets among nonelderly American households was below the cost-sharing requirements of many health insurance plans and significantly below the maximum out-of-pocket limits allowed for private insurance in 2016,[1] indicating potential challenges, especially for families with low incomes and/or significant medical bills.

Concerns about the cost of care have caused some Americans to delay or skip necessary health care. In a recent poll (n=1,302), more than a third of Americans indicated that they made health care decisions in the past year based on costs, including 44 percent who reported not going to the doctor when they were sick or injured, 40 percent who reported going without a routine physical or other preventive care, 40 percent who reported skipping a medical test or treatment, and 32 percent who reported either not filling a prescription or taking less than the prescribed dose.[2]

Patients and physicians alike encounter a dilemma when an ACA-designated preventive service that is provided without patient cost-sharing identifies early stage illness, and subsequent medical interventions can impose significant out-of-pocket costs on patients. At the same time, such interventions can be characterized as "high-value" care -- they potentially minimize human suffering, maximize the opportunity for beneficial medical intervention, save the health care system the costs of treating advanced disease, and save society the costs of losing productive individuals. Inherently, "high-value" care is subjective and challenging to define -- the same service can be life-saving for one patient and over-treatment for another patient. Accordingly, rather than restricting "high-value" care with one specific definition, experts explain that the key is for the health care system to embrace the concept that not all care provides equal value.[3] It is not necessary for all to agree which services must always be considered "high-value." Instead, simply building consensus around some selected services and aligning payer, provider, and patient incentives around those services is beneficial. This report explores opportunities to identify high-value care, some of the ways in which incentives are currently misaligned, methods already being used successfully to promote more optimal alignment, and policy recommendations to advance progress in this space.

SUCCESSES AND CHALLENGES IN IMPLEMENTING THE ACA PREVENTIVE SERVICES BENEFITS

The ACA's mandated zero-dollar coverage for select preventive services enjoys strong bipartisan support. A recent poll found that the ACA provision eliminating out-of-pocket costs for certain preventive services was favored by 83 percent of Americans (n=1,202) surveyed, including 89 percent of Democrats, 83 percent of Independents, and 77 percent of Republicans.[4] Prior to the ACA it was estimated that Americans received only about half of the preventive services that are recommended.[5] While it is estimated that 71 million Americans received expanded coverage of one or more preventive services in 2011 and 2012 as a result of the ACA, studies examining the utilization of preventive services over a limited time horizon post-ACA have found mixed results.[6] For example, among adults (age 18 to 64), the ACA was associated with an increase in physicians' provision of preventive cardiovascular services, including the use of diabetes screening, tobacco use screening, hypertension screening, and aspirin therapy in men.[7] It was also associated with increases in up-to-date rates of routine checkups and flu vaccinations.[8] However, changes in blood pressure checks, cholesterol checks, and certain cancer screenings were not associated with the ACA.[9] A review of studies focused on the ACA's impact on cancer screening found mixed results. While studies indicated that some cancer screening (pap smear test, mammography, and colorectal

cancer screening) did not increase post-ACA implementation,[10] other studies found statistically significant increases in earlier diagnosis of certain cancers associated with Medicaid expansion and parents' ability to maintain insurance coverage for their children up to age 26.[11] Multiple studies also have found evidence of substantial positive impacts among low-socioeconomic status groups and groups subject to high cost-sharing prior to the ACA.[12] While such initial studies are informative, additional research across longer time horizons is necessary to fully understand the impact of the ACA benefit that removed cost-sharing for select preventive services on utilization and health outcomes.

Similarly, even with cost-sharing barriers removed, additional barriers to provision of preventive services still exist and may include inconsistently applied definitions of key terminology, limited knowledge of preventive service guidelines, and limited time with patients. For example, the classification of a service as "screening," "diagnostic," or "therapeutic" can be unclear. Some of this confusion can be traced back to legal definitions of "preventive care." As explored in greater detail below, preventive care takes on legal significance in the context of health savings accounts (HSAs) associated with eligible high deductible health plans (HDHPs), as these plans generally cannot cover medical items or services until the deductible is met. A preventive care safe harbor via Section 223(c)(2)(C) of the Internal Revenue Code provides an exception to this rule for certain preventive care.[13] However, preventive care is not clearly defined by law.[14] Given the significant inconsistency and confusion that persists when referring to preventive services, this report will avoid use of the commonly confused terms. Additionally, patients are not familiar with the preventive services that are available to them without cost-sharing.[15] Three and half years after the ACA took effect, less than half the population (43 percent) reported being aware that the ACA eliminated out-of-pocket expenses for preventive services.[16]

Underinsurance & Cost-Related Non-Adherence (CRN): While increasing access to health insurance has been beneficial to patients, it is nevertheless critical to recognize the challenges posed by underinsurance and CRN. Rates of underinsurance – defined as out-of-pocket costs that are high relative to income – have risen, with 13 percent of adults underinsured in 2005,[17] and 28 percent of adults underinsured in 2016.[18] Even when a service is covered by a health plan, patients may incur significant costs in the form of co-payments, coinsurance, and/or large medical bills that they must pay before meeting their deductible. Such costs have been shown to cause people, especially those in low-income and vulnerable populations, to forgo not only unnecessary but also necessary care.[19] In fact, as little as a $10 rise in co-payments has been associated with a significant decline in outpatient visits and a concurrent increase in hospital utilization among an elderly population.[20] Similarly, CRN refers to a state in which patients are unable to pursue recommended medical care due to financial barriers.[21] Sub-optimal use of evidence-based medical services can lead to negative clinical outcomes, increased disparities, and in some cases, higher aggregate costs.[22] CRN has been identified across the entire continuum of clinical care -- physician visits, preventive screenings, prescription drugs, etc. -- and it is especially problematic for vulnerable populations, such as those with multiple chronic conditions, and for socioeconomically and racially disparate populations.[23] For example, greater out-of-pocket costs for medication to treat certain chronic conditions has been found to reduce initiation and adherence, lower the likelihood of achieving desired health outcomes, and sometimes, increase utilization of acute care services.[24] At the same time, studies have demonstrated that reducing or eliminating cost-sharing leads to improvements in medication adherence[25] and reductions in socioeconomic and racial disparities.[26]

Both underinsurance and CRN can be exacerbated in the context of the rising prevalence of HDHPs. HDHPs are insurance plans associated with lower premiums, higher deductibles and greater cost-sharing requirements as compared with traditional health plans.[27] An HDHP is frequently combined with a personal health account, a combination referred to as a "consumer-

directed health plan."[28] A personal health account can either be a HSA or health reimbursement arrangement (also known as a health reimbursement account or HRA).[29] HSAs are tax-free accounts used to pay for qualified medical expenses, and they must be paired with an HDHP.[30] HRAs are employer-funded accounts used to reimburse employees for qualified medical expenses. HRAs need not be paired with an HDHP.[31] While employees can keep unspent money in an HSA and accumulate savings from year to year, unspent HRA funds are forfeited to the employer at the end of a calendar or benefit year. Enrollment in HDHPs by individuals younger than 65 years who have private health insurance has increased sharply – from 25.3 percent of the population studied in 2010, to 47.0 percent in the first three months of 2018.[32] Moreover, the size of deductibles has increased dramatically. In 2003, only one percent of adults enrolled in a private plan had a deductible of $3,000 or more, but by 2016, that percentage rose to 13.[33] HDHPs appear to reduce health care costs by decreasing the use of both appropriate care (such as recommended cancer screenings) and inappropriate care (such as low-severity emergency department visits).[34] Greater consumer cost-sharing is frequently used as a lever to minimize the growth of health insurance premiums.[35] Studies have found that families who have members with chronic disease and who are enrolled in HDHPs are more likely to go without care due to cost and/or face substantial financial burdens, such as trouble paying bills, than families enrolled in traditional plans.[36] Another study found that enrollment in an HDHP, combined with an HRA or HSA, led to significant increases in out-of-pocket spending, with more than half of the enrollees with lower-incomes and more than one-third of the enrollees with chronic conditions facing "excessive financial burden."[37]

At the same time, patients' deductibles are only a fraction of their total out-of-pocket spending. Once coinsurance and co-payments are also factored in, a recent study of individuals enrolled in large employer health plans (n=between 1.05 and 15.3 million per year) found that total out-of-pocket spending rose by 54 percent between 2006 and 2016, from an average of $525 in 2006 to an average of $808 in 2016.[38] Moreover, individuals in the top 15 percent of health spenders (who account for 79 percent of total health spending), had out-of-pocket costs averaging $2,837 in 2016.[39] Exacerbating this challenge is the fact that while out-of-pocket health care costs have been rising in recent years, wages have been relatively stagnant.[40]

In light of these significant financial concerns, it is especially important that patients understand the availability of certain preventive services without any cost-sharing. Moreover, as described later in this report, efforts are underway to remove legislative and regulatory barriers to innovative insurance plan designs that could better align incentives around high-value services.

Coding, Billing, and Payment Challenges: The mismatch between the clinical intent of expert organizations' evidence-based recommendations and the ACA's mandated insurance coverage of recommended preventive services has added complexity to billing and payment practices, sometimes resulting in unexpected, and perhaps unintended, patient cost-sharing. Some specific challenges include:

- When a patient receives a designated preventive service, a private health insurance plan may still impose cost-sharing if: (1) the provider bills the services and the visit separately; or (2) the preventive service was not the primary purpose of the visit. Moreover, guidance is not clear regarding who determines what constitutes the primary purpose of a visit.
- If the expert organization does not specify the "frequency, method, treatment or setting" for a service, private health plans may use "reasonable medical management techniques" and "the relevant evidence base" to shape coverage/coverage limitations.[41]
- A private health plan may impose cost-sharing for treatment that is needed subsequent to a designated preventive service.

- Certain USPSTF recommendations apply only to "average risk" or certain "high-risk" populations. As a result, only those patients are entitled to receive the preventive service without cost-sharing. Federal guidance has clarified that the designation of "high-risk" is left to the attending provider. However, it can be unclear how a health plan is to know when a service was provided to a patient who is entitled to the service at no cost-share. Current Procedural Terminology (CPT) modifier 33 can be used when billing for ACA-designated preventive services. The addition of modifier 33 communicates to a commercial payer that a given service was provided as an ACA preventive service. While modifier 33 does not apply to Medicare patients, the CPT modifier was developed to indicate that a colonoscopy that was scheduled as a screening was converted into a diagnostic or therapeutic procedure. Nevertheless, review of the literature indicates that confusion and inconsistency persist among providers and payers in coding and paying these claims and may be contributing to the misaligned expectations observed throughout the health care industry.
- It is unclear what state and federal systems are in place to monitor and ensure enforcement of the ACA requirements. Even if individuals know they are entitled to receive certain preventive services without cost-sharing, they may not know how to seek redress if they are charged for these services.

EXPANDING ACCESS TO HIGH-VALUE SERVICES

In addition to the implementation challenges described above, patients and physicians find themselves challenged when findings from a zero-dollar preventive service lead to very expensive subsequent medical care. Furthermore, preventive interventions not designated by ACA that are deployed to prevent significant morbidity may be associated with significant patient cost-sharing. Accordingly, health plan financial incentives for patients do not always support the goal of proactively managing medical risk and preventing serious morbidity.

The juxtaposition of legitimate patient financial concerns and the high value of many preventive interventions highlights significant misalignment of clinical and financial incentives that pervades our health care system. While designation by expert organizations of preventive services to be provided without cost-sharing is a start, an initial designated service may be insufficient to achieve broader clinical goals. Instead, subsequent necessary steps can require significant financial outlays by the patient. In these cases, the clinical impact of a recommended service may not fulfill its potential if patients are unable to follow through on their physicians' guidance due to financial barriers. Several of the current system's misaligned incentives are illustrated below.

Misaligned Incentives – More Invasive Services: For clinical and economic reasons, it can make sense to promote less expensive, less-invasive screening as a first step, and progress to invasive tests when medically indicated. However, the current system sometimes incentivizes the opposite, when lower cost-sharing levels sometimes apply to more expensive, more invasive procedures. For example, consider a primary care physician who wants to follow the USPSTF's recommendation[42] and encourage a 55 year-old patient to receive colorectal cancer screening. The physician discusses the recommendation with the patient, and the patient refuses to receive a colonoscopy (citing fear of the bowel preparation, fear of anesthesia, etc.). The physician and the patient agree that for this patient, Cologuard®, a non-invasive stool test, is an appropriate initial method of screening. The Cologuard® is provided to the patient without cost-sharing. However, when the results of the Cologuard® are positive, the physician advises that a colonoscopy is necessary to complete the colorectal cancer screening. While this colonoscopy would have been provided without cost-sharing had it been chosen as the first screening method, a colonoscopy that follows a positive stool test sometimes results in imposition of a significant cost-sharing burden on the patient.[43] The

potential cost burden, in addition to the patient's already established concerns regarding colonoscopy, may dissuade the patient from completing the screening process.

Misaligned Incentives – Individual Risk Factors: In striving to prevent advanced disease, physicians often identify individual risk factors that subject their patients to a greater than average risk of various diseases. Some may be at higher risk for breast cancer, and others at higher risk for diabetes, and some may be at heightened risk for multiple serious diseases. Ideally, financial incentives would encourage patients to receive high-value services that are most likely to help them as individuals, and prioritize those over services that are less aligned with their individual risk profile. However, under our current health care system, individuals at heightened risk can be precluded from cost-sharing incentives for some high-value services.

For example, the USPSTF recommends breast cancer screening mammography for asymptomatic women who are not at high risk for breast cancer.[44] Women at high risk include those who have preexisting breast cancer, a previously diagnosed high risk breast lesion, a known underlying genetic mutation (such as a *BRCA1* or *BRCA2* gene mutation or other familial breast cancer syndrome), or a history of chest radiation at a young age.[45] A biannual mammogram will be free of cost-sharing to a woman at average risk. However, women who are at heightened risk, who need the test most frequently, and for whom the test may more often be positive, must share in often significant costs. While screening mammography is not provided without cost-sharing to patients at increased risk for breast cancer, the USPSTF recommends that "for women who are at increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene."[46] Thus, a patient at increased risk for breast cancer may receive risk-reducing medications without cost-sharing, but must share in the costs of mammography.

Misaligned Incentives – Detection vs. Monitoring, Treatment, and Continuing Prevention: When physicians choose to screen their patients for a given disease, their goal is not to simply provide a diagnosis, but rather to help their patients manage risk and promote long-term health. Under our current health care system, risk can be identified without cost-sharing, but the management of that risk can burden patients with significant financial costs.

For example, the USPSTF recommends that fair skinned young adults, adolescents, children, and parents of young children receive counseling regarding minimizing exposure to ultraviolet radiation to reduce their risk of skin cancer.[47] Counseling would be covered without patient cost-sharing. However, consider a situation where the counseling primary care physician refers a fair skinned young adult to a dermatologist for a visual skin examination. A visual skin exam by a dermatologist may help prevent or detect skin cancer. However, the USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of visual skin examinations by clinicians and whether such exams reduce skin cancer-related morbidity and mortality. A visual skin exam conducted by a dermatologist would likely result in patient cost-sharing, which may be significant, especially if the patient has not yet met their plan deductible. If the dermatologist decides to biopsy a mole, the procedure and pathology may incur significant cost-sharing for the patient. If the biopsy indicates early stage malignancy, removing the mole may prevent serious morbidity, but it may result in substantial additional cost-sharing. Finally, to ensure that subsequent disease is prevented and/or eradicated before it becomes invasive, a treating physician would want to incentivize this patient to practice on-going preventive habits such as purchasing and utilizing sunscreen and committing to follow-up visits with a dermatologist. However, since the purchase of sunscreen and dermatologist visits are outside the scope of the USPSTF, these valuable items and services will impose significant lifetime costs on the patient.

One can anticipate how similar misaligned incentives pervade our current system, in attempts to prevent morbidity from cancer, mental illness, and many other chronic diseases. For example, the USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese.[48] Moreover, the USPSTF encourages clinicians to offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity.[49] However, an array of evidence-based services to prevent onset of diabetes (e.g., community health worker diabetes prevention programs (DPPs)[50] and combined diet and physical activity promotion programs[51]) and/or to prevent disease advancement and morbidity (e.g., insulin to keep blood glucose well-managed, regular eye and foot examinations, etc.[52]) are outside the scope of the ACA's mandated zero-dollar benefit and subject to significant patient cost-sharing. While studies have found savings of approximately $1,300 for every Medicare Advantage (MA) patient who completed a diabetes education program, insured patients may, due to cost-sharing, expend hundreds of dollars to participate.[53] Consider this in the context of the finding, described above, that even a $10 increase in co-payments has been associated with a significant decline in outpatient visits and a concurrent increase in hospital utilization among an elderly population.[54] Recognizing the value of prevention programs, some payers interpret the USPSTF recommendation broadly and/or develop a commitment to covering DPPs as an evidence-based preventive program that mitigates rising risk. Such payers, including commercial health plans, as well as some Medicare and Medicaid programs, offer DPPs as a preventive service without patient cost-sharing.

An additional facet of misaligned incentives arises when patients find themselves "penalized in the form of high cost-sharing simply because of their biology."[55] For example, consider patients with major depressive disorder. Some patients may respond well to generic medications that are subject to the lowest level of cost-sharing. Other patients, though, may not achieve the desired clinical outcome with the less expensive medication, and to prevent disease progression, those patients may require medication that is only available at a higher level of cost-sharing. This higher level of cost-sharing, however, can disincentivize medication initiation and adherence.

Consistent with long-standing AMA policy that promotes testing individuals and population groups only when adequate treatment and follow-up can be arranged for the abnormal conditions and risk factors that are identified, high-value services clearly span a broad spectrum of care.[56] Great value can be achieved by preventing adverse consequences that could arise from early stage or more advanced disease.[57] The challenges in effectively describing "value" to optimally promote it through regulations contribute to the misaligned incentives observable across the spectrum of care.

VALUE-BASED INSURANCE DESIGN AS A METHOD FOR ALIGNING INCENTIVES AROUND HIGH-VALUE SERVICES

To ensure that people get the medical care they need, they must be able to afford treatment associated with identified risk factors and diagnosed disease. More Americans are afraid of the costs associated with a serious illness than of the illness itself.[58] Accordingly, while zero-dollar screenings are a significant advance, health insurance must also provide access to affordable on-going care for patients at higher risk for serious disease and/or advancement of existing disease.

Aligning Incentives Across Supply and Demand Sides: As outlined in Council on Medical Service (CMS) Report 9-A-16 and CMS Report 10-A-17 and consistent with Policy H-385.913, the AMA recognizes the continuing importance of alternative payment models (APMs) and the roles physicians should play in developing APMs. Provider-facing initiatives such as payment reform (including APMs), health information technology, and practice redesign operate on the supply side of the health care economic market.[59] On the supply side, some financial incentives are aligned

between payers and providers around quality metrics. The other critical piece of the health care economic model, of course, is the consumer demand side, which includes health care literacy programs, shared decision making, price transparency, and benefit design.[60] With benefit design, financial incentives are created between patients and third-party payers, and these incentives impact what care patients will pursue. While both payment reform and benefit design may theoretically be working toward the same goal of "quality" health care, unless those supply side and demand side incentives are actually, intentionally aligned, it can be excessively and unfairly challenging for patients, providers, and payers to achieve their shared goal of quality. For example, a quality metric for primary care physicians may be the extent to which their patients' blood glucose is within an acceptable range. To help their patients manage uncontrolled blood glucose, primary care physicians may wish to refer their patients to an endocrinologist and/or to a DPP. However, if the patients' insurance benefits impose significant cost-sharing for specialist visits and/or for DPP enrollment, the patients may not have the financial means to follow through with their primary care physicians' advice. As a result of these misaligned incentives, the system may face: (a) primary care physicians who cannot meet their quality metrics due to patient non-compliance; (b) patients who forgo high-value care due to financial barriers and subsequently become sicker; (c) employers that lose productivity due to employee illness; and (d) payers that ultimately pay more money to care for sicker patients. Clearly, this is an avoidable result that benefits no one. Accordingly, in considering actions that can be taken to improve access to high-value care, it is imperative to look at both the supply side (payment reform) and the demand side (benefit design) and ensure that both systems are designed to support each other and incentivize consistent behavior across the health care economy. Moreover, services established as quality metrics (eg, by the National Quality Forum or the National Committee for Quality Assurance) can be strong examples of "high-value" services around which patient, provider, and payer financial incentives could be aligned.

Value-Based Insurance Design (VBID): Health plans can apply VBID principles to design benefits that reduce financial barriers to and incentivize use of high-value care. VBID was designated as a federal policy priority in the ACA,[61] and the AMA has long supported VBID, with the Council on Medical Service issuing a report at the 2013 Annual Meeting that set forth principles to guide implementation of VBID initiatives.[62] As explained in CMS Report 2-A-13, traditional health insurance benefit designs use patient cost-sharing primarily as a way to control health care costs. In contrast, VBID uses cost-sharing as a tool to encourage the use of specific health care services based on "value," which is defined as the clinical benefit gained for the money spent.[63] While traditional benefit designs apply a standard set of cost-sharing requirements to all services and all patients, VBID determines coverage and cost-sharing rules based on an assessment of the clinical value of individual health care treatments or services.[64] VBID plans vary patients' out-of-pocket costs, such as co-payments, coinsurance, and deductibles, based on the value of specific services. Specifically, VBID plans are designed in accordance with the tenets of "clinical nuance," recognizing that (1) medical services may differ in the amount of health produced; and (2) the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided.[65]

Applying "clinical nuance," health plans can address some of the misaligned incentives. Returning to the example of a patient with uncontrolled blood glucose introduced above, to prevent complications associated with diabetes, and to incentivize adherence to evidence-based measures, a VBID plan may choose to reduce the cost-sharing associated with critical diabetes items or services such as insulin therapy or vision exams. VBID principles can be applied to prescription drug formularies according to a "reward the good soldier" or "step edit with co-pay relief" strategy.[66] Under such models, if a patient tries a first-line lower-cost therapy, and that therapy proves to be ineffective in achieving the desired clinical outcome for that patient, the patient would be able to

access an otherwise more expensive therapy at a lower cost-sharing level. A recent systematic literature review found that using a VBID approach to decreasing cost-sharing for targeted prescription drug classes was significantly associated with improved medication adherence, and limited evidence also indicated improvement in clinical outcomes and quality.[67] Moreover, there was no effect on total health care spending, suggesting that the increased spending on prescription medication was offset by decreased spending on other medical items or services.[68]

VBID Program Expansion: Currently, hundreds of private self-insured employers, public organizations, nonprofits and insurance plans have designed and tested VBID programs, and VBID experts believe the design method has reached a "tipping point."[69] The recently enacted Bipartisan Budget Act of 2018 incorporates the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 and requires expansion of the Medicare Advantage Value-Based Insurance Design Model to all 50 states by no later than January 1, 2020.[70] The model allows MA plans the flexibility to reduce cost-sharing or offer supplemental benefits to enrollees with specified chronic conditions, focusing on the services that are of highest clinical value to them.

In addition to the MA VBID model, the federal government continues to embrace VBID by supporting expanded application of VBID principles by public and private payers. The Centers for Medicare & Medicaid Services MA Final Rule for contract year 2019 provides greater flexibility around the MA uniformity requirement to allow for the implementation of VBID principles throughout the MA program.[71] This flexibility gives MA plans new tools to improve care and outcomes for enrollees by allowing MA plans to reduce cost-sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer different deductibles for beneficiaries who meet specific medical criteria.[72] TRICARE is also working to improve health outcomes and enhance the experience of care for US Armed Forces military personnel, military retirees, and their dependents through VBID pilot programs. The 2017 National Defense Authorization Act (NDAA) commissioned a pilot program to demonstrate and test the feasibility of incorporating VBID into the TRICARE program, and the 2018 NDAA further incorporates VBID principles into the TRICARE Pharmacy Benefits Program.[73]

Connecticut implemented a collectively bargained state-based VBID program for its state employees that is one of the first to apply VBID to not only prescription drugs, but to reduce cost-sharing for enrollees across the spectrum of care, including medical services for chronic diseases.[74] Moreover, this Connecticut program both removed financial barriers to services known to be clinically valuable and instituted requirements that enrollees obtain certain preventive services, with the goal of encouraging enrollees to participate in their preventive and chronic disease care. Connecticut implemented its program in 2011, and early results were published in 2016. While more research is needed to inform optimal design of VBID plans, early evidence is encouraging. Highlights of the Connecticut model include:

- Enrollees overwhelmingly chose to enter and stay in the VBID plan. While participation in the plan was voluntary, first year enrollment exceeded 98 percent and about 98 percent of the enrollees were deemed compliant with the plan requirements at the end of each of the first two years of the program.
- There were significant gains in preventive office visits and nearly all of the targeted preventive screenings in both the first and second years of the program.
- The total number of emergency department visits without a resulting hospital admission decreased significantly in both the first and second years of the program.
- For the chronic diseases studied, there were significant increases in physician office visits and medication possession ratios, relative to a comparison group.

Connecticut's experience suggests that payers considering VBID programs should proactively weigh the benefits of potentially improved health and productivity against the potential for higher costs that can be associated with increased use of high-value services.[75] Connecticut's program also highlights critically intertwined drivers of health care spending: (a) the majority of overall health care spending is dedicated to chronic disease; (b) most chronic diseases have evidence-based quality metrics; (c) evidence indicates suboptimal performance on those quality metrics; and (d) patient out-of-pocket spending is a significant contributor to underutilization of care. Other payers could replicate the Connecticut plan's focus on chronic conditions.[76]

Centers for Disease Control and Prevention (CDC) 6|18 Initiative: The CDC's 6|18 initiative is another example of efforts underway to align purchasers, payers, and providers to improve health and control costs through increased coverage of evidence-based preventive interventions. The initiative focuses on preventing chronic and infectious disease by increasing coverage, access, utilization, and quality. The CDC is specifically targeting six common and costly health conditions – tobacco use, high blood pressure, health care-associated infections, asthma, unintended pregnancies, and diabetes.[77] Eighteen evidence-based interventions have been identified as a starting point of discussions with purchasers, payers, and providers.[78] The CDC is providing technical assistance to state Medicaid programs and public health departments to implement the prioritized interventions and to private payers to help them identify interventions that will help their beneficiaries.

Barriers to VBID Expansion: Obstacles will likely prevent optimal customization of VBID plans in the short-term, as there are significant administrative burdens associated with identifying which services are highest value for which plan beneficiaries. However, plans should be encouraged to experiment with innovative plan designs that implement discrete elements of VBID, and legislative and regulatory changes would facilitate this goal.

HSA-HDHPs are among the fastest-growing plan types in the United States, and while current Internal Revenue Service (IRS) regulations permit a "safe harbor" that allows for coverage of specified preventive services prior to satisfaction of the plan deductible, that safe harbor is significantly limited.[79] IRS regulations state that clinical services meant to treat "an existing illness, injury, or condition" cannot be included in pre-deductible coverage.[80] Thus, even if a health plan would like to develop an HSA-HDHP according to VBID principles, many essential clinical services used to manage chronic illness could not be covered in HSA-HDHPs before the entire deductible is met. However, when HSA-HDHP enrollees with existing conditions or risk factors are required to pay out-of-pocket for necessary services prior to meeting the plan deductible, the results can be lower utilization of care, potentially resulting in poorer health outcomes and higher costs.[81]

VBID experts refer to a natural evolution from the current HSA-HDHP system to a "High-Value Health Plan" (HVHP) system that grants insurers the flexibility to provide pre-deductible coverage for high-value services across the spectrum of clinical care.[82] Legislative and regulatory barriers should not prevent this evolution, and bipartisan efforts are underway to remove these barriers. The bipartisan, bicameral "Chronic Disease Management Act of 2018" (S.2410, H.R.4978) was introduced in February 2018, and if enacted, would permit HDHPs "to provide chronic disease prevention services to plan enrollees prior to satisfying their plan deductible."[83] VBID experts explain that this strategy would lower US health care expenditures and provide millions of Americans expanded plan options that better meet their clinical needs and contribute to their financial well-being.[84] America's Health Insurance Plans has also explained that this approach would improve the value of HSA-qualified plans for consumers and improve access to care for chronic conditions.[85]

While VBID is not a panacea to singlehandedly expand access to and utilization of all critical high-value preventive interventions, it is a powerful tool. Other tools include literacy programs, health-information technology interventions and alternative clinician payment models,[86] all of which are consistent with AMA policy.

AMA POLICY

The AMA has extensive policy supporting evidence-based preventive services. Policy H-165.840 advocates for evidence-based prevention to be covered for all patients. Policy H-425.997 supports coverage for evidence-based, cost-effective preventive services; Policy H-165.848 supports a requirement that preventive health care be included as minimal coverage and Policy H-390.849 supports providing patients with information and incentives to encourage appropriate utilization of preventive services. Regarding alignment of covered benefits, Policy H-425.994 emphasizes the importance of only pursuing testing in patients when adequate treatment and follow-up can be arranged for identified abnormal conditions and risk factors and Policy D-385.966 encourages reasonable payment for mandated benefits in health insurance policies. Additionally, Policy H-165.846 sets forth principles to guide the evaluation of the adequacy of health insurance coverage options.

Moreover, Policy H-425.986 encourages communication and cooperation among physicians and public health agencies to address challenges in preventive medicine. Policies D-330.967 and H-425.987 support continued collaboration with national medical specialty societies and interest groups to encourage coverage for evidence-based recommendations regarding preventive services, especially for populations at high risk for a given condition. Policy H-440.875 emphasizes the AMA's commitment to collaborating to assure access to ACIP-recommended vaccines. Policy H-425.988 supports continuing collaboration with the federal government, specialty societies, and others, to develop guidelines for, and effective means of delivery of, clinical preventive services. Similarly, Policy D-330.935 states that the AMA will collaborate with relevant stakeholders, including appropriate medical specialty societies, to actively promote to the public and the profession the value of Medicare-covered preventive services and support the expansion of first-dollar coverage for a preventive visit and required tests anytime within the first year of enrollment in Medicare Part B. Policy H-425.992 advocates for revision of current Medicare guidelines to include coverage of appropriate preventive medical services.

Various AMA policies call for coverage with no cost-sharing, including: Policy H-185.969 regarding immunizations, Policy D-330.935 regarding Medicare preventive service benefits, and Policy H-290.972 for preventive coverage for HSA holders in the Medicaid program. Policy D-425.992 expresses concern regarding the effect that USPSTF recommendations can have on limiting access to preventive care for Americans (e.g., regarding access to screening mammography and prostate specific antigen screening) and encourages the USPSTF to implement procedures that allow for meaningful input on recommendation development from specialists and stakeholders in the topic area under study.

Finally, AMA policy strongly supports APMs, VBID, and innovative insurance design. Policy H-385.913 sets forth principles to guide physician-focused APMs. Policy H-450.938 has principles to guide physician value-based decision-making and emphasizes that physicians should seek opportunities to integrate prevention services into office visits. Policy H-155.960 supports value-based decision-making and reducing the burden of preventable disease as broad strategies for addressing rising health care costs. Moreover, this policy recognizes the role of physician leadership and collaboration among physicians, patients, insurers, employers, unions, and government in successful cost-containment and quality-improvement initiatives. The policy

encourages third-party payers to use targeted benefit design, whereby patient cost-sharing is determined based on the clinical value of a health care service or treatment, with consideration given to further tailoring cost-sharing to patient income and other factors known to impact compliance. Policy H-185.939 broadly supports flexibility in the design and implementation of VBID programs and outlines a series of guiding principles including that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements. Consistent with calls to remove legislative and regulatory barriers to innovation in HSA-HDHP plan design, Policy H-165.856 states that the regulatory environment should enable rather than impede private market innovation in product development and purchasing arrangements. At the same time, Policy H-165.856 states that benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options.

AMA ACTIVITY

In addition to the substantial volume of related AMA policy, AMA activities regarding high-value services have included:

- Serving as a liaison to expert organizations including the USPSTF, the ACIP, and Bright Futures.
- At the 2018 Annual Meeting, Policy H-185.960 was modified to specify that the AMA will develop a coding guide regarding colorectal cancer screening services to promote common understanding among health care providers, payers, health care information technology vendors, and patients.
- At the 2018 Annual Meeting, Resolution 226-A-18 regarding routine preventive prostate cancer screening was referred, and the Council on Medical Service is preparing a report for the 2019 Annual Meeting.
- As part of its strategic focus on improving health outcomes, the AMA has partnered with the CDC and DPPs to prevent type 2 diabetes and supports key legislation to prevent type 2 diabetes and improve care for current patients. As a part of these efforts, the AMA has also urged both private and public health care payers to offer DPPs under their health plans to give more people access to these proven programs.[87]
- To address significant barriers to colorectal cancer screening for the Medicare population, AMA advocacy efforts supported requiring Medicare to waive the coinsurance for colorectal screening tests, regardless of whether therapeutic intervention is required during the procedure.
- Various AMA advocacy efforts have supported expansion of the MA VBID Model, including support for flexibility in MA uniformity (which would allow plan sponsors to target enhanced benefit design to certain patients) and support for the Bipartisan Budget Act of 2018 (which incorporates the CHRONIC Care Act of 2017, which includes expansion of the MA VBID Model to all 50 states).
- In July 2018, the AMA sent a letter to Chairman Kevin Brady and Ranking Member Richard Neal of the House of Representatives Committee on Ways and Means supporting H.R. 6301, “to amend the Internal Revenue Code of 1986 to provide high deductible health plans with first dollar coverage flexibility.” H.R. 6301 would expand the access and enhance the utility of HSAs by offering health plans some flexibility in their plan design while still maintaining eligibility for HSA contributions.
- To help AMA members better understand the USPSTF’s methods for making evidence-based recommendations on clinical preventive services and how VBID can be used to expand affordable access to high-value services, the AMA held a continuing medical education session at the 2018 Annual Meeting.

DISCUSSION

Stakeholders throughout the health care community -- providers, payers, community health professionals, and patients -- can benefit from common understanding of which preventive services are covered without patient cost-sharing, and how such services should be coded. Moreover, stakeholders throughout the health care community should contribute to patient education regarding both the health care and economic value of zero-dollar preventive services so that patients can make well-informed decisions about their care. Physicians must be well-aware of recommended services available without cost-sharing so that they can have optimally productive consultations with their patients. The fact that these services are evidence-based and available at no cost to the patient may help physicians communicate the value of these services and help patients understand that cost should not be a barrier to this care. At the same time, proactive conversations between physicians and their patients about how a zero-dollar preventive service can lead to additional items or services that will incur cost-sharing will foster trust and understanding, and avoid unexpected medical bills. Additionally, public health organizations and payers (eg, employers and health plans) should be encouraged to educate the public/their members about recommended preventive services and their availability without cost-sharing. Such educational initiatives will empower patients to have productive conversations with their physicians about whether these services are appropriate for them.

The AMA can play a critical leadership role in building needed common understanding. The AMA, as the authority on CPT, is in a unique position to issue educational materials that can be seen as a source of truth in aligning recommended preventive services with the proper CPT codes for billing. Accordingly, the Councils recommend that the AMA develop coding guidance to help physicians correctly bill, and help payers correctly pay for, recommended preventive services. Additionally, the Councils recommend that the AMA develop physician education tools that help physicians prepare for conversations with their patients about the scope of preventive services provided without cost-sharing. This physician education can be designed to address two needs. First, these educational tools can address underutilization of zero-dollar preventive services by helping physicians communicate the clinical and financial value of these services to their patients. Second, these educational tools can address the patient experience of unexpected medical bills by preparing physicians (and their staff) to have proactive conversations about what is and is not provided within the scope of zero-dollar preventive services.

The USPSTF and the other ACA-designated expert organizations cannot reasonably be expected to develop recommendations on every risk-reducing course of action for every disease. At the same time, it is difficult to rationalize why some individuals at heightened risk for some diseases receive valuable preventive interventions without cost-sharing and others do not. To supplement the work being done by the expert organizations, health plans can choose to incorporate VBID principles to better align patients' clinical and financial incentives, and thereby enhance access to high-value care.

As described above, the AMA has strong policy supporting APMs and VBID. The Councils recommend supporting initiatives that align provider-facing financial incentives created through payment reform, such as APMs, with patient-facing financial incentives created through benefit design reform, to ensure that patient, provider, and payer incentives all promote the same quality care. Such initiatives may include reducing patient cost-sharing for items and services that are tied to provider quality metrics. Additionally, the Councils recommend reaffirming Policy H-155.960 which supports VBID principles, Policy H-185.939 which supports flexibility in VBID program design, and Policy H-165.856 which supports a regulatory environment that enables private market innovation in product development and purchasing arrangements.

It may be challenging to reasonably limit what qualifies as a high-value service designated for reduced cost-sharing. Similarly, the full costs and benefits of VBID plans may only be evident over extended time horizons, so the evidence base will continue to evolve. Accordingly, rather than recommending any single plan design, it is important to support the creation of a legal and regulatory environment that cultivates innovation and freedom to experiment with transformational plan designs. At the same time, innovations in plan design should be consistent with the principles of adequacy of health insurance coverage outlined in Policy H-165.846. Specifically, the AMA should support: removing legal and regulatory barriers to innovative plan designs that seek to encourage high-value care with reduced costs to patients; promoting not only screenings to identify risk, but also high-value care to help patients manage that risk and prevent advanced disease; and allowing HSA-HDHPs to provide pre-deductible coverage for preventive and chronic care management services. In addition, the Councils recommend that as health plans experiment with innovative VBID plans, these plans incorporate the tenets of "clinical nuance" to recognize individual variation and to respect individual needs.

While continuing to advocate for legal change, there are concrete actions physicians can currently take to apply VBID principles. As plans continue to innovate around VBID, organized medicine and physicians will have a critical role in helping plans understand the highest value care they want to encourage. The exact same service may be highly valuable for some patients, but constitute over-treatment for other patients, and the physician community can lead the way in shaping policies that recognize and embrace this approach to payment reform and benefit design. Continuing with the breast cancer prevention example introduced above, for some women, the USPSTF recommended screening mammography may be all that is needed to effectively manage breast cancer risk. For other women, however, more frequent imaging can be life-saving, high-value care. While these services could be expensive in the short-term, they can prevent more likely cases of deadly (and expensive) disease.

Accordingly, it will be incumbent upon organized medicine, specifically national medical specialty societies, to collaborate with payers, educating them about the circumstances under which their specialties are providing especially high-value care, care that is most clinically important to incentivize. Physicians can work to identify and highlight the items and services within their areas of specialty that are of highest value, such as those that promote proactive healthy behaviors and/or manage risk or chronic conditions. For example, in looking to evidence-based quality metrics as indicators of high-value care, physicians of all specialties can play a critical role in shaping VBID programs to come. National medical specialty societies should collaborate with payers to shape the designation of "high-value" services and the financial and other incentives that would promote their access and utilization.

RECOMMENDATIONS

The Council on Medical Service and the Council on Science and Public Health recommend that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-155.960, which: supports "value-based decision-making" and reducing the burden of preventable disease as broad strategies for addressing rising health care cost; recognizes the important role of physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government in successful cost-containment and quality-improvement initiatives; and encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment,

with consideration given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance. (Reaffirm HOD Policy)

2. That our AMA reaffirm Policy H-185.939, which supports flexibility in the design and implementation of Value-Based Insurance Design (VBID) programs and outlines guiding principles including that VBID explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing or other benefit design elements, and that practicing physicians, including appropriate specialists, must be actively involved in the development of VBID programs. (Reaffirm HOD Policy)

3. That our AMA reaffirm Policy H-165.856, which supports a regulatory environment that enables rather than impedes private market innovation in product development and purchasing arrangements. (Reaffirm HOD Policy)

4. That our AMA support VBID plans designed in accordance with the tenets of "clinical nuance," recognizing that (1) medical services may differ in the amount of health produced, and (2) the clinical benefit derived from a specific service depends on the person receiving it, as well as when, where, and by whom the service is provided. (New HOD Policy)

5. That our AMA support initiatives that align provider-facing financial incentives created through payment reform and patient-facing financial incentives created through benefit design reform, to ensure that patient, provider, and payer incentives all promote the same quality care. Such initiatives may include reducing patient cost-sharing for the items and services that are tied to provider quality metrics. (New HOD Policy)

6. That our AMA develop coding guidance tools to help providers appropriately bill for zero-dollar preventive interventions and promote common understanding among health care providers, payers, patients, and health care information technology vendors regarding what will be covered at given cost-sharing levels. (Directive to Take Action)

7. That our AMA develop physician educational tools that prepare physicians for conversations with their patients about the scope of preventive services provided without cost-sharing and instances where and when preventive services may result in financial obligations for the patient. (Directive to Take Action)

8. That our AMA continue to support requiring private health plans to provide coverage for evidence-based preventive services without imposing cost-sharing (such as co-payments, deductibles, or coinsurance) on patients. (New HOD Policy)

9. That our AMA continue to support implementing innovative VBID programs in Medicare Advantage plans. (New HOD Policy)

10. That our AMA support legislative and regulatory flexibility to accommodate VBID that (a) preserves health plan coverage without patient cost-sharing for evidence-based preventive services; and (b) allows innovations that expand access to affordable care, including changes needed to allow High Deductible Health Plans paired with Health Savings Accounts to provide pre-deductible coverage for preventive and chronic care management services. (New HOD Policy)

11. That our AMA encourage national medical specialty societies to identify services that they consider to be high-value and collaborate with payers to experiment with benefit plan designs that align patient financial incentives with utilization of high-value services. (New HOD Policy)

Fiscal Note: $6,000

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APPENDIX

Policies Recommended for Reaffirmation

H-155.960 Strategies to Address Rising Health Care Costs
Our AMA:
(1) recognizes that successful cost-containment and quality-improvement initiatives must involve physician leadership, as well as collaboration among physicians, patients, insurers, employers, unions, and government;
(2) supports the following broad strategies for addressing rising health care costs: (a) reduce the burden of preventable disease;
(b) make health care delivery more efficient; (c) reduce non-clinical health system costs that do not contribute value to patient care; and
(d) promote "value-based decision-making" at all levels;
(3) will continue to advocate that physicians be supported in routinely providing lifestyle counseling to patients through: adequate third-party reimbursement; inclusion of lifestyle counseling in quality measurement and pay-for-performance incentives; and medical education and training;
(4) will continue to advocate that sources of medical research funding give priority to studies that collect both clinical and cost data; use evaluation criteria that take into account cost impacts as well as clinical outcomes; translate research findings into useable information on the relative cost-effectiveness of alternative diagnostic services and treatments; and widely disseminate cost-effectiveness information to physicians and other health care decision-makers;
(5) will continue to advocate that health information systems be designed to provide physicians and other health care decision-makers with relevant, timely, actionable information, automatically at the point of care and without imposing undue administrative burden, including: clinical guidelines and protocols; relative cost-effectiveness of alternative diagnostic services and treatments; quality measurement and pay-for-performance criteria; patient-specific clinical and insurance information; prompts and other functionality to support lifestyle counseling, disease management, and case management; and alerts to flag and avert potential medical errors;
(6) encourages the development and adoption of clinical performance and quality measures aimed at reducing overuse of clinically unwarranted services and increasing the use of recommended services known to yield cost savings;
(7) encourages third-party payers to use targeted benefit design, whereby patient cost-sharing requirements are determined based on the clinical value of a health care service or treatment. Consideration should be given to further tailoring cost-sharing requirements to patient income and other factors known to impact compliance; and
(8) supports ongoing investigation and cost-effectiveness analysis of non-clinical health system spending, to reduce costs that do not add value to patient care.
(9) Our AMA will, in all reform efforts, continue to identify appropriate cost savings strategies for our patients and the health care system.
(CMS Rep. 8, A-07 Reaffirmed: CMS Rep. 7, A-08 Reaffirmed in lieu of Res. 828, I-08 Reaffirmation A-09 Reaffirmation I-09 Reaffirmation A-11 Reaffirmation I-11 Appended: Res. 239, A-12 Reaffirmed in lieu of Res. 706, A-12 Reaffirmed: CMS Rep. 1, I-12 Modified: CMS Rep. 2, A-13 Reaffirmed in lieu of Res. 122, A-15 Reaffirmed in lieu of: Res. 121, A-16 Reaffirmed: CMS Rep. 05, I-16 Reaffirmation I-16 Reaffirmed in lieu of: Res. 712, A-17)

H-165.856 Health Insurance Market Regulation
Our AMA supports the following principles for health insurance market regulation:
(1) There should be greater national uniformity of market regulation across health insurance markets, regardless of type of sub-market (e.g., large group, small group, individual), geographic location, or type of health plan.
(2) State variation in market regulation is permissible so long as states demonstrate that departures from national regulations would not drive up the number of uninsured, and so long as variations do not unduly hamper the development of multi-state group purchasing alliances, or create adverse selection.
(3) Risk-related subsidies such as subsidies for high-risk pools, reinsurance, and risk adjustment should be financed through general tax revenues rather than through strict community rating or premium surcharges.
(4) Strict community rating should be replaced with modified community rating, risk bands, or risk corridors. Although some degree of age rating is acceptable, an individual's genetic information should not be used to determine his or her premium.
(5) Insured individuals should be protected by guaranteed renewability.
(6) Guaranteed renewability regulations and multi-year contracts may include provisions allowing insurers to single out individuals for rate changes or other incentives related to changes in controllable lifestyle choices.
(7) Guaranteed issue regulations should be rescinded.
(8) Health insurance coverage of pre-existing conditions with guaranteed issue within the context of an individual mandate, in addition to guaranteed renewability.
(9) Insured individuals wishing to switch plans should be subject to a lesser degree of risk rating and pre-existing conditions limitations than individuals who are newly seeking coverage.
(10) The regulatory environment should enable rather than impede private market innovation in product development and purchasing arrangements. Specifically: (a) legislative and regulatory barriers to the formation and operation of group purchasing alliances should, in general, be removed; (b) benefit mandates should be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options; and (c) any legislative and regulatory barriers to the development of multi-year insurance contracts should be identified and removed. (CMS Rep. 7, A-03 Reaffirmed: CMS Rep. 6, A-05 Reaffirmation A-07 Reaffirmed: CMS Rep. 2, I-07 Reaffirmed: BOT Rep. 7, A-09 Appended: Res. 129, A-09 Reaffirmed: CMS Rep. 9, A-11 Reaffirmed in lieu of Res. 811, I-11 Reaffirmed in lieu of Res. 109, A-12 Reaffirmed in lieu of Res. 125, A-12 Reaffirmed: Res. 239, A-12 Reaffirmed: CMS Rep. 9, A-14 Reaffirmation: A-17 Reaffirmed: Res. 518, A-17)

H-185.939 Value-Based Insurance Design
Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles:
a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements.
b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists.
c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan.
d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients.

e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design.
f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices.
g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties.
h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence.
i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines (Policy H-450.947), and AMA policy on physician economic profiling and tiered, narrow or restricted networks (Policies H-450.941 and D-285.972).
(CMS Rep. 2, A-13 Reaffirmed in lieu of Res. 122, A-15 Reaffirmed in lieu of: Res. 121, A-16 Reaffirmed: CMS Rep. 05, I-16 Reaffirmation I-16 Reaffirmed: Joint CMS/CSAPH Rep. 01, I-17)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 002
(I-18)

Introduced by: GLMA: Health Professionals Advancing LGBTQ Equality

Subject: Protecting the Integrity of Public Health Data Collection

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Todd M. Hertzberg, MD, Chair)

Whereas, Our American Medical Association is dedicated to improving the nation's health; and

Whereas, The National Institutes of Health (NIH) has underscored the need to better understand the health of sexual and gender minorities and the 2011 Institute of Medicine report on the Health of Lesbian, Gay, Bisexual, and Transgender People and a follow-up report in 2013 both highlighted the need for inclusion of sexual and gender identity data collection in federal and state surveys, surveillance systems, and health registries[1-2]; and

Whereas, Healthy People 2020 Guidelines highlight the importance of sexual orientation and gender identity data collection in national surveys[3]; and

Whereas, There have been several attempts to remove sexual orientation and gender identity data from national surveys and surveillance systems, including but not limited to the National Survey of Older American Act[5] and National Crime Victimization Survey[6]; and

Whereas, This is part of an alarming trend within the federal government aimed at limiting knowledge about sexual and gender minority (i.e. lesbian, gay, bisexual, transgender, queer) people, despite the fact that these data are vital to policy making and designing evidence-based interventions to improve health and well-being; and

Whereas, The collection of sexual orientation and gender identity data allows researchers, clinicians, and public health professionals to address health disparities and ensure individuals can lead long, healthy lives and appropriate data collection allows for the reduction in disease transmission and progression, increases in mental and physical well-being, reductions in health care costs, and improved quality of life; and

Whereas, To eliminate health disparities, there must be widespread collection of sexual orientation and gender identity data using standard, reliable questions[7]; therefore be it

RESOLVED, That our American Medical Association advocate for the inclusion of demographic data inclusive of sexual orientation and gender identity in national and state surveys, surveillance systems, and health registries; including but not limited to the Current Population Survey, United States Census, National Survey of Older Americans Act Participants, all-payer claims databases (New HOD Policy); and be it further

RESOLVED, That our AMA advocate against the removal of demographic data inclusive of sexual orientation and gender identity in national and state surveys, surveillance systems, and health registries without plans for updating measures of such demographic data. (New HOD Policy)

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

Received: 10/11/18

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RELEVANT AMA POLICY

Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation H-315.967

Our AMA: (1) supports the voluntary inclusion of a patient's biological sex, current gender identity, sexual orientation, and preferred gender pronoun(s) in medical documentation and related forms, including in electronic health records, in a culturally-sensitive and voluntary manner; and (2) will advocate for collection of patient data that is inclusive of sexual orientation/gender identity for the purposes of research into patient health.
Citation: Res. 212, I-16; Reaffirmed in lieu of: Res. 008, A-17

Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations H-160.991

1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ patients; (iii) encouraging the development of educational programs in LGBTQ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk

for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors.
3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ health issues.
4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ people.
Citation: CSA Rep. C, I-81; Reaffirmed: CLRPD Rep. F, I-91; CSA Rep. 8 - I-94; Appended: Res. 506, A-00; Modified and Reaffirmed: Res. 501, A-07; Modified: CSAPH Rep. 9, A-08; Reaffirmation A-12; Modified: Res. 08, A-16; Modified: Res. 903, I-17; Modified: Res. 904, I-17; Res. 16, A-18

Goal of Health Care Data Collection H-406.999
The AMA (1) continues to advocate that health care data collected by government and third party payers be used for education of both consumers and providers; and (2) believes that government, third party payers and self-insured companies should make physician-specific utilization information available to medical societies.
Citation: BOT Rep. W, A-92; Reaffirmed: Res. 719, A-93; BOT Rep. Y, I-85; Reaffirmed CLRPD Rep. 2, I-95; CMS Rep. 10, A-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmed: CMS Rep. 01, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 003
(I-18)

Introduced by: Indiana

Subject: Mental Health Issues and Use of Psychotropic Drugs for Undocumented Immigrant Children

Referred to: Reference Committee on Amendments to Constitution and Bylaws (Todd M. Hertzberg, MD, Chair)

Whereas, Federal government immigration officials recently elected to separate children from their parent or parents and to place these children in foster care situations or other public facilities. The children were as young as 3 years of age. In some cases, this occurred with little or no forewarning, so that the parents were not able to prepare their children for the separation. Some children became quite stressed and agitated. In some cases, the children were moved thousands of miles for the foster care. Previous administrations have had a policy allowing unaccompanied minors access to the U.S. This policy produced concerns about the possibility of entry into gangs and the risk of physical and mental trauma in the absence of a supervising adult; and

Whereas, A single major childhood emotional trauma can predispose a person to chronic psychiatric disease as an adult. Many of these border-crossing children have experienced multiple traumas already on their travels to the U.S.; and

Whereas, Some of the minor immigrant children were given psychotropic drugs without parental permission or court order. These children protested injection verbally. They were held by guards at detention centers and psychotropic drugs were given; therefore be it

RESOLVED, That our American Medical Association officially object to policies separating undocumented immigrant parents and/or guardians from children, as well as allowing unaccompanied undocumented minors access to the U.S. (New HOD Policy); and be it further

RESOLVED, That our AMA condemn the practice of administering psychotropic drugs to immigrant children without parental or guardian consent or court order except in the case of imminent danger to self or others (New HOD Policy); and be it further

RESOLVED, That our AMA support a position whereby federal immigration officials would become more aware of the emotional decompensation in this immigrant population, with the establishment of policies designed to decrease stress and emotional trauma. (New HOD Policy)

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

Received: 10/09/18

RELEVANT AMA POLICY

https://policysearch.ama-assn.org/policyfinder/search/undocumented%20children/relevant/1/

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 215
(I-18)

Introduced by: American Academy of Pediatrics

Subject: Extending the Medical Home to Meet Families Wherever They Go

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, The Medical Home model for care has been demonstrated to improve patient outcomes and reduce total cost of care; and

Whereas, Technologic advances are empowering physician practices to extend their reach to care for families in innovative ways including Telehealth; and

Whereas, Current scope of licensure in the majority of states limits physician practice abilities to continue to meet the needs of their families when they travel outside the state in which the physician is licensed; and

Whereas, Some states have joined the Interstate Medical Licensure Compact to facilitate multistate licensure for physicians; and

Whereas, Payers provide telehealth options for patients who need to access primary care services at times when access to the office of the primary care physician is difficult or impossible; and

Whereas, Most primary care physicians are available to talk with patients, or participate in telehealth primary care encounters, on a 24-7 basis; and

Whereas, Entrepreneurial telehealth for-profit entities are contracting with payers to provide inferior quality telehealth primary care, delivered by non-physician providers, for patients; and

Whereas, The primary care physician who knows the patient and has 24-7 access to the medical records of the patient will provide higher quality and more cost-effective health care for the patient than will an out-of-state urgent care center, a hospital emergency department, or a for-profit telehealth entity; therefore be it

RESOLVED, That our American Medical Association develop model legislation to permit primary care physicians, who work in medical homes/primary care practices that satisfy the National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home Recognition Program guidelines, and who have documented a face-to-face patient-care relationship, to provide telehealth services for the patient when the patient travels to any of the fifty states. (Directive to Take Action)

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

Received: 10/10/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 216
(I-18)

Introduced by: American Society of Clinical Oncology

Subject: Medicare Part B Competitive Acquisition Program (CAP)

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, The Competitive Acquisition Program (CAP) was introduced in 2006 as a voluntary program in which physicians have the option to acquire drugs from vendors who are selected in a competitive bidding process[1]; and

Whereas, CAP was intended to save physicians time and paperwork, while also lowering drug costs for beneficiaries and the Medicare program; and

Whereas, CAP was suspended by CMS due to lack of vendor competition, lack of physician participation and limited cost savings; and

Whereas, The CMS Center for Medicare and Medicaid Innovation (CMMI) issued a Request for Information (RFI) in July 2018 seeking public feedback on leveraging the authority for the CAP for Part B drugs for a potential CMS Innovation Center model[2]; and

Whereas, CAP modifications must protect patients and practices from unexpected financial toxicity; therefore be it

[1] Centers for Medicare and Medicaid Services. *Competitive Acquisition for Part B Drugs & Biologicals*. 2013. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html (Accessed September 19, 2018).

[2] Department of Health and Human Services, Centers for Medicare and Medicaid Services. *Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model.* 83 Federal Register 147 (37212-37217). https://www.gpo.gov/fdsys/pkg/FR-2018-07-31/pdf/2018-15958.pdf (Accessed September 19, 2018).

RESOLVED, That our American Medical Association advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

(1) it must be genuinely voluntary and not penalize practices which choose not to participate;

(2) it should provide supplemental payments to support complex care coordination and management for cancer patients, including reimbursement for costs associated with the administration of anticancer drugs such as special handling and storage for hazardous drugs;

(3) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;

(4) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;

(5) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician; and

(6) it should not be tied to negotiated discounts such as rebates to pharmacy benefit managers given in exchange for implementing utilization management policies like step therapy. (New HOD Policy)

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

Received: 10/11/18

RELEVANT AMA POLICY

Strengthening Medicare Through Competitive Bidding H-330.886

1. Our AMA supports the following principles to guide the use of competitive bidding among health insurers in the Medicare program:

a. Eligible bidders should be subject to specific quality and financial requirements to ensure sufficient skill and capacity to provide services to beneficiaries.

b. Bidding entities must be able to demonstrate the adequacy of their physician and provider networks.

c. Bids must be based on a clearly defined set of standardized benefits that should include, at a minimum, all services provided under the traditional Medicare program and a cap on out-of-pocket expenses.

d. Bids should be developed based on the cost of providing the minimum set of benefits to a standardized Medicare beneficiary within a given geographic region.

e. Geographic regions should be defined to ensure adequate coverage and maximize competition for beneficiaries in a service area.

f. All contracting entities should be required to offer beneficiaries a plan that includes only the standardized benefit package. Expanded benefit options could also be offered for beneficiaries willing to pay higher premiums.

g. Processes and resources must be in place to provide beneficiary education and support for choosing among alternative plans.

2. Our AMA supports using a competitive bidding process to determine federal payments to Medicare Advantage plans.

Citation: (CMS Rep. 7, I-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 217
(I-18)

Introduced by: American Society of Clinical Oncology

Subject: Opposition to Medicare Part B to Part D Changes

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, The Administration's "American Patients First Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" proposes moving drugs from Medicare Part B to Part D if the move would achieve savings; and

Whereas, 9 million Part B beneficiaries do not have Part D coverage[1] and would therefore be at risk of losing coverage or experiencing higher out-of-pocket costs if this were implemented; and

Whereas, Co-insurance and out-of-pocket costs for therapies provided under Medicare Part D plans are typically higher than cost for therapies covered under Part B and that difference can be financially devastating for patients; and

Whereas, Shifting drugs from Part B to Part D would heighten the role that pharmacy benefit managers (PBMs) play in patient care even though they already generate issues such as treatment delays, medication switching without physician notification, and unnecessary administrative burdens; and

Whereas, Most Part B beneficiaries have supplemental insurance through Medigap programs that assist with Part B cost sharing and would not assist with Part D cost sharing; and

Whereas, There is insufficient data to suggest that moving Part B drugs to Part D would result in savings, as Acumen[2], Avalere[3] and HHS[4] studies all vary on the outcome of this move; and

Whereas, Physician payments for patient services and reimbursement for drugs together form the total resources available for practices to treat patients, thus it is vital to have an effective system for drug coverage in order to ensure optimal care and patient outcomes; therefore be it

RESOLVED, That our American Medical Association advocate against Medicare changes which would recategorize Medicare Part B drugs into Part D. (New HOD Policy)

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[1] Medicare Payment Advisory Commission. *Health Care Spending and the Medicare Program: A Data Book*. Washington, DC: MedPAC, June, 2018. http://www.medpac.gov/docs/default-source/data-book/jun18_databookentirereport_sec.pdf?sfvrsn=0 (Accessed October 3, 2018)

[2] Marrufo G, Rusev E, Piccinini K, Coombs E, Ueda K, and Schecter E. *Estimating the Effects of Consolidating Drugs under Part D or Part B.* Burlingame, CA: Acumen, LLC, 2011. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf (Accessed September 17, 2018).

[3] Brow M and Kane R. *Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D.* May 21, 2018. http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d?utm_source=newsletter&utm_medium=email&utm (Accessed September 17, 2018)

[4] Leavitt M. *Department of Health and Human Services Report to Congress: Transitioning Medicare Part B Covered Drugs to Part D*. 2005. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtbtoPtD_2005_4.pdf (Accessed September 17, 2018).

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

Received: 10/11/18

RELEVANT AMA POLICY

Opposition to the CMS Medicare Part B Drug Payment Model D-330.904
1. Our AMA will request that the Centers for Medicare & Medicaid Services (CMS) withdraw the proposed Part B Drug Payment Model.
2. Our AMA will support and actively work to advance Congressional action to block the proposed Part B Drug Payment Model if CMS proceeds with the proposal.
3. Our AMA will advocate against policies that are likely to undermine access to the best course of treatment for individual patients and oppose demonstration programs that could lead to lower quality of care and do not contain mechanisms for safeguarding patients.
4. Our AMA will advocate for ensuring that CMS solicits and takes into consideration feedback from patients, physicians, advocates, or other stakeholders in a way that allows for meaningful input on any Medicare coverage or reimbursement policy that impacts patient access to medical therapies, including policies on coverage and reimbursement.
Citation: Res. 241, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 218
(I-18)

Introduced by: Colorado

Subject: Alternatives to Tort for Medical Liability

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, The stated purpose of tort mediated malpractice litigation is threefold:

1. To compensate patients harmed during the course of medical care;
2. To identify and hold accountable doctors and other clinicians for provision of inappropriate or unsafe care;
3. To make medical care safer through exposure of negligent and flawed practice; and thus identify areas for improvement; and

Whereas, Patients generally have no recourse other than medical tort actions to be made whole after medical injury; and

Whereas, Linking compensation for harm to liability for negligence encourages lawsuits when there is no causal linkage between care and outcome (e.g. most cases of cerebral palsy[1]); and

Whereas, The tort system typically takes 3 years to resolve medical malpractice cases and usually in favor of defendants leaving most harmed patients uncompensated at the end of a long, inefficient and expensive process; and

Whereas, Only a small number of medical errors trigger a tort action leaving most cases of medical harm unaddressed; and

Whereas, Most medical injuries are not the result of negligence[2]; and

Whereas, The usual course of litigation over adverse outcomes sets patients and their doctors in adversarial positions when they should be most aligned to respond therapeutically; and

Whereas, According to the IOM's "To err is human" report, "…clinicians working in a culture of blame and punishment do not report all errors, primarily because they fear punishment … Fears of reprisal and punishment have led to a norm of silence. But silence kills, and health care professionals need to have conversations about their concerns … including errors and dangerous behavior of coworkers.[62] … When individuals and organizations are able to move from individual blame toward a culture of safety, where the blame and shame of errors is eliminated and reporting is rewarded, organizations are enabled to institutionalize reporting systems and increase reporting of all types of errors.[64, 65] … clinicians and others must know that safety can be improved by non-punitive reporting of error and that organizational flaws cause errors.[1];" and

[1] https://www.cdc.gov/ncbddd/cp/causes.html
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3576054/

Whereas, Research has shown a 5% cost reduction in hospital costs when the threat of tort litigation is removed[3]; and

Whereas, Our AMA does have considerable policy on medical liability reform (H-435.973, H-435.969, D 435.992), but none of these address the type of reform that is suggested below for further study; therefore be it

RESOLVED, That our American Medical Association review options for alternatives to the tort system that will assure fair compensation to individuals harmed in the process of receiving medical care and separately identify and hold accountable physicians and other practitioners for dangerous or unacceptable practice as well as identify opportunities for improving systems to maximize the safety of medical care (as in New Zealand and other countries) (Directive to Take Action); and be it further

RESOLVED, That our AMA develop new policy which can be used for advocacy or development of model state legislation to replace the current tort system. (Directive to Take Action)

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

Received: 10/05/18

[3] http://www.nber.org/papers/w24846

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 219
(I-18)

Introduced by: Indiana

Subject: Promotion and Education of Breastfeeding

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, There is considerable science-based evidence for the benefits of breastfeeding over the use of commercial formulas for both infant and mother; and

Whereas, The rate of breastfeeding of infants under the age of six months around the world is only 40 percent, and

Whereas, The representatives of United States government to the World Health Assembly/World Health Organization vigorously discouraged a resolution by that body to advocate the preference and emphasize the health benefits of breastfeeding; and

Whereas, Mothers who wish to nurse still face some substantial impediments in many states; therefore be it

RESOLVED, That our American Medical Association encourage the federal government to legislate appropriate disclosures of the health benefits or limitations of synthetic infant formulas, develop a breast feeding awareness education program, ensure that our representatives to global meetings comport themselves in an unbiased manner that better represents a compromise of all views of this particular issue and promote development of an affordable and more equivalent substitute for breast milk for women who absolutely are unable to nurse (New HOD Policy); and be it further

RESOLVED, That our AMA and all state medical associations support legislation for workplace accommodation for nursing mothers in those states that do not already have such laws. (New HOD Policy)

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

Received: 10/09/18

RELEVANT AMA POLICY

AMA Support for Breastfeeding H-245.982

1. Our AMA: (a) recognizes that breastfeeding is the optimal form of nutrition for most infants; (b) endorses the 2012 policy statement of American Academy of Pediatrics on Breastfeeding and the use of Human Milk, which delineates various ways in which physicians and hospitals can promote, protect, and support breastfeeding practices; (c) supports working with other interested organizations in actively seeking to promote increased breastfeeding by Supplemental Nutrition Program for Women, Infants, and Children (WIC Program) recipients, without reduction in other benefits; (d) supports the availability and appropriate use of breast pumps as a cost-effective tool to promote breast feeding; and (e) encourages public facilities to provide designated areas for breastfeeding and breast pumping; mothers nursing babies should not be singled out and discouraged from nursing their infants in public places.

2. Our AMA: (a) promotes education on breastfeeding in undergraduate, graduate, and continuing medical education curricula; (b) encourages all medical schools and graduate medical education programs to support all residents, medical students and faculty who provide breast milk for their infants, including appropriate time and facilities to express and store breast milk during the working day; (c) encourages the education of patients during prenatal care on the benefits of breastfeeding; (d) supports breastfeeding in the health care system by encouraging hospitals to provide written breastfeeding policy that is communicated to health care staff; (e) encourages hospitals to train staff in the skills needed to implement written breastfeeding policy, to educate pregnant women about the benefits and management of breastfeeding, to attempt early initiation of breastfeeding, to practice "rooming-in," to educate mothers on how to breastfeed and maintain lactation, and to foster breastfeeding support groups and services; (f) supports curtailing formula promotional practices by encouraging perinatal care providers and hospitals to ensure that physicians or other appropriately trained medical personnel authorize distribution of infant formula as a medical sample only after appropriate infant feeding education, to specifically include education of parents about the medical benefits of breastfeeding and encouragement of its practice, and education of parents about formula and bottle-feeding options; and (g) supports the concept that the parent's decision to use infant formula, as well as the choice of which formula, should be preceded by consultation with a physician.

3. Our AMA: (a) supports the implementation of the WHO/UNICEF Ten Steps to Successful Breastfeeding at all birthing facilities; (b) endorses implementation of the Joint Commission Perinatal Care Core Measures Set for Exclusive Breast Milk Feeding for all maternity care facilities in the US as measures of breastfeeding initiation, exclusivity and continuation which should be continuously tracked by the nation, and social and demographic disparities should be addressed and eliminated; (c) recommends exclusive breastfeeding for about six months, followed by continued breastfeeding as complementary food are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant; (d) recommends the adoption of employer programs which support breastfeeding mothers so that they may safely and privately express breast milk at work or take time to feed their infants; and (e) encourages employers in all fields of healthcare to serve as role models to improve the public health by supporting mothers providing breast milk to their infants beyond the postpartum period.

4. Our AMA supports the evaluation and grading of primary care interventions to support breastfeeding, as developed by the United States Preventive Services Task Force (USPSTF).

5.Our AMA's Opioid Task Force promotes educational resources for mothers who are breastfeeding on the benefits and risks of using opioids or medication-assisted therapy for opioid use disorder, based on the most recent guidelines.

Citation: CSA Rep. 2, A-05; Res. 325, A-05; Reaffirmation A-07; Reaffirmation A-12; Modified in lieu of Res. 409, A-12 and Res. 410, A-12; Appended: Res. 410, A-16; Appended: Res. 906, I-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 220
(I-18)

Introduced by: Indiana

Subject: Supporting Mental Health Training Programs for Corrections Officers and Crisis Intervention Teams for Law Enforcement

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, It is estimated that 168,082 individuals in Indiana have a severe mental illness (SMI), of which 79,783 are currently untreated; and

Whereas, It is estimated that 2,413 individuals with SMI are in state, private and psychiatric units in general hospitals in Indiana; and

Whereas, It is estimated that 6,393 individuals, or 15 percent of inmates in Indiana jails and prisons, are SMI, making the odds of an SMI person being in jail or prison compared with being treated in a hospital 2.6 to 1; and

Whereas, Corrections Officers (COs) can play a vital role in the proper treatment of offenders with mental illness but generally receive very little training in mental health issues, making violence between inmates and officers commonplace; and

Whereas, The National Alliance on Mental Illness (NAMI) Indiana chapter, in conjunction with the Indiana University School of Medicine Department of Psychiatry, developed a 10-hour education program that taught COs the major categories of psychiatric disorders, the biology and treatment behind mental illness and effective ways to interact with mentally ill inmates, which led to a significant reduction in the use of force by COs and the number of assaults with bodily waste by the offenders; and

Whereas, According to a NAMI volunteer and member of the NAMI-Indiana Board of Directors, the Indiana Department of Correction has embedded this course within its training curriculum for prison COs, but this training is not in place in the majority of Indiana county jails; and

Whereas, Police officers may perceive mental health-related calls as unpredictable and dangerous, which without adequate training in de-escalation could cause them to approach in a manner that inadvertently escalates the situation; and

Whereas, It is estimated that 1 in 4 fatal police encounters ends the life of an individual with SMI, making the risk of being killed during a police incident 16 times greater for individuals with untreated mental illness than for other civilians; and

Whereas, A crisis intervention team (CIT) is an evidence-supported program that improves the way law enforcement responds to individuals experiencing a mental health crisis by (1) building partnerships between local law enforcement agencies, mental health providers and mental health advocates, including but not limited to NAMI-Indiana; (2) providing officers with a 40-hour curriculum consisting of lectures, on-site visitation, interaction with individuals with mental illness and scenario-based de-escalation skill training; and 3) directing individuals with mental illness toward treatment rather than incarceration; and

Whereas, The Fort Wayne Police Department's CIT reported diverting 99 percent of mental health calls away from jail and into the mental health system in 2012; and

Whereas, Despite evidence showing that CIT improves public safety and significantly decreases the number of arrests and re-arrests of SMI individuals, only 10 of 92 Indiana counties have an active CIT program; and

Whereas, The AMA (1) continues to support jail diversion and community-based treatment options for mental illness; (2) supports implementation of law enforcement-based crisis intervention training programs for assisting those individuals with a mental illness, such as the CIT model programs; and (3) supports federal funding to encourage increased community and law enforcement participation in crisis intervention training programs; therefore be it

RESOLVED, That our American Medical Association support legislation and federal funding for evidence-based training programs aimed at educating corrections officers in effectively interacting with mentally ill populations in federal prisons. (New HOD Policy)

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

Received: 10/09/18

RELEVANT AMA POLICY

https://policysearch.ama-assn.org/policyfinder/search/mental%20illness%20in%20jails/relevant/1/.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 221
(I-18)

Introduced by: Kentucky

Subject: Regulatory Relief from Burdensome CMS "HPI" EHR Requirements

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, The AMA has adopted principles that support that information technology available to physicians should support the physician's obligation to put the interests of patients first; and

Whereas, The information technology available to physicians should support the integrity and autonomy of physicians; and

Whereas, The AMA has affirmed a commitment to working with federal and state agencies, policy makers and other relevant stakeholders to improve EHRs; and

Whereas, Dissatisfaction among EHR end-users has contributed to physician burnout, and a diminished patient-physician relationship; and

Whereas, The Centers for Medicaid and Medicare Services (CMS) has determined that the History of Present Illness (HPI) cannot be performed incident to the physician by ancillary employees (ie, RN, LPN, MA or any other individual not able to bill Medicare for physicians' services); and

Whereas, The "keystroking" of the information contained in the HPI as contained by the EHR is NOT necessarily validation that a face to face visit by the physician was performed; and

Whereas, The "keystroking" of orders signed by a physician is acceptable to CMS and these orders are much more likely to directly result in error; and

Whereas, A physician's signature and declarative sentences regarding the nature of their work and involvement in the "HPI" portion of patient care should be sufficient to document their involvement in the care of the patient and doing so does not indicate that this information was treated as anything less than preliminary; therefore be it

RESOLVED, That our American Medical Association advocate for regulatory relief from the burdensome Centers for Medicare and Medicaid Services (CMS) History of Present Illness (HPI) requirements arbitrarily equating "keystroking" in an electronic health record (EHR) with validation of the fact that a face to face encounter has been performed by the physician/NPP (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for the acceptance of the physician's electronic signature as substantiation and verification that the HPI was reviewed and appropriate additional information was obtained and recorded whomever "keystroked" this information. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.
Received: 10/05/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 222
(I-18)

Introduced by: Maryland

Subject: Patient Privacy Invasion by the Submission of Fully Identified Quality Measure Data to CMS

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, There are two types of quality measure reports that are required to be produced by Meaningful Use Stage 2 Certified EHRs: QRDA I reports provide detailed information about patients including names, dates of birth, addresses, race and ethnicity and conditions such as diabetes, drug and alcohol abuse, obesity, depression, etc. and QRDA III reports which are summary reports which do not contain personal information about patients; and

Whereas, Patients do not give permission to submit the personally identified QRDA I reports for either PQRS for Medicare and Medicaid or for Meaningful Use Quality Reporting; and

Whereas, The release of private information without permission can undermine the willingness of patients to confide in their provider and may undermine the provider-patient relationship; and

Whereas, The quality measures include very sensitive information; and

Whereas, There are no guarantees that the database containing this personally identified information can be protected from illegal access; and

Whereas, There are no guarantees that the database will not be released deliberately, by act of law or regulation, sometime in the future, without patient permission; therefore be it

RESOLVED, That our American Medical Association work to establish regulation and/or legislation requiring that all quality measure data be collected in summary format only with no personally identified information included. (Directive to Take Action)

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

Received: 10/11/18

RELEVANT AMA POLICY

3.1.1 Privacy in Health Care
Protecting information gathered in association with the care of the patient is a core value in health care. However, respecting patient privacy in other forms is also fundamental, as an expression of respect for patient autonomy and a prerequisite for trust.
Patient privacy encompasses a number of aspects, including personal space (physical privacy), personal data (informational privacy), personal choices including cultural and religious affiliations (decisional privacy), and personal relationships with family members and other intimates (associational privacy).
Physicians must seek to protect patient privacy in all settings to the greatest extent possible and should:
(a) Minimize intrusion on privacy when the patients privacy must be balanced against other factors.
(b) Inform the patient when there has been a significant infringement on privacy of which the patient would otherwise not be aware.
(c) Be mindful that individual patients may have special concerns about privacy in any or all of these areas.
AMA Principles of Medical Ethics: I,IV
The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.
Issued: 2016

Patient Privacy and Confidentiality H-315.983
1. Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (a) That there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; (b) That patients' privacy should be honored unless waived by the patient in a meaningful way or in rare instances when strong countervailing interests in public health or safety justify invasions of patient privacy or breaches of confidentiality, and then only when such invasions or breaches are subject to stringent safeguards enforced by appropriate standards of accountability; (c) That patients' privacy should be honored in the context of gathering and disclosing information for clinical research and quality improvement activities, and that any necessary departures from the preferred practices of obtaining patients' informed consent and of de-identifying all data be strictly controlled; (d) That any information disclosed should be limited to that information, portion of the medical record, or abstract necessary to fulfill the immediate and specific purpose of disclosure; and (e) That the Health Insurance Portability and Accountability Act of 1996 (HIPAA) be the minimal standard for protecting clinician-patient privilege, regardless of where care is received.
2. Our AMA affirms: (a) that physicians and medical students who are patients are entitled to the same right to privacy and confidentiality of personal medical information and medical records as other patients, (b) that when patients exercise their right to keep their personal medical histories confidential, such action should not be regarded as fraudulent or inappropriate concealment, and (c) that physicians and medical students should not be required to report any aspects of their patients' medical history to governmental agencies or other entities, beyond that which would be required by law.
3. Employers and insurers should be barred from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions against individuals. (a) Release forms that authorize access should be explicit about to whom access is being granted and for what purpose, and should be as narrowly tailored as possible. (b) Patients, physicians, and medical students should be educated about the consequences of signing overly-broad consent forms. (c) Employers and insurers should adopt explicit and public

policies to assure the security and confidentiality of patients' medical information. (d) A patient's ability to join or a physician's participation in an insurance plan should not be contingent on signing a broad and indefinite consent for release and disclosure.
4. Whenever possible, medical records should be de-identified for purposes of use in connection with utilization review, panel credentialing, quality assurance, and peer review.
5. The fundamental values and duties that guide the safekeeping of medical information should remain constant in this era of computerization. Whether they are in computerized or paper form, it is critical that medical information be accurate, secure, and free from unauthorized access and improper use.
6. Our AMA recommends that the confidentiality of data collected by race and ethnicity as part of the medical record, be maintained.
7. Genetic information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual.
8. When breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest possible to achieve the necessary end.
9. Law enforcement agencies requesting private medical information should be given access to such information only through a court order. This court order for disclosure should be granted only if the law enforcement entity has shown, by clear and convincing evidence, that the information sought is necessary to a legitimate law enforcement inquiry; that the needs of the law enforcement authority cannot be satisfied by non-identifiable health information or by any other information; and that the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains. These records should be subject to stringent security measures.
10. Our AMA must guard against the imposition of unduly restrictive barriers to patient records that would impede or prevent access to data needed for medical or public health research or quality improvement and accreditation activities. Whenever possible, de-identified data should be used for these purposes. In those contexts where personal identification is essential for the collation of data, review of identifiable data should not take place without an institutional review board (IRB) approved justification for the retention of identifiers and the consent of the patient. In those cases where obtaining patient consent for disclosure is impracticable, our AMA endorses the oversight and accountability provided by an IRB.
11. Marketing and commercial uses of identifiable patients' medical information may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must first give their uncoerced permission after being fully informed about the purpose of such disclosures
12. Our AMA, in collaboration with other professional organizations, patient advocacy groups and the public health community, should continue its advocacy for privacy and confidentiality regulations, including: (a) The establishment of rules allocating liability for disclosure of identifiable patient medical information between physicians and the health plans of which they are a part, and securing appropriate physicians' control over the disposition of information from their patients' medical records. (b) The establishment of rules to prevent disclosure of identifiable patient medical information for commercial and marketing purposes; and (c) The establishment of penalties for negligent or deliberate breach of confidentiality or violation of patient privacy rights.
13. Our AMA will pursue an aggressive agenda to educate patients, the public, physicians and policymakers at all levels of government about concerns and complexities of patient privacy and confidentiality in the variety of contexts mentioned.
14. Disclosure of personally identifiable patient information to public health physicians and departments is appropriate for the purpose of addressing public health emergencies or to

comply with laws regarding public health reporting for the purpose of disease surveillance.
15. In the event of the sale or discontinuation of a medical practice, patients should be notified whenever possible and asked for authorization to transfer the medical record to a new physician or care provider. Only de-identified and/or aggregate data should be used for "business decisions," including sales, mergers, and similar business transactions when ownership or control of medical records changes hands.
16. The most appropriate jurisdiction for considering physician breaches of patient confidentiality is the relevant state medical practice act. Knowing and intentional breaches of patient confidentiality, particularly under false pretenses, for malicious harm, or for monetary gain, represents a violation of the professional practice of medicine.
17. Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of genetic testing.
18. Our AMA supports privacy standards that would require pharmacies to obtain a prior written and signed consent from patients to use their personal data for marketing purposes.
19. Our AMA supports privacy standards that require pharmacies and drug store chains to disclose the source of financial support for drug mailings or phone calls.
20. Our AMA supports privacy standards that would prohibit pharmacies from using prescription refill reminders or disease management programs as an opportunity for marketing purposes.
21.Our AMA will draft model state legislation requiring consent of all parties to the recording of a physician-patient conversation.
Citation: BOT Rep. 9, A-98; Reaffirmation I-98; Appended: Res. 4, and Reaffirmed: BOT Rep. 36, A-99; Appended: BOT Rep. 16 and Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: Res. 246 and 504 and Appended Res. 504 and 509, A-01; Reaffirmed: BOT Rep. 19, I-01; Appended: Res. 524, A-02; Reaffirmed: Sub. Res. 206, A-04; Reaffirmed: BOT Rep. 24, I-04; Reaffirmed: BOT Rep. 19, I-06; Reaffirmation A-07; Reaffirmed: BOT Rep. 19, A-07; Reaffirmed: CEJA Rep. 6, A-11; Reaffirmed in lieu of Res. 705, A-12; Reaffirmed: BOT Rep. 17, A-13; Modified: Res. 2, I-14; Reaffirmation: A-17; Modified: BOT Rep. 16, A-18; Appended: Res. 232, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 223
(I-18)

Introduced by: Michigan

Subject: Permanent Reauthorization of the State Children's Health Insurance Program

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, Our AMA supports health insurance coverage for all children as a national priority; and

Whereas, The State Children's Health Insurance Program (SCHIP) provides comprehensive health care insurance to over 8.9 million children and 360,000 pregnant women across the country; and

Whereas, The purpose of SCHIP is to provide health insurance to children from socioeconomically disadvantaged backgrounds; and

Whereas, Children are covered by SCHIP if their parents earn too much for Medicaid but cannot afford private insurance; and

Whereas, The proportion of uninsured children dropped from 15 percent to 9 percent of all children since SCHIP's establishment in 1997 and the rates of uninsured children within the typical SCHIP family income range fell from 22.8 percent to 6.7 percent from 1997 to 2015; and

Whereas, Children in SCHIP have better access to care, fewer unmet needs, better educational performance, and greater financial protection compared to when they were uninsured; and

Whereas, SCHIP is jointly funded by federal and state governments, and funds are administered individually at the state level; and

Whereas, Federal funding for SCHIP expired on September 30, 2017, because of political arguments unrelated to health care and stable funding was not restored until January 23, 2018; and

Whereas, During the first four months of FY 2018, states operated SCHIP without renewal of federal funding until Congress extended SCHIP with a 6-year extension on January 22, 2018; and

Whereas, Prior to the 6-year extension, 31 states were projected to exhaust SCHIP funds by March 2018 and by the end of fiscal year 2018, all 50 states would have exhausted remaining CHIP funding; and

Whereas, During this lapse in funding, 14 states planned on freezing, phasing out, or terminating coverage for children once their funds ran out, which would have left 611,052 children without health insurance on February 1, 2018; and

Whereas, Seven other states planned to close or cap total enrollment, three planned to decrease or terminate funds for pregnant women, and a handful would have transitioned children from CHIP to Medicaid programs; thereby, increasing state costs through the lower Medicaid reimbursement rate; and

Whereas, During previous state freezes in SCHIP enrollment, affected children went almost entirely without access to health care services and families faced financial hardship; and

Whereas, A permanent extension and reauthorization of SCHIP would prevent these vulnerable populations from going without access to health care and would prevent SCHIP from being inappropriately used in future political arguments; and

Whereas, Long-term funding of SCHIP saves money for state and federal governments, evidenced by the Congressional Budget Office's official estimates stating that a five-year CHIP extension would cost $800 million but a 10-year extension would save $6 billion; and

Whereas, Despite SCHIP's current authorization lasting for 10 years, multiple United States Senators have advocated for a permanent reauthorization of CHIP, which would save money for state and federal governments, as well as provide certainty to those governments and the families who need it; therefore be it

RESOLVED, That our American Medical Association amend policy H-290.971, "Expanding Enrollment for the State Children's Health Insurance Program (SCHIP)," by addition and deletion to read as follows:

Our AMA continues to support:
a. health insurance coverage of all children as a strategic priority;
b. efforts to expand coverage to uninsured children who are eligible for the State Children's Health Insurance Program (SCHIP) and Medicaid through improved and streamlined enrollment mechanisms;
c. the permanent reauthorization of SCHIP ~~in 2007~~; and
d. supports the use of enrollment information for participation in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and/or the federal school lunch assistance program as documentation for SCHIP eligibility in order to allow families to avoid duplication and the cumbersome process of re-documenting income for child health coverage (Modify Current HOD Policy); and be it further

RESOLVED, That our American Medical Association amend policy D-290.982, "State Children's Health Insurance Program Reauthorization (SCHIP)," by addition and deletion to read as follows:

1. Our AMA strongly supports the permanent reauthorization of the State Children's Health Insurance Program ~~reauthorization~~ and will lobby toward this end.
2. Our AMA will lobby Congress to:
a. provide performance-based financial assistance for new coverage costs with expanded coverage of uninsured children through SCHIP through an enhanced federal match;
b. allow states to use SCHIP funds to augment employer-based coverage;
c. allow states to explicitly use SCHIP funding to cover eligible pregnant women;
d. allow states the flexibility to cover all eligible children residing in the United States and pregnant women through the SCHIP program without a mandatory waiting period;
e. provide $60 billion in additional funding for SCHIP to ensure adequate funding of the SCHIP program and incentivize states to expand coverage to qualified children, and support incentives for physicians to participate; and
f. ensure predictable funding of SCHIP in the future.
3. Our AMA will urge Congress to provide targeted funding for SCHIP enrollment outreach (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA actively lobby the United States Congress for a permanent reauthorization of the Children's Health Insurance Program. (Directive to Take Action)

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

Received: 10/10/18

RELEVANT AMA POLICY

Expanding Enrollment for the State Children's Health Insurance Program (SCHIP) H-290.971
Our AMA continues to support:
a. health insurance coverage of all children as a strategic priority;
b. efforts to expand coverage to uninsured children who are eligible for the State Children's Health Insurance Program (SCHIP) and Medicaid through improved and streamlined enrollment mechanisms;
c. the reauthorization of SCHIP in 2007; and
d. supports the use of enrollment information for participation in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and/or the federal school lunch assistance program as documentation for SCHIP eligibility in order to allow families to avoid duplication and the cumbersome process of re-documenting income for child health coverage.
Citation: (Res. 118, A-07; CMS Rep. 1, A-07; Reaffirmation A-14)

Enhanced SCHIP Enrollment, Outreach, and Reimbursement H-290.976
1. It is the policy of our AMA that prior to or concomitant with states' expansion of State Children's Health Insurance Programs to adult coverage, our American Medical Association urge all states to maximize their efforts at outreach and enrollment of SCHIP eligible children, using all available state and federal funds.
2. Our AMA affirms its commitment to advocating for reasonable SCHIP and Medicaid reimbursement for its medical providers, defined as at minimum 100% of RBRVS Medicare allowable.
Citation: Res. 103, I-01; Reaffirmation A-07; Reaffirmation A-11; Reaffirmed: CMS Rep. 7, I-14; Reaffirmation A-15; Reaffirmed: CMS Rep. 3, A-15; Reaffirmation: A-17

State Children's Health Insurance Program Reauthorization (SCHIP) D-290.982
1. Our AMA strongly supports the State Children's Health Insurance Program reauthorization and will lobby toward this end.
2. Our AMA will lobby Congress to:
a. provide performance-based financial assistance for new coverage costs with expanded coverage of uninsured children through SCHIP through an enhanced federal match;
b. allow states to use SCHIP funds to augment employer-based coverage;
c. allow states to explicitly use SCHIP funding to cover eligible pregnant women;
d. allow states the flexibility to cover all eligible children residing in the United States and pregnant women through the SCHIP program without a mandatory waiting period;
e. provide $60 billion in additional funding for SCHIP to ensure adequate funding of the SCHIP program and incentivize states to expand coverage to qualified children, and support incentives for physicians to participate; and
f. ensure predictable funding of SCHIP in the future.
3. Our AMA will urge Congress to provide targeted funding for SCHIP enrollment outreach.
Citation: (Res. 117, A-07; Res. 118, A-07; Res. 119, A-07; Reaffirmation A-14)

Protecting Children, Adolescents and Young Adults in Medicaid and the State Children's Health Insurance (SCHIP) Program D-290.985
Our AMA will actively: (1) encourage state and county medical societies to advocate for initiatives to ensure that all eligible children, adolescents, and young adults are enrolled in Medicaid and SCHIP; (2) advocate for federal and state funding for Medicaid and SCHIP so that funding is sufficient to support enrollment of and provision of necessary services to all eligible children, adolescents, and young adults; and (3) encourage state and county medical societies to work to ensure that services to children, adolescents, and young adults meet Early Periodic Screening, Diagnosis, and Treatment (EPSDT) Standards.
Citation: (Res. 108, A-06; Reaffirmation A-14)

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 224
(I-18)

Introduced by: New York

Subject: Fairness in the Centers for Medicare & Medicaid Services Authorized Quality Improvement Organization's (QIO) Medical Care Review Process

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, The Center for Medicare & Medicaid has authorized quality improvement organizations (QIO) to review medical services provided to Medicare patients; and

Whereas, The QIOs perform reviews of healthcare provided to Medicare patients to determine if the care meets professionally recognized standards of care; and

Whereas, QIOs conduct these reviews to investigate complaints initiated by beneficiaries or the patients' representatives about the health care they received; and

Whereas, The QIO peer reviewer is stated to be either a physician or other practitioner who matches, as closely as possible, the variables of licensure, specialty, and practice setting of the physician or practitioner under review; and

Whereas, When the QIO peer reviewer has no peer match available, the QIO may use another physician reviewer without the same expertise; and

Whereas, The practitioner should be made aware when a reviewer is outside their area of expertise; and

Whereas, The QIO should report annually on the number of peer reviews where the reviewer was outside the reviewer's area of expertise; and

Whereas, If, after reviewing the Peer Review, the QIO determines that the Peer Reviewer has identified a concern(s) for which the standard(s) of care was not met, the practitioner and/or provider must be offered the opportunity to discuss the concern(s); and

Whereas, In instances when the practitioner and/or provider requests to submit new and/or additional medical information, the QIO advises the practitioner and/or provider of his/her right to request a reconsideration and that any new and/or additional medical information can be considered during the reconsideration process; and

Whereas, Reconsideration is the additional review performed by the QIO when requested by the beneficiary and/or the practitioner/provider when any of the parties is not pleased with the outcome of the QIO's Initial Determination; and

Whereas, If a reconsideration review is undertaken, that constitutes the QIO final decision and there are no further appeal rights available; and

Whereas, The only opportunity for the provider to respond is after the initial review and if the initial review finds no quality of care concern, the practitioner has no reason to respond; and

Whereas, If the beneficiary requests a reconsideration review and the finding is different from the initial finding, there is no recourse for the practitioner to respond; and

Whereas, If the second review has a quality of care concern identified, it is entered into the CMS database and if the QIO feels the issue may have significance beyond a single episode, a determination may be made that further intervention activities are required; and

Whereas, The CMS manual states that “In the rare instance when a Reconsideration Peer Reviewer identifies a new concern, the Reviewer must notify the QIO for the QIO to initiate processing of the newly identified concern at the Quality of Care Review Stage. The Reconsideration Peer Reviewer must not evaluate the concern because the matter will be eligible for review by an Initial Determination Peer Reviewer”; and

Whereas, QIOs are not interpreting this to allow for a new review in cases where the initial peer review found no quality of care issue; and

Whereas, CMS states that the Peer review is intended to be a collegial interaction with the goal of improving patient care; and

Whereas, The CMS QIO manual states that it is a “basic premise of fairness that beneficiaries, practitioners and/or providers are notified of the ability to file a request for reconsideration”; and

Whereas, By extension it is a basic premise of fairness that a practitioner should be able to defend an allegation of a deviation from a standard of care; and

Whereas, QIOs purport that their primary purpose is to identify areas where health care services can be improved and provide feedback to facilities and practitioners; and

Whereas, The QIOs state that the Peer review is intended to be a collegial interaction with the goal of improving patient care; therefore, be it

RESOLVED, That our American Medical Association seek by regulation and/or legislation to amend the Centers for Medicare and Medicaid Services (CMS) quality improvement organization (QIO) process to mandate an opportunity for practitioners and/or providers to request an additional review when the QIO initial determination peer review and the QIO reconsideration peer review are in conflict (Directive to Take Action); and be it further

RESOLVED, That our AMA seek by regulation and/or legislation to require CMS authorized QIOs to disclose to practitioners and/or providers when the QIO peer reviewer is not a peer match and is reviewing a case outside of their area of expertise (Directive to Take Action); and be it further

RESOLVED, That our AMA seek by regulation and/or legislation to require CMS authorized QIOs to disclose in their annual report, the number of peer reviews performed by reviewers without the same expertise as the physician being reviewed. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.
Received: 10/09/18

Reference:
https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/qio110c05.pdf

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 225
(I-18)

Introduced by: New York

Subject: "Surprise" Out of Network Bills

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, Legislation is under consideration in the United State Senate to create new rules for payment of "surprise" out of network bills for patients treated in hospitals; and

Whereas, Components of this draft legislation would call for health insurers to pay for out of network "surprise" bills as a percentage of in-network rates; and

Whereas, These "surprise" out of network bills are often the result of health insurers creating narrow networks that limit patient choice and dis-incentivize physician participation; and

Whereas, Failure to ensure fair payment for out of network emergency care could have an enormously adverse impact on the ability of hospitals to assure necessary availability of on-call specialty physician care to meet patient need; and

Whereas, Several states across the country have enacted laws that provide patients protection against these "surprise" bills; and

Whereas, The AMA has adopted policy H-285.904, "Out-of-Network Care," that includes a component that "Insurers must meet appropriate network adequacy standards that include adequate patient access to care, including access to hospital-based physician specialties"; and

Whereas, AMA Policy H-285.904 also states that "Out-of-network payments must not be based on a contrived percentage of the Medicare rate or rates determined by the insurance company"; and

Whereas, AMA policy H-285.904 also states, with regard to "unanticipated" out of network services, that "Minimum coverage standards should pay out-of-network providers at the usual and customary out-of-network charges for services, with the definition of usual and customary based upon a percentile of all out-of-network charges for the particular health care service performed by a provider in the same or similar specialty and provided in the same geographical area as reported by a benchmarking database. Such a benchmarking database must be independently recognized and verifiable, completely transparent, independent of the control of either payers or providers and maintained by a non-profit organization. The non-profit organization shall not be affiliated with an insurer, a municipal cooperative health benefit plan or health management organization"; and

Whereas, Current AMA policy does not expressly call for the AMA to advocate for federal legislation consistent with these principles; and

Whereas, Current federal legislation does not address health insurer network adequacy problems; and

Whereas, Federal legislation has the potential to pre-empt state laws that have been shown to address these problems in ways that are fair to patients, health insurers, hospitals and physicians; and

Whereas, Even if such federal legislation were to not pre-empt state law, it has the potential to create new standards that states with existing “surprise” bill laws may seek to match; therefore be it

RESOLVED, That our American Medical Association advocate that any federal legislation on “surprise” out of network medical bills be consistent with AMA Policy H-285.904, “Out-of-Network Care,” and apply to ERISA plans not subject to state regulation (New HOD Policy); and be it further

RESOLVED, That our AMA advocate that such federal legislation protect state laws that do not limit surprise out of network medical bills to a percentage of Medicare or health insurance fee schedules. (New HOD Policy)

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

Received: 10/10/18

RELEVANT AMA POLICY

Out-of-Network Care H-285.904
1. Our AMA adopts the following principles related to unanticipated out-of-network care:
A. Patients must not be financially penalized for receiving unanticipated care from an out-of-network provider.
B. Insurers must meet appropriate network adequacy standards that include adequate patient access to care, including access to hospital-based physician specialties. State regulators should enforce such standards through active regulation of health insurance company plans.
C. Insurers must be transparent and proactive in informing enrollees about all deductibles, copayments and other out-of-pocket costs that enrollees may incur.
D. Prior to scheduled procedures, insurers must provide enrollees with reasonable and timely access to in-network physicians.
E. Patients who are seeking emergency care should be protected under the "prudent layperson" legal standard as established in state and federal law, without regard to prior authorization or retrospective denial for services after emergency care is rendered.
F. Out-of-network payments must not be based on a contrived percentage of the Medicare rate or rates determined by the insurance company.
G. Minimum coverage standards for unanticipated out-of-network services should be identified. Minimum coverage standards should pay out-of-network providers at the usual and customary out-of-network charges for services, with the definition of usual and customary based upon a percentile of all out-of-network charges for the particular health care service performed by a provider in the same or similar specialty and provided in the same geographical area as reported by a benchmarking database. Such a benchmarking database must be independently recognized and verifiable, completely transparent, independent of the control of either payers or providers and maintained by a non-profit organization. The non-profit organization shall not be affiliated with an insurer, a municipal cooperative health benefit plan or health management organization.
H. Mediation should be permitted in those instances where a physicians unique background or skills (e.g. the Gould Criteria) are not accounted for within a minimum coverage standard.
2. Our AMA will advocate for the principles delineated in Policy H-285.904 for all health plans, including ERISA plans.
Citation: Res. 108, A-17; Reaffirmation: A-18; Appended: Res. 104, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 226
(I-18)

Introduced by: Utah

Subject: Support for Interoperability of Clinical Data

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, As of 2016 78% of physicians and 96% of hospitals routinely use electronic health records (EHRs) during care,[1] and nationally only half of hospitals have necessary patient information electronically available from providers or sources outside their systems at the point of care[2]; and

Whereas, Accessing patient data through a health information exchange (HIE) in an emergency department has been shown to reduce hospital admissions, and decrease unneeded diagnostic imaging and procedures[3]; and

Whereas, An HIE increases provider access to data necessary for treatment such as results of tests conducted in another health care practice while lack of exchange may result in duplicate and unnecessary testing[3-6]; and

Whereas, An HIE has been shown to reduce net annual costs for patient care, even after accounting for costs related to the HIE,[3,7] and cost reductions are seen in healthcare markets that have operational HIEs caring for Medicare patients[8,9]; and

Whereas, Clinicians across the country need ready access to data from clinical settings outside their own to deliver cost effective, non-duplicative care for their patients; and
to be competitive in new payment arrangements that incentivize coordinated care, reduction in unneeded testing and imaging, and a view of the health of their patient in and outside of the clinical setting; therefore be it

RESOLVED, That our American Medical Association review and advocate for the implementation of appropriate recommendations from the “Consensus Statement: Feature and Function Recommendations to Optimize Clinician Usability of Direct Interoperability to Enhance Patient Care,” a physician-directed set of recommendations, to EHR vendors and relevant federal offices such as, but not limited to, the Office of the National Coordinator, and the Centers for Medicare and Medicaid Services. (Directive to Take Action)

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

Received: 10/11/18

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 227
(I-18)

Introduced by: American College of Rheumatology, American Academy of Allergy, Asthma & Immunology, American Academy of Dermatology, American Academy of Neurology, American Academy of Physical Medicine and Rehabilitation, American Association of Clinical Endocrinologists, American Clinical Neurophysiology Society, American Gastroenterological Association, American Psychiatric Association, American Society of Clinical Oncology, Endocrine Society, Infectious Diseases Society of America, Maryland, North American Neuro-Ophthalmology Society, Society for Investigative Dermatology, Kentucky, Georgia

Subject: CMS Proposal to Consolidate Evaluation and Management Services

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

Whereas, Our AMA and the state and specialty medical societies of the AMA federation are committed to working with the Centers for Medicare and Medicaid Services (CMS) to reduce provider burden and increase Medicare beneficiaries' access to appropriate care; and

Whereas, CMS is to be commended for recognizing the problems with the current evaluation and management documentation guidelines and codes, and for including a significant proposal to address them in the CY 2019 Medicare physician fee schedule proposed rule; and

Whereas, CMS in its physician fee schedule proposed rule put forward a plan to cut and consolidate evaluation and management services, which would severely reduce Medicare patients' access to care by cutting payments for complex office visits, adversely affecting the care and treatment of patients with complex conditions; and

Whereas, The proposals to consolidate the billing codes for physician evaluation and management so as to pay the same amount for office visits regardless of the complexity of the patient would cut payments for visits that are currently reimbursed at higher levels than simple or routine office visits, penalizing doctors who treat sicker or complex patients, or patients with multiple conditions; and

Whereas, Payments from newly proposed add-on codes, which have been put forward with the intention of protecting complex care by making up for severe cuts, are not certain and likely would not be sufficient to ensure continued patient access, and moreover the application of new codes to some specialties and not others would effectively result in CMS picking winners and losers; and

Whereas, We agree with CMS' ultimate goal of increasing the amount of time physicians have to spend with patients instead of paperwork and computers, but the collapsing of evaluation and management codes would have an immediate and lasting effect of restricting patient access to care; and

Whereas, CMS is expected to release the CY 2019 physician fee schedule final rule in November of 2018, less than two months ahead of the proposed implementation date of January 1, 2019; and

Whereas, Given the negative impacts of this well-intentioned proposal, CMS should not finalize these concepts as proposed; and

Whereas, The physician community stands ready to work with CMS to identify alternative approaches that would accomplish its goal of reducing paperwork and administrative burden without endangering patient access to care, and while ensuring that physicians have the resources they need to provide patients with the high-quality care they deserve; therefore be it

RESOLVED, That our American Medical Association actively seek and support congressional action before January 1, 2019 that would prevent implementation of changes to consolidate evaluation and management services as put forward in the CY 2019 Medicare physician fee schedule proposed rule if CMS in the final rule moves forward with the consolidation of evaluation and management services. (Directive to Take Action)

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

Received: 10/11/18

RELEVANT AMA POLICY

Medicare Guidelines for Evaluation and Management Codes H-70.952
Our AMA (1) seeks Federal regulatory changes to reduce the burden of documentation for evaluation and management services; (2) will use all available means, including development of new Federal legislation and/or legal measures, if necessary, to ensure appropriate safeguards for physicians, so that insufficient documentation or inadvertent errors in the patient record, that does not meet evaluation and management coding guidelines in and of itself, does not constitute fraud or abuse; (3) urges CMS to adequately fund Medicare Carrier distribution of any documentation guidelines and provide funding to Carriers to sponsor educational efforts for physicians; (4) will work to ensure that the additional expense and time involved in complying with documentation requirements be appropriately reflected in the Resource Based Relative Value Scale (RBRVS); (5) will facilitate review and corrective action regarding the excessive content of the evaluation and management documentation guidelines in collaboration with the national medical specialty societies and to work to suspend implementation of all single system examination guidelines until approved by the national medical specialty societies affected by such guidelines; (6) continues to advise and educate physicians about the guidelines, any revisions, and their implementation by CMS; (7) urges CMS to establish a test period in a specific geographic region for these new guidelines to determine any effect their implementation will have on quality patient care, cost effectiveness and efficiency of delivery prior to enforcement of these mandated regulations; (8) opposes adoption of the Medicare evaluation and management documentation guidelines for inclusion in the CPT; and (9) AMA policy is that in medical documentation the inclusion of any items unrelated to the care provided (e.g., irrelevant negatives) not be required.
Citation: (Sub. Res. 801, I-97; Reaffirmation I-00; Reaffirmed: CMS Rep. 6, A-10)

Preservation of Evaluation/Management CPT Codes H-70.985
It is the policy of the AMA to (1) oppose the bundling of procedure and laboratory services within the current CPT Evaluation/Management (E/M) services; (2) oppose the compression of E/M codes and support efforts to better define and delineate such services and their codes; (3) seek feedback from its members on insurance practices that advocate bundling of procedures and

laboratory services with or the compression of codes in the CPT E/M codes, and express its views to such companies on behalf of its members; (4) continue to work with the PPRC and all other appropriate organizations to insure that any modifications of CPT E/M codes are appropriate, clinically meaningful, and reflective of the considered views of organized medicine; and (5) work to ensure that physicians have the continued opportunity to use CPT as a coding system that is maintained by the medical profession.
Citation: (Sub. Res. 98, A-90; Reaffirmed by Res. 850, A-98; Reaffirmed: Res. 814, A-00; Reaffirmation I-00; Reaffirmed: CMS Rep. 6, A-10)

Preservation of Five Levels of Evaluation and Management Services D-70.979
Our AMA will communicate to the Centers for Medicare and Medicaid Services and to private payers that the current levels of Evaluation and Management services should be maintained and not compressed, with appropriate payment for each level.
Citation: Sub. Res. 804, I-01; Reaffirmation A-06; Reaffirmed in lieu of Res. 823, I-06; Modified: CMS Rep. 01, A-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 602
(I-18)

Introduced by: Indiana

Subject: AMA Policy Statement with Editorials

Referred to: Reference Committee F
(Greg Tarasidis, MD, Chair)

Whereas, Freedom of speech is essential and all side of an issue deserve to be discussed; and

Whereas, Our AMA has good policy on most medical issues; and

Whereas, The Aug. 22-29, 2017, *JAMA* published an editorial on MOC contrary to AMA policy; therefore be it

RESOLVED, Our American Medical Association include a policy statement after all editorials in which policy has been established to clarify our position. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/09/18

RELEVANT AMA POLICY

AMA Publications G-630.090
AMA policy on its publications includes the following:
(1) JAMA and other AMA scientific journals should display a disclaimer in prominent print that the editorial views are not necessarily AMA policy.
(2) Our AMA, in all of its publications and correspondence, will use the correct title for the medical specialist.
(3) Our AMA recommends that medical journal articles using acronyms should have a small glossary of acronyms and phrases displayed prominently in the article.
(4) The House of Delegates affirms that JAMA and The JAMA Network journals shall continue to have full editorial independence as set forth in the AMA Editorial Governance Plan.
Res. 294, A-90 BOT Rep. G, A-91 BOT Rep. VV, I-92 BOT Rep. PP, A-93 Res. 622, I-96 Res. 612, A-97 Reaffirmed: Sunset Report and Appended: BOT Rep. 22, I-00 Consolidated: CLRPD Rep. 3, I-01 Appended: BOT Rep. 32, A-04 Modified: CCB/CLRPD Rep. 3, A-12 Modified: Speakers Rep., A-15

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 603
(I-18)

Introduced by: Minority Affairs Section

Subject: Support of AAIP's "Desired Qualifications for Indian Health Service Director"

Referred to: Reference Committee F
(Greg Tarasidis, MD, Chair)

Whereas, The Indian Health Service is a federal agency with a multi-billion dollar budget that provides health care to American Indian and Alaska Native members of federally recognized Tribes; and

Whereas, The basis of this health care provision is a special government-to-government relationship established in 1787, by Article 1, Section 8 of the United States Constitution; and

Whereas, The director of the Indian Health Service is a political appointment that requires confirmation by the United States Senate; and

Whereas, In consideration of the unique demands for the Indian Health Service Director, the Association of American Indian Physicians adopted "Desired Qualifications for the Director of the Indian Health Service"[1], as follows:

1. Health profession, preferably an MD or DO, degree and at least five years of clinical experience.
2. Demonstrated long-term interest, commitment, and activity within the field of Indian Health.
3. Lived on tribal lands or rural American Indian or Alaska Native community or has interacted closely with an urban Indian community.
4. Leadership position in American Indian/Alaska Native health care or a leadership position in an academic setting with activity in American Indian/ Alaska Native health care.
5. Experience in the Indian Health Service or has worked extensively with Indian Health Service, Tribal, or Urban Indian health programs.
6. Knowledge and understanding of social and cultural issues affecting the health of American Indian and Alaska Native people.
7. Knowledge of health disparities among Native Americans / Alaska Natives, including the pathophysiological basis of the disease process and the social determinants of health that affect disparities.
8. Experience working with Indian Tribes and Nations and an understanding of the Trust Responsibility of the Federal Government for American Indian and Alaska Natives as well as an understanding of the sovereignty of American Indian and Alaska Native Nations.
9. Experience with management, budget, and federal programs; therefore be it

[1] AAIP "Desired Qualifications for the Director of the Indian Health Service" http://files.constantcontact.com/82ca0b6a001/17d8e3c8-755a-4644-8814-bb60ce9c667c.pdf?ver=1512063577000

RESOLVED, That our American Medical Association support the "Desired Qualifications for the Director of the Indian Health Service" set forth by the Association of American Indian Physicians. (New HOD Policy)

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

Received: 10/03/18

RELEVANT AMA POLICY

Indian Health Service H-350.977
The policy of the AMA is to support efforts in Congress to enable the Indian Health Service to meet its obligation to bring American Indian health up to the general population level. The AMA specifically recommends: (1) Indian Population: (a) In current education programs, and in the expansion of educational activities suggested below, special consideration be given to involving the American Indian and Alaska native population in training for the various health professions, in the expectation that such professionals, if provided with adequate professional resources, facilities, and income, will be more likely to serve the tribal areas permanently; (b) Exploration with American Indian leaders of the possibility of increased numbers of nonfederal American Indian health centers, under tribal sponsorship, to expand the American Indian role in its own health care; (c) Increased involvement of private practitioners and facilities in American Indian care, through such mechanisms as agreements with tribal leaders or Indian Health Service contracts, as well as normal private practice relationships; and (d) Improvement in transportation to make access to existing private care easier for the American Indian population.
(2) Federal Facilities: Based on the distribution of the eligible population, transportation facilities and roads, and the availability of alternative nonfederal resources, the AMA recommends that those Indian Health Service facilities currently necessary for American Indian care be identified and that an immediate construction and modernization program be initiated to bring these facilities up to current standards of practice and accreditation.
(3) Manpower: (a) Compensation for Indian Health Service physicians be increased to a level competitive with other Federal agencies and nongovernmental service; (b) Consideration should be given to increased compensation for service in remote areas; (c) In conjunction with improvement of Service facilities, efforts should be made to establish closer ties with teaching centers, thus increasing both the available manpower and the level of professional expertise available for consultation; (d) Allied health professional staffing of Service facilities should be maintained at a level appropriate to the special needs of the population served; (e) Continuing education opportunities should be provided for those health professionals serving these communities, and especially those in remote areas, and, increased peer contact, both to maintain the quality of care and to avert professional isolation; and (f) Consideration should be given to a federal statement of policy supporting continuation of the Public Health Service to reduce the great uncertainty now felt by many career officers of the corps.
(4) Medical Societies: In those states where Indian Health Service facilities are located, and in counties containing or adjacent to Service facilities, that the appropriate medical societies should explore the possibility of increased formal liaison with local Indian Health Service physicians. Increased support from organized medicine for improvement of health care provided under their direction, including professional consultation and involvement in society activities should be pursued.
(5) Our AMA also support the removal of any requirement for competitive bidding in the Indian Health Service that compromises proper care for the American Indian population.
Citation: (CLRPD Rep. 3, I-98; Reaffirmed: CLRPD Rep. 1, A-08; Reaffirmation A-12; Reaffirmed: Res. 233, A-13)

Improving Health Care of American Indians H-350.976
Our AMA recommends that: (1) All individuals, special interest groups, and levels of government recognize the American Indian people as full citizens of the U.S., entitled to the same equal rights and privileges as other U.S. citizens.
(2) The federal government provide sufficient funds to support needed health services for American Indians.
(3) State and local governments give special attention to the health and health-related needs of nonreservation American Indians in an effort to improve their quality of life.
(4) American Indian religions and cultural beliefs be recognized and respected by those responsible for planning and providing services in Indian health programs.
(5) Our AMA recognize the "medicine man" as an integral and culturally necessary individual in delivering health care to American Indians.
(6) Strong emphasis be given to mental health programs for American Indians in an effort to reduce the high incidence of alcoholism, homicide, suicide, and accidents.
(7) A team approach drawing from traditional health providers supplemented by psychiatric social workers, health aides, visiting nurses, and health educators be utilized in solving these problems.
(8) Our AMA continue its liaison with the Indian Health Service and the National Indian Health Board and establish a liaison with the Association of American Indian Physicians.
(9) State and county medical associations establish liaisons with intertribal health councils in those states where American Indians reside.
(10) Our AMA supports and encourages further development and use of innovative delivery systems and staffing configurations to meet American Indian health needs but opposes overemphasis on research for the sake of research, particularly if needed federal funds are diverted from direct services for American Indians.
(11) Our AMA strongly supports those bills before Congressional committees that aim to improve the health of and health-related services provided to American Indians and further recommends that members of appropriate AMA councils and committees provide testimony in favor of effective legislation and proposed regulations.
Citation: (CLRPD Rep. 3, I-98; Reaffirmed: Res. 221, A-07; Reaffirmation A-12; Reaffirmed: Res. 233, A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 806
(I-18)

Introduced by: AMDA – The Society for Post-Acute and Long-Term Care Medicine

Subject: Telemedicine Models and Access to Care in Post-Acute and Long-Term Care

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

Whereas, The Centers for Medicare and Medicaid Services (CMS) authorized virtual clinical visits and payments for such services under the new Physician Fee Schedule (PFS) and Quality Payment Program (QPP) announced in July 2018; and

Whereas, CMS and numerous participating skilled nursing facilities (SNFs) have generated savings and created efficiencies and better outcomes, including a reduction in avoidable rehospitalizations in post-acute care of Medicare recipients by way of Medicare innovation programs (CMMI), including use of telemedicine and increased availability of medical practitioners onsite; and

Whereas, CMS has restricted the number of telemedicine encounters allowed per Medicare beneficiary to one per month, instead of frequency based on medical necessity, even as there is demonstrable benefit of such visits for patients who are frail, elderly and have multiple chronic and complex medical care needs along with a lack of ready and timely access to clinical practitioners; therefore be it

RESOLVED, That our American Medical Association advocate for removal of arbitrary limits on telemedicine visits by medical practitioners in nursing facilities and instead base them purely on medical necessity, and collaborate with AMDA – The Society for Post-Acute and Long-Term Care Medicine to effect a change in Medicare's policy regarding this matter under the provisions of Physician Fee Schedule (PFS) and Quality Payment Program (QPP) (New HOD Policy); and be it further

RESOLVED, That our AMA work with AMDA-The Society for Post-Acute and Long-Term Care Medicine and other stakeholders to influence Congress to broaden the scope of telemedicine care models in post-acute and long-term care and authorize payment mechanisms for models that are evidence based, relevant to post-acute and long-term care and continue to engage primary care physicians and practitioners in the care of their patients. (Directive to Take Action)

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

Received: 10/03/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 807
(I-18)

Introduced by: American College of Emergency Physicians

Subject: Emergency Department Copayments for Medicaid Beneficiaries

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

Whereas, Copayments (copays) for emergency department services have been shown to create a significant barrier to necessary emergency care for Medicaid enrollees[1]; and

Whereas, Many Medicaid programs utilize the current federally allowed copay up to eight dollars for emergency department services determined to be non-emergent[2]; and

Whereas, For the purposes of determining non-emergency, and therefore imposition of copays for Medicaid enrollees, many states use the Emergency Severity Index (ESI) triage levels or final diagnoses rather than the Prudent Layperson Standard[3] as directed in the CMS guidance for implementation of such copays[4]; and

Whereas, Our AMA Policy H-130.970 opposes implementation of policies that violate the Prudent Layperson Standard of determining when to seek emergency care[5]; and

Whereas, States are using Section 1115 Medicaid waiver demonstrations to implement emergency department copays of increasing amounts and to apply such emergency department copays even for emergent services; and

Whereas, Medicaid programs that have copays for non-emergent use of the emergency department do not decrease such non-emergent use[6] and do not decrease overall Medicaid costs[7]; and

Whereas, The calculated effect of Indiana's increased Medicaid emergency department copay ($25), allowed by a 2015 CMS Medicaid waiver demonstration, used a retrospective definition of "emergency," disregarding the federal Prudent Layperson Standard; and

Whereas, Copays requested at the time of registration in the emergency department could intimidate patients from receiving a mandated medical screening exam, thus placing the hospital at risk for an EMTALA violation[8]; therefore be it

RESOLVED, That our American Medical Association oppose imposition of copays for Medicaid beneficiaries seeking care in the emergency department. (New HOD Policy)

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

Received: 10/10/18

RELEVANT AMA POLICY

Access to Emergency Services H-130.970
1. Our AMA supports the following principles regarding access to emergency services; and these principles will form the basis for continued AMA legislative and private sector advocacy efforts to assure appropriate patient access to emergency services:
(A) Emergency services should be defined as those health care services that are provided in a hospital emergency facility after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in: (1) placing the patient's health in serious jeopardy; (2) serious impairment to bodily function; or (3) serious dysfunction of any bodily organ or part.
(B) All physicians and health care facilities have an ethical obligation and moral responsibility to provide needed emergency services to all patients, regardless of their ability to pay. (Reaffirmed by CMS Rep. 1, I-96)
(C) All health plans should be prohibited from requiring prior authorization for emergency services.
(D) Health plans may require patients, when able, to notify the plan or primary physician at the time of presentation for emergency services, as long as such notification does not delay the initiation of appropriate assessment and medical treatment.
(E) All health payers should be required to cover emergency services provided by physicians and hospitals to plan enrollees, as required under Section 1867 of the Social Security Act (i.e., medical screening examination and further examination and treatment needed to stabilize an "emergency medical condition" as defined in the Act) without regard to prior authorization or the emergency care physician's contractual relationship with the payer.
(F) Failure to obtain prior authorization for emergency services should never constitute a basis for denial of payment by any health plan or third party payer whether it is retrospectively determined that an emergency existed or not.
(G) States should be encouraged to enact legislation holding health plans and third party payers liable for patient harm resulting from unreasonable application of prior authorization requirements or any restrictions on the provision of emergency services.
(H) Health plans should educate enrollees regarding the appropriate use of emergency facilities and the availability of community-wide 911 and other emergency access systems that can be utilized when for any reason plan resources are not readily available.
(I) In instances in which no private or public third party coverage is applicable, the individual who seeks emergency services is responsible for payment for such services.
2. Our AMA will work with state insurance regulators, insurance companies and other stakeholders to immediately take action to halt the implementation of policies that violate the prudent layperson standard of determining when to seek emergency care.
Citation: CMS Rep. A, A-89; Modified by CMS Rep. 6, I-95; Reaffirmation A-97; Reaffirmed by Sub. Res. 707, A-98; Reaffirmed: Res. 705, A-99; Reaffirmed: CMS Rep. 3, I-99; Reaffirmation A-00; Reaffirmed: Sub. Res. 706, I-00; Amended: Res. 229, A-01; Reaffirmation and Reaffirmed: Res. 708, A-02; Reaffirmed: CMS Rep. 4, A-12; Reaffirmed: CMS Rep. 07, A-16; Appended: Res. 128, A-17; Reaffirmation: A-18

References:

[1] Artiga S, Ubri P, Zur J. The effects of premiums and cost sharing on low-income populations: updated review of research findings. Kaiser Family Foundation. June 1, 2017. https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/
[2] Medicaid: Cost Sharing Out of Pocket Costs. https://www.medicaid.gov/medicaid/cost-sharing/out-of-pocket-costs/index
[3] Prudent Layperson Standard - 42 U.S.C.1395w-22(d)(3)(B) & 1396u-2(b)(2)(C)
[4] Medicaid Cost-sharing. https://www.medicaid.gov/medicaid/cost-sharing/index.html based on 42 CFR 447.5
[5] Access to Emergency Services (H-130.970). Reaffirmed A-18. https://policysearch.ama-assn.org/policyfinder/detail/130.970?uri=%2FAMADoc%2FHOD.xml-0-270.xml
[6] Mortensen, K. Copayments did not reduce Medicaid enrollees' nonemergency use of emergency departments. *Health Affairs*. 2010: 29(9), abstract http://content.healthaffairs.org/content/29/9/1643.abstract
[7] MACPAC. July 2014. Revisiting Emergency Department Use in Medicaid. https://www.macpac.gov/wp-content/uploads/2015/01/MACFacts- EDuse_2014-07.pdf
[8] Emergency Medical Treatment and Labor Act - 42 United States Code (U.S.C.) 1395dd

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 808
(I-18)

Introduced by: Tennessee

Subject: The Improper Use of Beers or Similar Criteria and Third-Party Payer Compliance Activities (H-185.940)

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

Whereas, The delegation of Tennessee has reviewed Policy H-185.940, adopted A-12, "Beers or Similar Criteria And Third-Party Payer Compliance Activities"; and

Whereas, There is evidence of fiscal harm to physicians and damage to their professional reputations by the improper application of Beers Criteria within compliance activity; and

Whereas, A health insurance company doing business in Tennessee has expanded this practice regionally to other states; therefore be it

RESOLVED, That our American Medical Association identify and establish a workgroup with insurers that are inappropriately applying Beers or similar criteria to quality rating programs and work with the insurers to resolve internal policies that financially penalize physicians (Directive to Take Action); and be it further

RESOLVED, That our AMA study and report back to the House of Delegates the 2019 Interim Meeting, the potential inappropriate use of Beers Criteria by insurance companies looking at which companies are involved and the effect of the use of these criteria on physicians' practices (Directive to Take Action); and be it further

RESOLVED, That our AMA provide a mechanism for members to report possible abuses of Beers Criteria by insurance companies. (Directive to Take Action)

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

Received: 10/10/18

RELEVANT AMA POLICY

Beers or Similar Criteria and Third Party Payer Compliances Activities H-185.940
Our AMA adopts policy: (1) discouraging health insurers, benefit managers, and other payers from using the Beers Criteria and other similar lists to definitively determine coverage and/or reimbursement, and inform health insurers and other payers of this policy; and (2) clarifying that while it is appropriate for the Beers Criteria to be incorporated in quality measures, such measures should not be applied in a punitive or onerous manner to physicians and must recognize the multitude of circumstances where deviation from the quality measure may be appropriate, and inform health insurers and other payers of this policy.
Citation: (BOT Rep. 14, A-12)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 809
(I-18)

Introduced by: American Society of Clinical Oncology

Subject: Medicaid Clinical Trials Coverage

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

Whereas, Clinical trials are often a patient's best clinical option for combating disease progression; and

Whereas, Guaranteed access to clinical trials is an important part of high-quality care that should be available to all patients with life-threatening conditions regardless of financial circumstances; and

Whereas, Sixty percent of the U.S. population resides at or below 400 percent of the federal poverty level (FPL); therefore, a significant proportion of patients with cancer may be vulnerable to financial toxicity related to the cost of their care;[1] and

Whereas, Nearly 73.4 million people were enrolled in Medicaid and CHIP as of June 2018[2]; and

Whereas, Costs related to clinical trial participation include those of new drugs or interventions as well those related to routine clinical care; and

Whereas, Routine costs include the non-experimental costs of treating a patient who is participating in a clinical trial, such as physician visits and laboratory studies; and

Whereas, The Centers for Medicare & Medicaid Services (CMS) issued a Medicare National Coverage Determination (NCD) for the Routine Costs in Clinical Trials effective July 9, 2007[3] which provided for coverage of these routine costs; and

Whereas, The Patient Protection and Affordable Care Act (ACA) prohibits private health plans or insurers from limiting or denying coverage of routine costs to patients who participate in clinical trials[4]; and

Whereas, Medicaid statutes do not require state Medicaid programs to provide coverage for the routine costs of clinical trials; and

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[1] The Kaiser Family Foundation. *Distribution of the Total Population by Federal Poverty Level (above and below 400% FPL).* 2016. http://www.kff.org/other/state-indicator/population-up-to-400-fpl/ (Accessed September 17, 2018).
[2] Centers for Medicare & Medicaid Services. *June 2018 Medicaid & CHIP Enrollment Data Highlights.* 2018. https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html (Accessed September 18, 2018).
[3] Centers for Medicare & Medicaid Services. *National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)*. July 9, 2007. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R74NCD.pdf (Accessed September 20, 2018).
[4] The Patient Protection and Affordable Care Act, 42 U.S.C.A. § 300gg-8. *Coverage for individuals participating in approved clinical trials*. 2010. https://medicine.yale.edu/ycci/comply/insurance/ACA%20Statute%2042%20USCA%20300gg-8_175006_174718_10115_v1.pdf (Accessed September 20, 2018).

Whereas, State Medicaid programs which do cover the routine costs of patients on clinical trials have policies that vary significantly by state[5]; and

Whereas, Minorities are not well represented in clinical trials, and Medicaid serves a large portion of under-represented minorities; and

Whereas, Reducing participant burdens in clinical trials is advantageous to recruiting minority populations[6], which helps to address unacceptable health disparities in cancer; and

Whereas, Several studies demonstrate that providing coverage for the routine costs of clinical trials have a minimal effect on overall care costs[7]; therefore be it

RESOLVED, That our American Medical Association actively lobby for and support federal legislation that guarantees coverage of routine patient care costs for Medicaid enrollees who participate in clinical trials. (Directive to Take Action)

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

Received: 10/11/18

RELEVANT AMA POLICY

Increasing Minority Participation in Clinical Research H-460.911
1. Our AMA advocates that:
a. The Food and Drug Administration (FDA) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations.
b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and
c. Resources be provided to community level agencies that work with those minorities who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.
2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities in clinical trials:
a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs;
b. Increased outreach to female physicians to encourage recruitment of female patients in clinical trials;
c. Continued minority physician education on clinical trials, subject recruitment, subject safety, and possible expense reimbursements;
d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and

[5] American Society of Clinical Oncology. *Insurance Coverage of Clinical Trials.* 2018. https://www.asco.org/research-progress/clinical-trials/insurance-coverage-clinical-trials#ACA (Accessed September 20, 2018).
[6] Paskett E, Reeves K, McLaughlin J, Katz M, Scheck McAlearney A, Ruffin M, Hughes Halbert C, Merete C, Davis F, Gehlert S. *Recruitment of Minority and Underserved Populations in the United States: The Centers for Population Health and Health Disparities Experience*. Contemporary Clinical Trials. 2008 Nov; 29(6):847-861. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2642621/ (Accessed September 19, 2018).
[7] Polite BN, Griggs JJ, Moy B, Lathan Christopher, duPont NC, Villani G, Wong S, Halpern MT. *American Society of Clinical Oncology Policy Statement on Medicaid Reform*. Journal of Clinical Oncology. 2014 Dec; 32(36): 4162-416. http://jco.ascopubs.org/content/early/2014/11/12/JCO.2014.56.3452.full.pdf+html (Accessed September 19, 2018).

e. Fiscal support for minority recruitment efforts and increasing trial accessibility through transportation, child care, reimbursements, and location.

3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.

Citation: BOT Rep. 4, A-08; Reaffirmed: CSAPH Rep. 01, A-18

7.1.1 Physician Involvement in Research

Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients, rather than to the specific benefit of the individuals who participate as research subjects.

However, research involving human participants should be conducted in a manner that minimizes risks and avoids unnecessary suffering. Because research depends on the willingness of participants to accept risk, they must be able to make informed decisions about whether to participate or continue in a given protocol.

Physician researchers share their responsibility for the ethical conduct of research with the institution that carries out research. Institutions have an obligation to oversee the design, conduct, and dissemination of research to ensure that scientific, ethical, and legal standards are upheld. Institutional review boards (IRBs) as well as individual investigators should ensure that each participant has been appropriately informed and has given voluntary consent.

Physicians who are involved in any role in research with human participants have an ethical obligation to ensure that participants interests are protected and to safeguard participants welfare, safety, and comfort.

To fulfill these obligations, individually, physicians who are involved in research should:

(a) Participate only in those studies for which they have relevant expertise.

(b) Ensure that voluntary consent has been obtained from each participant or from the participants legally authorized representative if the participant lacks the capacity to consent, in keeping with ethics guidance. This requires that:

(i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;

(ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;

(iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.

(c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.

(d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.

(e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.

(f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research.

AMA Principles of Medical Ethics: I,II,III,V

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 810
(I-18)

Introduced by: American Society of Clinical Oncology

Subject: Medicare Advantage Step Therapy

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

Whereas, The Centers for Medicare & Medicaid Services (CMS) announced that Medicare Advantage (MA) plans will have the choice of implementing step therapy to manage Part B drugs beginning January 1, 2019; and

Whereas, This proposal is part of the agency's ongoing activities to deliver on the Trump Administration's American Patients First Blueprint and overall drug pricing initiative; and

Whereas, Step therapy delays patient access to proper treatments by requiring patients to try and fail on lower cost medications before they can access the appropriate medication prescribed by their physician; and

Whereas, In life-threatening illness, including many cancers, step therapy could require use of drug not recommended by the patient's physician, and that failure to optimize treatment at the outset could harm the patient's chances for successful treatment; and

Whereas, Due to the individualized nature of modern cancer treatment and lack of interchangeable clinical options, step therapy policies are inappropriate for use in oncology treatment; and

Whereas, Our AMA's Prior Authorization and Utilization Management Reform Principles emphasize the importance of clinical validity, continuity of care, transparency and fairness, timely access and administrative efficiency, and alternatives and exemptions in order to ensure patient access to appropriate care while reducing the administrative burden associated with policy compliance;[1] and

Whereas, Step therapy is not an effective utilization management policy and hinders access to high-quality, high-value care; therefore be it

RESOLVED, That our American Medical Association continue strong advocacy for the rejection of step therapy in Medicare Advantage plans and impede the implementation of the practice before it takes effect on January 1, 2019. (Directive to Take Action)

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

Received: 10/11/18

[1] American Medical Association. *Prior Authorization and Utilization Management Reform Principles.* January 25, 2017. https://wire.ama-assn.org/ama-news/21-principles-reform-prior-authorization-requirements (Accessed September 20, 2018).

RELEVANT AMA POLICY

Prescription Drug Plans and Patient Access D-330.910
Our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the Centers for Medicare and Medicaid Services and other appropriate organizations to resolve them.
Citation: (Res. 135, A-14)

Prior Authorization and Utilization Management Reform H-320.939
1. Our 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.**
Citation: CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18

Medicare Pharmaceutical Benefit H-330.899
Our AMA utilizes the following principles in evaluating legislative proposals for the addition of a Medicare pharmaceutical benefit:
(1) Any pharmaceutical benefit should be fully funded by additional budgetary allocations, separate from existing budget provisions. The benefit should provide for adequate accounting so that drug program expenditures can be tracked separately from all other expenditures.
(2) The pharmaceutical benefit should be targeted to reduce hardship for those with low-incomes and those with catastrophic costs.
(3) Any legislation should provide a pharmaceutical benefit that is equal across geographic regions.
(4) A pharmaceutical benefit should be designed in a way that allows for benefits options under both the traditional Medicare fee-for-service program and any version of the Medicare program that relies on the private marketplace. Different levels of drug benefits for different products would be permissible.
(5) A pharmaceutical benefit should include a tiered deductible and co-payment structure that encourages economically responsible behavior.
(6) Any pharmaceutical benefit should be designed to prevent adverse selection.
(7) Any pharmaceutical benefit should be designed in a manner that prevents interference with clinical decision-making and physician prescribing decisions.
(8) Any pharmaceutical benefit should be designed in a manner that minimizes the administrative burden placed on physicians.
(9) Any pharmaceutical benefit should be designed in a manner that ensures beneficiary access to local pharmacies, and not be limited to mail order pharmacies.
(10) In the implementation of any Medicare drug benefit, employers are highly encouraged to preserve existing coverage, and for Medicare beneficiaries with existing drug coverage, any Medicare benefit should be supplemental to and coordinated with that existing coverage.
Citation: BOT Rep. 27, A-00; Reaffirmed: Res. 103, A-01; Modified: CMS Rep. 11, A-02; Modified: CMS Rep. 9, A-03; Appended: Res. 723, I-03; Reaffirmation I-04; Renumbered: CMS Rep. 7, I-05; Reaffirmation A-06; Reaffirmed: CMS Rep. 01, A-16

Emerging Trends in Utilization Management H-320.958
The AMA will: (1) maintain a leadership role in coordinating private sector efforts to develop and refine utilization management and quality assessment programs; (2) **establish an active role in the development of any national utilization management and quality assessment programs that are proposed in the ongoing health system reform debate; and (3) advocate strongly for utilization management and quality assessment programs that are non-intrusive, have reduced administrative burdens, and allow for adequate input by the medical profession**.
Citation: CMS Rep. 9, I-93; Reaffirmed and Modified: CMS Rep. 7, A-05; Reaffirmed: CMS Rep. 1, A-15; Reaffirmed in lieu of: Res. 242, A-17; Reaffirmation: A-17; Reaffirmation: I-17

Eliminate Fail First Policy in Addiction Treatment H-320.941
Our AMA will advocate for the elimination of the "fail first" policy implemented at times by some insurance companies and managed care organizations for addiction treatment.
Citation: Res. 802, I-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 811
(I-18)

Introduced by: American Society for Reproductive Medicine

Subject: Infertility Benefits for Active-Duty Military Personnel

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

Whereas, According to Pentagon figures, over 200,000 women are in the active-duty US military, including 74,000 in the Army, 53,000 in the Navy, 62,000 in the Air Force, and 14,000 in the Marine Corps in 2011;[1] and

Whereas, According to the 2012 Committee Opinion on "Health care for women in the military and women Veterans" from the American College of Obstetricians and Gynecologists (ACOG), "military service is associated with unique risks to women's reproductive health …. Obstetrician-gynecologists should be aware of high prevalence problems (e.g., posttraumatic stress disorder, intimate partner violence, and military sexual trauma) that can threaten the health and well-being of these women;"[3] and

Whereas, Both men and women in our US military can suffer from infertility, sometimes directly as a result of blast traumas and spinal cord injuries;[4] and

Whereas, The US Department of Defense currently covers the cost of in vitro fertilization (IVF) and infertility services for certain injured active duty personnel;[5] and

Whereas, Under current Tricare policy, active-duty military personnel and their dependents have some limited coverage for infertility care and oocyte cryopreservation services (with use by only 7181 over 5 years[6]) at seven specific military treatment facilities: Walter Reed National Military Medical Center in Bethesda MD; Womack Army Medical Center at Fort Bragg in Fayetteville NC; San Antonio Military Medical Center in San Antonio TX; San Diego Naval Medical Center in San Diego CA; Tripler Army Medical Center in Honolulu HI; Wright-Patterson Air Force Base Medical Center in Dayton OH; and Madigan Army Medical Center in Seattle-Tacoma WA); and

Whereas, This critical medical service is not fully available to active duty members of the military and those working with the DOD; and

Whereas, In 2016, our AMA passed policy H-510.984 "infertility Benefits for Veterans" [6] which states in part that:

3) "Our AMA encourages the Department of Defense (DOD) to offer service members fertility counseling and information on relevant health care benefits through TRICARE and the VA at pre-deployment and during the medical discharge process.

4) Our AMA supports efforts by the DOD and VA to offer service members comprehensive health care services to preserve their ability to conceive a child and provide treatment within the standard of care to address infertility due to service-related injuries."; and

Whereas, Unfortunately, many active-duty military personnel are not aware of their infertility benefits under current Tricare policy; therefore be it

RESOLVED, That our American Medical Association work with the Department of Defense, the American Society for Reproductive Medicine and other interested organizations to inform beneficiaries regarding the current availability of low-cost infertility care and gamete cryopreservation services at military treatment facilities for active-duty military personnel under Tricare (Directive to Take Action); and be it further

RESOLVED, That our AMA work with the American Society for Reproductive Medicine (and the American College of Obstetricians and Gynecologists (ACOG) and the American Urological Association (AUA)) and other interested organizations to encourage Tricare to fully cover infertility diagnosis and treatment for active-duty military personnel and others covered by Tricare (Directive to Take Action); and be it further

RESOLVED, That our AMA work with the American Society for Reproductive Medicine (and ACOG and AUA) and other interested organizations to encourage Tricare to fully cover gamete preservation prior to deployment for active-duty military personnel (Directive to Take Action); and be it further

RESOLVED, That our AMA report back on this issue at the 2019 Interim Meeting. (Directive to Take Action)

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

Received: 10/11/18

References:
1 “By the Numbers: Women in the U.S. Military,” by CNN.com on 1/24/13, accessed at: http://www.cnn.com/2013/01/24/us/military-women-glance/ on 10/25/15
2 Department of Veterans Affairs, Office of Public Affairs, Fact Sheet, accessed at: http://www.va.gov/WOMENVET/docs/WomenVeteransPopulationFactSheet.pdf on 10/25/15
3 “Health care for women in the military and women Veterans. Committee Opinion No 547. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012; 120:1538-42.
4 “Helping Wounded Vets Start Families” by Rebecca Sokol (ASRM President) in the Baltimore Sun on 10/18/15, accessed at: http://www.baltimoresun.com/news/opinion/oped/bs-ed-veterans-ivf-20151018-story.html on 10/25/15
5 “Access to Infertility Care: Challenges and Potential Solutions”, by Erin Kramer (ASRM staff), ASRM 10/8/18
6 AMA policy H-510.984 on “Infertility Benefits for Veterans” (below)

RELEVANT AMA POLICY

Infertility Benefits for Veterans H-510.984
1. Our AMA supports lifting the congressional ban on the Department of Veterans Affairs (VA) from covering in vitro fertilization (IVF) costs for veterans who have become infertile due to service-related injuries.
2. Our AMA encourages interested stakeholders to collaborate in lifting the congressional ban on the VA from covering IVF costs for veterans who have become infertile due to service-related injuries.
3. Our AMA encourages the Department of Defense (DOD) to offer service members fertility counseling and information on relevant health care benefits provided through TRICARE and the VA at pre-deployment and during the medical discharge process.
4. Our AMA supports efforts by the DOD and VA to offer service members comprehensive health care services to preserve their ability to conceive a child and provide treatment within the standard of care to address infertility due to service-related injuries.
Citation: CMS Rep. 01, I-16

Veterans Administration Health System H-510.991
Our AMA supports approaches that increase the flexibility of the Veterans Health Administration to provide all veterans with improved access to health care services.
Citation: (CMS Rep. 8, A-99; Reaffirmed: CMS Rep. 5, A-09)

Health Care for Veterans and Their Families D-510.994
Our AMA will: (1) work with all appropriate medical societies, the AMA National Advisory Council on Violence and Abuse, and government entities to assist with the implementation of all recommendations put forth by the President's Commission on Care for America's Wounded Warriors; and (2) advocate for improved access to medical care in the civilian sector for returning military personnel when their needs are not being met by resources locally available through the Department of Defense or the Veterans Administration.
Citation: (BOT Rep. 6, A-08; Reaffirmed: Sub. Res. 709, A-15)

Health Care Policy for Veterans H-510.990
Our AMA encourages the Department of Veterans Affairs to continue to explore alternative mechanisms for providing quality health care coverage for United States Veterans, including an option similar to the Federal Employees Health Benefit Program (FEHBP).
Citation: (Sub. Res.115, A-00; Reaffirmation I-03; Reaffirmed: CMS Rep. 4, A-13)

Ensuring Access to Care for our Veterans H-510.986
1. Our AMA encourages all physicians to participate, when needed, in the health care of veterans.
2. Our AMA supports providing full health benefits to eligible United States Veterans to ensure that they can access the Medical care they need outside the Veterans Administration in a timely manner.
3. Our AMA will advocate strongly: a) that the President of the United States take immediate action to provide timely access to health care for eligible veterans utilizing the healthcare sector outside the Veterans Administration until the Veterans Administration can provide health care in a timely fashion; and b) that Congress act rapidly to enact a bipartisan long term solution for timely access to entitled care for eligible veterans.
4. Our AMA recommends that in order to expedite access, state and local medical societies create a registry of doctors offering to see our veterans and that the registry be made available to the veterans in their community and the local Veterans Administration.
Citation: (Res. 231, A-14; Reaffirmation A-15; Reaffirmed: Sub. Res. 709, A-15)

Access to Health Care for Veterans H-510.985
Our American Medical Association: (1) will continue to advocate for improvements to legislation regarding veterans' health care to ensure timely access to primary and specialty health care within close proximity to a veteran's residence within the Veterans Administration health care system; (2) will monitor implementation of and support necessary changes to the Veterans Choice Program's "Choice Card" to ensure timely access to primary and specialty health care within close proximity to a veteran's residence outside of the Veterans Administration health care system; (3) will call for a study of the Veterans Administration health care system by appropriate entities to address access to care issues experienced by veterans; (4) will advocate that the Veterans Administration health care system pay private physicians a minimum of 100 percent of Medicare rates for visits and approved procedures to ensure adequate access to care and choice of physician; (5) will advocate that the Veterans Administration health care system hire additional primary and specialty physicians, both full and part-time, as needed to provide care to veterans; and (6) will support, encourage and assist in any way possible all organizations, including but not limited to, the Veterans Administration, the Department of Justice, the Office of the Inspector General and The Joint Commission, to ensure comprehensive delivery of health care to our nation's veterans.
Citation: Sub. Res. 111, A-15; Reaffirmed: CMS Rep. 06, A-17

Supporting Awareness of Stress Disorders in Military Members and Their Families H-510.988
Our AMA supports efforts to educate physicians and supports treatment and diagnosis of stress disorders in military members, veterans and affected families and continue to focus attention and raise awareness of this condition in partnership with the Department of Defense and the Department of Veterans Affairs.
Citation: Sub. Res. 401, A-10; Reaffirmed in lieu of: Res. 001, I-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 812
(I-18)

Introduced by: Craig A. Backs, MD, Delegate

Subject: ICD Code for Patient Harm From Payer Interference

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

Whereas, The harm to patients caused by delayed implementation of prescribed treatment or compromise in treatments or testing prompted by payers that result in switching for reasons other than efficacy or toxicity cannot be quantified because its role cannot be coded by our current ICD system; and

Whereas, Other contributors to patient and public health harm are identified by the mining of data from ICD administrative codes, including but not limited to infections, poisons, assaults, insect bites, trauma, infections and lifestyle factors; therefore be it

RESOLVED, That our American Medical Association support the creation and implementation of an ICD code(s) to identify administrator or payer influence that affects treatment and leads to or contributes to, directly or indirectly, patient harm. (New HOD Policy)

Fiscal Note: Not yet determined

Received: 10/10/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 813
(I-18)

Introduced by: Indiana

Subject: Direct Primary Care Health Savings Account Clarification

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

Whereas, Indiana law defines direct primary care (DPC) as: (1) agrees to provide primary care health services to the individual patient for an agreed-upon fee and time; 2) does not bill any third parties on a fee-for-service basis; 3) charges a periodic fee for services; and 4) may charge a per-visit charge only if the charge is less than the monthly equivalent of the periodic fee; and

Whereas, Health savings accounts (HSAs) are unusable for DPC memberships under current Internal Revenue Code (IRC) provisions; and

Whereas, There is currently a bill in Congress, The Primary Care Enhancement Act (H.R. 6317), which clarifies HSA provisions regarding DPC in the tax code. The bill states DPC is not a health plan under IRC. DPC is a medical service and allows individuals with HSAs to pay for DPC services with HSAs; therefore be it

RESOLVED, That our American Medical Association seek federal changes to the Internal Revenue Code allowing health savings accounts to be used with direct primary care. (Directive to Take Action)

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

Received: 10/09/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 814
(I-18)

Introduced by: Indiana

Subject: Prior Authorization Relief in Medicare Advantage Plans

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

Whereas, Medical providers and hospitals were successful in the 2018 Indiana legislative session in getting some prior authorization (PA) relief through HEA 1143 (P.L.77-2018); and

Whereas, That bill addressed only PA hassles and inconsistencies in commercial health plans; and

Whereas, The same hassles and burdensome PA requirements are routinely applied in Medicaid and Medicaid managed care plans, as well as Medicare Advantage plans; and

Whereas, There is a need to request relief equally from all health plans; therefore be it

RESOLVED, That our American Medical Association support legislation that would apply the following legislative processes and parameters to prior authorization (PA) for Medicaid and Medicaid managed care plans and Medicare Advantage plans:

- Listing services that require a PA on a website.
- Notifying providers of any changes at least 45 days prior to change.
- Standardizing a PA request form.
- Not denying payment for PA that has been approved unless fraudulently obtained or ineligible at time of service.
- Defining a consistent process for appeals and grievances, including to Medicaid and Medicaid managed care plans (New HOD Policy); and be it further

RESOLVED, That our AMA apply these same legislative processes and parameters to PA for Medicaid and Medicaid managed care plans and Medicare Advantage plans, to include:

- Medications already working when a patient changes health plans cannot be changed by the plan without discussion and approval of the ordering physician.
- Minimizing PA requirements as much as possible within each plan.
- Making an easily accessible and reasonably responsive direct communication tool available to resolve disagreements between plan and ordering provider. (New HOD Policy)

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

Received: 10/09/18

RELEVANT AMA POLICY

Prior Authorization and Utilization Management Reform H-320.939
1. Our 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.
Citation: CMS Rep. 08, A-17; Reaffirmation: I-17; Reaffirmed: Res. 711, A-18

Prescription Drug Plans and Patient Access D-330.910
Our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the Centers for Medicare and Medicaid Services and other appropriate organizations to resolve them.
Citation: (Res. 135, A-14)

https://policysearch.ama-assn.org/policyfinder/search/medicare%20advantage/relevant/1/

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 815
(I-18)

Introduced by: Indiana

Subject: Uncompensated Physician Labor

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

Whereas, Physicians increasingly are using an electronic medical record; and

Whereas, A much-touted part of that record is communication with the patient electronically, as initiated either by the physician or the patient; and

Whereas, Patients are typically expecting a quick turnaround on questions they send, as well as other information coming from the physician's office. This expectation is now becoming a quality measure that forces physicians to log on and review messages in the evening and sometimes on the weekends and holidays; and

Whereas, Patients can initiate a new communication at any time, with some patients messaging multiple times a week; and

Whereas, It can be argued that instructions about lab results and complaints voiced in the office should be covered by the salary paid for an office visit. However, new after-hour and weekend messages from patients are typically not addressed in employment contacts from the standpoint of compensation for those services to the physician. The result is uncompensated labor that can run several hours a day and multiple days a week. This is unfair to the physician and contributes to physician burnout and dissatisfaction with their practice situation; therefore be it

RESOLVED, That our American Medical Association adopt policy that physicians should be compensated for reviewing and responding to new after-hour patient messages. (New HOD Policy)

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

Received: 10/09/18

RELEVANT AMA POLICY

11.3.1 Fees for Medical Services

Physicians are expected to conduct themselves as honest, responsible professionals. They should be knowledgeable about and conform to relevant laws and should adhere to professional ethical standards and sound business practice. Physicians should not recommend, provide, or charge for unnecessary medical services. Nor should they make intentional misrepresentations to increase the level of payment they receive or to secure noncovered health benefits for their patients.

With regard to fees for medical services, physicians should:

(a) Charge reasonable fees based on the:

(i) kind of service(s);

(ii) difficulty or uniqueness of the service(s) performed;

(iii) time required to perform the service(s);

(iv) skill required to perform the service(s);

(v) experience of the physician;

(vi) quality of the physician's performance.

(b) Charge only for the service(s) that are personally rendered or for services performed under the physicians direct personal observation, direction, or supervision. If possible, when services are provided by more than one physician, each physician should submit his or her own bill to the patient and be compensated separately. When physicians have professional colleagues assist in the performance of a service, the physician may pay a reasonable amount for such assistance and recoup that amount through fees charged to the patient, provided the patient is notified in advance of the financial arrangement.

(c) Itemize separately charges for diagnostic, laboratory, or clinical services provided by other health care professionals and indicate who provided the service when fees for others' services cannot be billed directly to the patient, in addition to charges for the physician's own professional services.

(d) Not charge excessive fees, contingent fees, or fees solely to facilitate hospital admission. Physicians must not charge a markup or commission, or profit on services rendered by other health care professionals.

(e) Extend professional courtesy at their discretion, recognizing that it is not an ethical requirement and is prohibited in many jurisdictions.

AMA Principles of Medical Ethics: II,VI

Issued: 2016

Definition of "Usual, Customary and Reasonable" (UCR) H-385.923

1. Our AMA adopts as policy the following definitions:
(a) "usual; fee means that fee usually charged, for a given service, by an individual physician to his private patient (i.e., his own usual fee);
(b) a fee is 'customary' when it is within the range of usual fees currently charged by physicians of similar training and experience, for the same service within the same specific and limited geographical area; and
(c) a fee is 'reasonable' when it meets the above two criteria and is justifiable, considering the special circumstances of the particular case in question, without regard to payments that have been discounted under governmental or private plans.
2. Our AMA takes the position that there is no relationship between the Medicare fee schedule and Usual, Customary and Reasonable Fees.
Citation: (Res. 109. A-07; Appended: Res. 107, A-13)

Physician Choice of Practice H-385.926
Our AMA: (1) encourages the growth and development of the physician/patient contract; (2) supports the freedom of physicians to choose their method of earning a living (fee-for-service, salary, capitation, etc.); (3) supports the right of physicians to charge their patients their usual fee that is fair, irrespective of insurance/coverage arrangements between the patient and the insurers. (This right may be limited by contractual agreement.) An accompanying responsibility of the physician is to provide to the patient adequate fee information prior to the provision of the service. In circumstances where it is not feasible to provide fee information ahead of time, fairness in application of market-based principles demands such fees be subject, upon complaint, to expedited professional review as to appropriateness; and (4) encourages physicians when setting their fees to take into consideration the out-of-pocket expenses paid by patients under a system of individually selected and owned health insurance.
Citation: BOT Rep. QQ, I-91; Reaffirmed: BOT Rep. TT, I-92; Reaffirmed: Ref. Cmte. A, A-93; Reaffirmed: BOT Rep. UU, A-93; Reaffirmed: CMS Rep. G, A-93; Reaffirmed: CMS Rep. E, A-93; Reaffirmed: Sub. Res. 701, A-93; Reaffirmation A-93; Reaffirmed: BOT Rep. 25, I-93; Reaffirmed: CMS Rep. 5, I-93; Reaffirmed: CMS Rep. 10, I-93; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: Sub. Res. 107, I-93; Res. 124, I-93; Reaffirmed: Sub. Res. 127, A-94; Reaffirmed: BOT Rep. 46, A-94; Reaffirmed: Sub. Res. 132, A-94; Reaffirmed: BOT Rep. 16, I-94; Reaffirmed: CMS Rep. 8, A-95; Reaffirmed: Sub. Res. 109, A-95; Reaffirmed: Sub. Res. 125, A-95; Reaffirmed: Sub. Res. 109, I-95; Reaffirmation A-96; Reaffirmation I-96; Reaffirmation A-97; Reaffirmation I-98; Reaffirmation A-99; Appended by Res. 127, A-98; Reaffirmed: CMS Rep. 6, A-99; Reaffirmation A-00; Reaffirmation A-00; Sub. Res. 116, I-00; Reaffirmation & Reaffirmed: Res. 217, A-01; Reaffirmation A-04; Consolidated and Renumbered: CMS Rep. 7, I-05; Reaffirmation A-07; Reaffirmation A-09; Reaffirmed: CMS Rep. 3, I-09; Reaffirmed in lieu of Res. 127, A-10; Reaffirmation I-13; Reaffirmation A-15; Reaffirmed: CMS Rep. 5, I-15; Reaffirmed: CMS Rep. 09, A-16; Reaffirmed: CMS Rep. 07, A-17

Payment for Physicians' Services H-385.990
Our AMA:
(1) Recognizes the validity of a pluralistic approach to third party reimbursement methodology and recognizes that indemnity reimbursement, as a schedule of benefits, as well as "usual and customary or reasonable" (UCR), have positive aspects which merit further study.
(2) Reaffirms its support for: (a) freedom for physicians to choose the method of payment for their services and to establish fair and equitable fees; (b) freedom of patients to select their course of care; and (c) neutral public policy and fair market competition among alternative health care delivery and financing systems.
(3) Reaffirms its policy encouraging physicians to volunteer fee information to patients and to discuss fees in advance of services, where feasible.
(4) Urges physicians to continue and to expand the practice of accepting third party reimbursement as payment in full in cases of financial hardship, and to voluntarily communicate to their patients through appropriate means their willingness to consider such arrangements in cases of financial need or other circumstances.
Citation: (CMS Rep. B, I-83; Reaffirmed: BOT Rep. TT, I-92; Reaffirmed: CMS Rep. E, A-93; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: Sub. Res. 137, A-94; Reaffirmed: CMS Rep. 5, A-04; Reaffirmed: BOT Rep. 10, I-05; Reaffirmed in lieu of Res. 127, A-10)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 816
(I-18)

Introduced by: Indiana

Subject: Medicare Advantage Plan Inadequacies

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

Whereas, Advantage plans have been a popular choice for 19 million seniors because of lower premium cost and the expectation that members were being given extra perks, such as gym membership, vision and dental insurance; and

Whereas, Seniors are lured to these advantage plans by misinformation and confusing sales techniques; and

Whereas, Administrative costs have run as high as 10 percent. In comparison, CMS administers the traditional Medicare plan at a cost of 3 percent or less; and

Whereas, Inadequacies of the plan have produced poor service for some members with lower quality scores due to difficulties with physical therapy and rehab services. The number of days approved has tended to be too short and the extent of rehab services too limited. There has also been a delay in nursing home placement for some members, resulting in a delay of hospital discharge and an increase in hospital costs; therefore be it

RESOLVED, That our American Medical Association investigate the deficiencies of Medicare Advantage plans, with the goal of improving nursing home, rehab and physical therapy benefits. Full transparency about the cost and coverage of the plan, as well as communication about plan limitations, should be required (Directive to Take Action); and be it further

RESOLVED, That our AMA issue an opinion on whether Medicare Advantage plans should be limited to healthier seniors with both a short problem list and short medication list, and whether there should be a cap on administrative costs for these plans. (Directive to Take Action)

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

Received: 10/09/18

RELEVANT AMA POLICY

https://policysearch.ama-assn.org/policyfinder/search/medicare%20advantage/relevant/1/

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 817
(I-18)

Introduced by: Indiana

Subject: Increase Reimbursement for Psychiatric Services

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

Whereas, The number of Hoosiers with mental health disorders appears to be growing over time, and yet, it is more and more difficult to refer these patients to a psychiatrist because of low numbers of practicing psychiatrists in most Indiana communities and low reimbursement to psychiatrists. Some psychiatrists will not even see Medicare patients due to reimbursement issues; and

Whereas, Untreated or inadequately treated psychiatric disease increases the risk of hospitalization but also crime, arrest and incarceration. A significant portion of the homeless population has chronic psychiatric conditions that are not adequately treated; and

Whereas, Most developed nations have more psychiatrists per 100,000 population than the United States. Monaco has 41 psychiatrists per 100,000 population; Norway has 29.7 psychiatrists per 100,000 population, while Indiana has fewer than 9 per 100,000 with the lowest rate in Muncie. Fort Wayne has 4.2 psychiatrists per 100,000 population; therefore be it

RESOLVED, That our American Medical Association support increasing reimbursement for psychiatric services through direct funding adjustments or via the relevant specialties pursuing a coding change through the established CPT Editorial Panel process. (New HOD Policy)

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

Received: 10/09/18

RELEVANT AMA POLICY

Medical, Surgical, and Psychiatric Service Integration and Reimbursement H-345.983
Our AMA advocates for: (1) health care policies that insure access to and reimbursement for integrated and concurrent medical, surgical, and psychiatric care regardless of the clinical setting; and (2) standards that encourage medically appropriate treatment of medical and surgical disorders in psychiatric patients and of psychiatric disorders in medical and surgical patients.
Citation: (Res. 135, A-99; Reaffirmation A-00; Reaffirmed: CMS Rep. 6, A-10; Reaffirmed: CMS Rep. 6, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 818
(I-18)

Introduced by: Indiana

Subject: Drug Pricing Transparency

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

Whereas, Indiana has an increasing number of diabetic patients struggling to access medications due to high costs; and

Whereas, The prices of insulin in Indiana and across the nation have increased exponentially over the past two decades, including an increase of more than 1,000 percent in Humalog; and

Whereas, States have produced legislation aimed at tracking unreasonable price increases in essential medications; therefore be it

RESOLVED, That our American Medical Association advocate to the U.S. Surgeon General for federal legislation that investigates all drug pricing. (Directive to Take Action)

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

Received: 10/09/18

RELEVANT AMA POLICY

https://policysearch.ama-assn.org/policyfinder/search/drug%20pricing/relevant/1/.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 819
(I-18)

Introduced by: Michigan

Subject: Medicare Reimbursement Formula for Oncologists Administering Drugs

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

Whereas, Oncologists currently purchase chemotherapeutic agents for in-office administration to patients and bill Medicare for the purchase cost plus an additional 6 percent of the cost of the chemotherapeutic agent as reimbursement for the infusion or injection of said agent; and

Whereas, The 6 percent reimbursement becomes 4.3 percent with prompt pay discounts; and

Whereas, The time and attention required to administer one chemotherapeutic agent compared to another has no relation to its cost; and

Whereas, The current Medicare reimbursement strategy poses financial risks to practices and creates a perverse incentive to prescribe a newer, more expensive drug when an older, less expensive drug may be equally effective; and

Whereas, It also drives up the medical costs of administering chemotherapy without adding value; and

Whereas, The failings of the buy-and-bill system impact all oncologists, but small independent practices shoulder the greater burden; and

Whereas, The very existence of small independent practices is threatened, and with it access to care for many of our most vulnerable patients; and

Whereas, “Freeing oncologists from dependency on drug revenues while keeping outpatient oncology viable requires a focus on reimbursement for services that are uncompensated or undercompensated in the current system;” therefore be it

RESOLVED, That our American Medical Association amend policy H-55.994 by addition to read as follows:

> Coverage of Chemotherapy in Physicians' Offices H-55.994
> The AMA<u>: (1) supports adequate reimbursement for outpatient oncology office visits that recognizes the complexity of the patient’s care management; and (2)</u> advocates that physicians who bill any third party payer for administering chemotherapy should ensure that the services billed for are described adequately and fully on the appropriate claim form and that the chemotherapy descriptors and code numbers provided by CPT are utilized (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA advocate for a change to the Medicare reimbursement formula such that the costs of chemotherapeutic agents are covered, plus an unrelated flat fee to cover the cost of the infusion or injection of said agents. (Directive to Take Action)

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

Received: 10/10/18

RELEVANT AMA POLICY

Coverage of Chemotherapy in Physicians' Offices H-55.994
The AMA advocates that physicians who bill any third party payer for administering chemotherapy should ensure that the services billed for are described adequately and fully on the appropriate claim form and that the chemotherapy descriptors and code numbers provided by CPT are utilized.
Citation: (CMS Rep. C, I-82; Reaffirmed: CLRPD Rep. A, I-92; Modified and Reaffirmed: CMS Rep. 10, A-03; Reaffirmed: CMS Rep. 4, A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 820
(I-18)

Introduced by: Michigan

Subject: Ensuring Quality Health Care for Our Veterans

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

Whereas, *USA Today* has reported on seriously deleterious physician hiring practices in the Veterans Health Administration; and

Whereas, These deleterious hiring practices include subjecting our nations' veterans to care by physicians who have faced dozens of malpractice cases, and who have been sanctioned and, in some cases, have lost their licenses to practice in at least one state; and

Whereas, The U.S. Government Accountability Office has recently reported that the U.S. Department of Veterans Affairs failed to report 90 percent of potentially dangerous medical providers in recent years to a national database; and

Whereas, *USA Today* has found that oversight of the Veteran's Administration is so lax that the Veterans Administration had no idea how many medical workers had been reported or if they had been reported at all; and

Whereas, The U.S. Government Accountability Office has discovered that at one facility, officials failed to report six providers to the national practitioner database because the officials were unaware that they had been delegated responsibility for reporting; and

Whereas, Patients receiving care in non-Veterans Health Administration institutions would not be subjected to similar substandard care; therefore be it

RESOLVED, That our American Medical Association amend policy H-510.986, "Ensuring Access to Care for our Veterans," by addition to read as follows:

Ensuring Access to <u>Safe and Quality</u> Care for our Veterans H-510.986
1. Our AMA encourages all physicians to participate, when needed, in the health care of veterans.
2. Our AMA supports providing full health benefits to eligible United States Veterans to ensure that they can access the Medical care they need outside the Veterans Administration in a timely manner.
3. Our AMA will advocate strongly: a) that the President of the United States take immediate action to provide timely access to health care for eligible veterans utilizing the healthcare sector outside the Veterans Administration until the Veterans Administration can provide health care in a timely fashion; and b) that Congress act rapidly to enact a bipartisan long term solution for timely access to entitled care for eligible veterans.
4. Our AMA recommends that in order to expedite access, state and local medical societies create a registry of doctors offering to see our veterans and that the

registry be made available to the veterans in their community and the local Veterans Administration.

5. Our AMA will strongly advocate that the Veterans Health Administration and Congress develop and implement necessary resources, protocols, and accountability to ensure the Veterans Health Administration recruits, hires and retains first-rate, competent, and ethical physicians and other health care professionals to deliver the safe, effective and high-quality care that our veterans have been promised and are owed.

6. Our AMA will engage the Veterans Health Administration in dialogue on accreditation practices by the Veterans Health Administration to assure they are similar to those of hospitals, state medical boards, and insurance companies. (Modify Current HOD Policy)

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

Received: 10/10/18

RELEVANT AMA POLICY

Ensuring Access to Care for our Veterans H-510.986
1. Our AMA encourages all physicians to participate, when needed, in the health care of veterans.
2. Our AMA supports providing full health benefits to eligible United States Veterans to ensure that they can access the Medical care they need outside the Veterans Administration in a timely manner.
3. Our AMA will advocate strongly: a) that the President of the United States take immediate action to provide timely access to health care for eligible veterans utilizing the healthcare sector outside the Veterans Administration until the Veterans Administration can provide health care in a timely fashion; and b) that Congress act rapidly to enact a bipartisan long term solution for timely access to entitled care for eligible veterans.
4. Our AMA recommends that in order to expedite access, state and local medical societies create a registry of doctors offering to see our veterans and that the registry be made available to the veterans in their community and the local Veterans Administration.
Citation: (Res. 231, A-14; Reaffirmation A-15; Reaffirmed: Sub. Res. 709, A-15)

Expansion of US Veterans' Health Care Choices H-510.983
1. Our AMA will continue to work with the Veterans Administration (VA) to provide quality care to veterans.
2. Our AMA will continue to support efforts to improve the Veterans Choice Program (VCP) and make it a permanent program.
3. Our AMA encourages the VA to continue enhancing and developing alternative pathways for veterans to seek care outside of the established VA system if the VA system cannot provide adequate or timely care, and that the VA develop criteria by which individual veterans may request alternative pathways.
4. Our AMA will support consolidation of all the VA community care programs.
5. Our AMA encourages the VA to use external assessments as necessary to identify and address systemic barriers to care.
6. Our AMA will support interventions to mitigate barriers to the VA from being able to achieve its mission.
7. Our AMA will advocate that clean claims submitted electronically to the VA should be paid within 14 days and that clean paper claims should be paid within 30 days.

8. Our AMA encourages the acceleration of interoperability of electronic personal and medical health records in order to ensure seamless, timely, secure and accurate exchange of information between VA and non-VA providers and encourage both the VA and physicians caring for veterans outside of the VA to exchange medical records in a timely manner to ensure efficient care.
9. Our AMA encourages the VA to engage with physicians providing care in the VA system to explore and develop solutions on improving the health care choices of veterans.
10. Our AMA will advocate for new funding to support expansion of the Veterans Choice Program.
Citation: CMS Rep. 06, A-17

Fixing the VA Physician Shortage with Physicians D-510.990
1. Our AMA will work with the VA to enhance its loan forgiveness efforts to further incentivize physician recruiting and retention and improve patient access in the Veterans Administration facilities.
2. Our AMA will call for an immediate change in the Public Service Loan Forgiveness Program to allow physicians to receive immediate loan forgiveness when they practice in a Veterans Administration facility.
3. Our AMA will work with the Veterans Administration to minimize the administrative burdens that discourage or prevent non-VA physicians without compensation (WOCs) from volunteering their time to care for veterans.
Citation: Res. 1010, A-16

Support for VA Health Services for Women Veterans H-510.981
Our AMA recognizes the disparity in access to care for women veterans, and encourages research to address this populations specific needs to improve patient outcomes.
Citation: Res. 825, I-17

Access to Health Care for Veterans H-510.985
Our American Medical Association: (1) will continue to advocate for improvements to legislation regarding veterans' health care to ensure timely access to primary and specialty health care within close proximity to a veteran's residence within the Veterans Administration health care system; (2) will monitor implementation of and support necessary changes to the Veterans Choice Program's "Choice Card" to ensure timely access to primary and specialty health care within close proximity to a veteran's residence outside of the Veterans Administration health care system; (3) will call for a study of the Veterans Administration health care system by appropriate entities to address access to care issues experienced by veterans; (4) will advocate that the Veterans Administration health care system pay private physicians a minimum of 100 percent of Medicare rates for visits and approved procedures to ensure adequate access to care and choice of physician; (5) will advocate that the Veterans Administration health care system hire additional primary and specialty physicians, both full and part-time, as needed to provide care to veterans; and (6) will support, encourage and assist in any way possible all organizations, including but not limited to, the Veterans Administration, the Department of Justice, the Office of the Inspector General and The Joint Commission, to ensure comprehensive delivery of health care to our nation's veterans.
Citation: Sub. Res. 111, A-15; Reaffirmed: CMS Rep. 06, A-17

Health Care for Veterans and Their Families H-510.989
Our AMA supports the recommendations of the President's Commission on Care for America's Wounded Warriors report "Serve, Support, Simplify."
Citation: BOT Rep. 6, A-08; Reaffirmed: BOT Rep. 09, A-18

Health Care for Veterans and Their Families D-510.994
Our AMA will: (1) work with all appropriate medical societies, the AMA National Advisory Council on Violence and Abuse, and government entities to assist with the implementation of all recommendations put forth by the President's Commission on Care for America's Wounded Warriors; and (2) advocate for improved access to medical care in the civilian sector for returning military personnel when their needs are not being met by resources locally available through the Department of Defense or the Veterans Administration.
Citation: (BOT Rep. 6, A-08; Reaffirmed: Sub. Res. 709, A-15)

Health Care Policy for Veterans H-510.990
Our AMA encourages the Department of Veterans Affairs to continue to explore alternative mechanisms for providing quality health care coverage for United States Veterans, including an option similar to the Federal Employees Health Benefit Program (FEHBP).
Citation: (Sub. Res.115, A-00; Reaffirmation I-03; Reaffirmed: CMS Rep. 4, A-13)

Veterans Administration Health System H-510.991
Our AMA supports approaches that increase the flexibility of the Veterans Health Administration to provide all veterans with improved access to health care services.
Citation: (CMS Rep. 8, A-99; Reaffirmed: CMS Rep. 5, A-09)

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 D-510.991
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.
Citation: (Sub. Res. 709, A-15)

Budgetary and Management Needs of the Veterans Health Administration H-510.995
Our AMA urges Congress and the President to provide the VHA: (1) with funding sufficient to allow its hospitals and clinics to provide proper care to the patients the VHA is mandated to treat; and (2) with maximum flexibility in eliminating unneeded or duplicative services and in closing clinics or hospitals.
Citation: (BOT Rep. EE, A-89; Reaffirmed: Sunset Report, A-00; Modified: CMS Rep. 6, A-10)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 821
(I-18)

Introduced by: Michigan

Subject: Direct Primary Care and Concierge Medicine Based Practices

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

Whereas, The current medical economic environment is creating many changes in the configurations of medical practices, as well as impacting how physicians decide whether to group together or work alone; and

Whereas, The hassle factors associated with accepting insurances represents a major cost to practices and causes frustration for physicians; and

Whereas, Physicians have no control over which insurances their patients subscribe to; and

Whereas, Physicians have no control over the divergent requirements of each individual insurance company; and

Whereas, An increasing subset of physicians have chosen to no longer accept insurance; instead, choosing to pursue rapidly growing models of primary care referred to as direct primary care and concierge medicine; and

Whereas, Some medical practices charge a membership fee which allows them to offer a complete range of primary care services, including those that insurance coverages do not allow; and

Whereas, Current Internal Revenue Service (IRS) rules and interpretations present barriers that impede individual participation in direct primary care and concierge medicine models; and

Whereas, These impediments include restrictions and prohibitions on the use of funds from health savings accounts to pay for certain fees attributed to membership in these care delivery models, as well as prohibiting an individual who has an arrangement with a direct primary care practice from contributing to a health savings account; therefore be it

RESOLVED, That our American Medical Association actively lobby for revision to the U.S. tax code to allow funds from health savings accounts to be used for concierge medicine and direct primary care without incurring a tax penalty. (Directive to Take Action)

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

Received: 10/10/18

RELEVANT AMA POLICY

Direct Primary Care H-385.912
Our AMA supports: (1) inclusion of Direct Primary Care as a qualified medical expense by the Internal Revenue Service; and (2) efforts to ensure that patients in Direct Primary Care practices have access to specialty care, including efforts to oppose payer policies that prevent referrals to in-network specialists.
Citation: Res. 103, A-16; Appended: Res. 246, A-18; Reaffirmation: A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 915
(I-18)

Introduced by: American College of Emergency Physicians

Subject: Mandatory Reporting

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, In general, mandatory reporting for conditions should seek to mitigate against risk to others in society as a result of their interaction with the patient triggering mandatory reporting, such as in cases of infectious disease, or should assist uniquely vulnerable populations, such as victims of child abuse or domestic violence; and

Whereas, Physician reporting requirements are increasingly being mandated for conditions that do not pose a public health threat or serve to protect vulnerable populations, including California's recent passage of a law requiring physicians and other health care providers diagnosing or providing treatment to Parkinson's disease patients to report each case of Parkinson's disease to the state Department of Public Health[1]; and

Whereas, Zealous commitment to alleviate specific conditions should not dictate broad-based public mandates; and

Whereas, Compliance with mandatory reporting requirements substantially adds to the significant and growing administrative burden borne by physicians and other health care providers; therefore be it

RESOLVED, That our American Medical Association oppose mandated reporting of entire classes of patients and specific diagnoses unless compelling evidence exists to demonstrate that a serious public health and/or safety risk will be mitigated as a result of such reporting. (New HOD Policy)

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

Received: 10/10/18

References:

[1] California HSC-Division 102-Part 2-Chapter 1.6
https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=102.&title=&part=2.&chapter=1.6.&article=

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 916
(I-18)

Introduced by: American Thoracic Society, Society of Critical Care Medicine, American College of Chest Physicians

Subject: Ban on Tobacco Flavoring Agents with Respiratory Toxicity

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, The Food and Drug Administration (FDA), under the family smoking prevention and tobacco control act, has authority to regulate all tobacco products, including electronic nicotine delivery systems (ENDS) such as e-cigarettes; and

Whereas, END use has dramatically increased among youth; and

Whereas, Youth report that END flavors are a compelling reason youth try and continue to use END products; and

Whereas, FDA Commissioner Scott Gottlieb MD has called the youth rise in e-cigarette use an "epidemic"; and

Whereas, Several flavoring agents currently use in END products, including diacetyl, 2,3 pentanedione, acetoin, cinnamaldehyde, banzaldehyde, eugenol, vanillin/ethyl vanillin, and menthol, have known toxicity when exposed to the lung; and

Whereas, Other flavoring agents have been tested for oral and digestive tract exposure but have not yet been tested adequately for inhalation and respiratory exposure; therefore be it

RESOLVED, That our American Medical Association call for the immediate ban on flavoring agents in ENDS and other tobacco products that have known respiratory toxicity including but not limited to diacetyl, 2,3 pentanedione, acetoin, cinnamaldehyde, banzaldehyde, eugenol, vanillin/ethyl vanillin, and menthol (Directive to Take Action); and be it further

RESOLVED, That our AMA urge the Food and Drug Administration (FDA) to require comprehensive testing of flavoring agents used in electronic nicotine delivery systems (ENDS) and other tobacco products to assess the potential negative health effects of chronic exposure to these flavoring agents. (Directive to Take Action)

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

Received: 10/11/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 917
(I-18)

Introduced by: American Thoracic Society, Society of Critical Care Medicine, American College of Chest Physicians

Subject: Protect and Maintain the Clean Air Act

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, The scientific literature clearly documenting that exposure to air pollution results in significant adverse health effects including premature mortality, reduced lung function, exacerbation of respiratory disease, missed school and work days, increased medication use and other health effects; and

Whereas, The Clean Air Act, which has been implemented and enforced by the Environmental Protection Agency, has made significant improvements in US air quality that have led to measurable improvements in public health; and

Whereas, The "New Source Review" section of the Clean Air Act (CAA) is an important section of the law that requires that when a major pollution emitting facility makes changes to its equipment or operations that are expected to result in increased annual pollution emissions, the facility must install pollution control emissions equipment; and

Whereas, Coal and oil-fired power plants are a major source of both greenhouse gas emissions and air pollution emissions in the U.S.; and

Whereas, The Administration has issued a proposed rule, called Affordable Clean Energy rule, to regulate greenhouse gas (GHG) emissions from coal and oil-fired power plants that would result in a mere 1.5% reduction in GHG emissions, but would allow power plants to increase annual emissions of other pollutants including particulate matter, sulfur oxides and nitrogen oxides without having to meet the CAA's New Source Review requirements; and

Whereas, The increase in annual air pollution emissions will result in an increase in adverse health effects for those living in the US; and

Whereas, The EPA estimates implementation of the proposed rule will result in an additional 1,400 premature deaths annually, 48,000 additional asthma attacks, and 21,000 missed school days posing a significant impact on an individual's quality of life and financial stability; and

Whereas, Cost effective pollution-reduction technology exists today and is in operation at power plants across the US; therefore be it

RESOLVED, That our American Medical Association oppose provisions of the Affordable Clean Energy proposed rule that would allow power plants to avoid complying with new source review requirements to install air pollution control equipment when annual pollution emissions increase (New HOD Policy); and be it further

RESOLVED, That our AMA send a letter to the Environmental Protection Agency (EPA) expressing our opposition to EPA's Affordable Clean Energy rule and its proposed amendments of the New Source Review requirements under the Clean Air Act. (Directive to Take Action)

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

Received: 10/11/18

RELEVANT AMA POLICY

Support the Health Based Provisions of the Clean Air Act H-135.950
Our AMA (1) opposes changes to the New Source Review program of the Clean Air Act; (2) urges the Administration, through the Environmental Protection Agency, to withdraw the proposed New Source Review regulations promulgated on December 31, 2002; and (3) opposes further legislation to weaken the existing provisions of the Clean Air Act.
Citation: (Res. 417, A-03; Reaffirmation A-05; Reaffirmation I-11)

Clean Air H-135.991
(1) The AMA supports setting the national primary and secondary ambient air quality standards at the level necessary to protect the public health. Establishing such standards at the level necessary to protect the public health. Establishing such standards at a level "allowing an adequate margin of safety," as provided in current law, should be maintained, but more scientific research should be conducted on the health effects of the standards currently set by the EPA.
(2) The AMA supports continued protection of certain geographic areas (i.e., those with air quality better than the national standards) from significant quality deterioration by requiring strict, but reasonable, emission limitations for new sources.
(3) The AMA endorses a more effective hazardous pollutant program to allow for efficient control of serious health hazards posed by airborne toxic pollutants.
(4) The AMA believes that more research is needed on the causes and effects of acid rain, and that the procedures to control pollution from another state need to be improved.
(5) The AMA believes that attaining the national ambient air quality standards for nitrogen oxides and carbon monoxide is necessary for the long-term benefit of the public health. Emission limitations for motor vehicles should be supported as a long-term goal until appropriate peer-reviewed scientific data demonstrate that the limitations are not required to protect the public health.
Citation: (BOT Rep. R, A-82; Reaffirmed: CLRPD Rep. A, I-92; Amended: CSA Rep. 8, A-03; Reaffirmation I-06; Reaffirmed in lieu of Res. 509, A-09; Reaffirmation I-09; Reaffirmation A-14)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 918
(I-18)

Introduced by: Indiana

Subject: Allergen Labeling on Food Packaging

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, Anaphylactic food allergies continue to increase in prevalence; and

Whereas, An anaphylactic food allergy may be fatal; and

Whereas, There has been a documented fatal anaphylactic food reaction in a teenager who unsuspectingly ate from packaging that resembled packaging of other, non-allergenic, food products; and

Whereas, Current Food and Drug Administration (FDA) food labeling guidelines are inadequate to prevent accidental allergen exposure when products are contained in familiar packaging that usually does not contain common allergens; therefore be it

RESOLVED, That our American Medical Association petition the Food and Drug Administration to pursue more obvious labeling on food packaging containing the eight most common food allergens: milk, eggs, peanuts, tree nuts, wheat, soy, fish and crustacean shellfish. (Directive to Take Action)

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

Received: 10/09/18

RELEVANT AMA POLICY

Support for Nutrition Label Revision and FDA Review of Added Sugars D-150.974
1. Our AMA will issue a statement of support for the newly proposed nutrition labeling by the Food and Drug Administration (FDA) during the public comment period.
2. Our AMA will recommend that the FDA further establish a recommended daily value (%DV) for the new added sugars listing on the revised nutrition labels based on previous recommendations from the WHO and AHA).
3. Our AMA will encourage further research into studies of sugars as addictive through epidemiological, observational, and clinical studies in humans.
Citation: (Res. 422, A-14)

Preventing Allergic Reactions in Food Service Establishments D-440.932
Our American Medical Association will pursue federal legislation requiring restaurants and food establishments to: (1) include a notice in menus reminding customers to let the staff know of any food allergies; (2) educate their staff regarding common food allergens and the need to remind customers to inform wait staff of any allergies; and (3) identify menu items which contain any of the major food allergens identified by the FDA (in the Food Allergen Labeling and Consumer Protection Act of 2004) and which allergens the menu item contains.
Citation: (Res. 416, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 919
(I-18)

Introduced by: Indiana

Subject: Opioid Mitigation

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, Indiana has suffered the scourge of opioid abuse, addiction, overdose and death. There has been much suffering among family and friends of Hoosier opioid users; and

Whereas, Clark County, IN, has enjoyed some success in lowering overdose deaths with several identified strategies that help mitigate the issue; and

Whereas, Huntington, WV, has enjoyed more success in its strategies to combat opioids. They can serve as an example of best practices, and one of the most effective tools is an opioid overdose team. This team visits the home of someone who has been discharged from the emergency department with a diagnosis of opioid overdose. This visit occurs typically on the day of the overdose. The goal of the visit is to educate the individual about all the services available for opioid users in Huntington and its associated Cabell County. The most important information presented relates to options for drug rehabilitation. Encouragement and support are also part of the message; and

Whereas, The success of the West Virginia program is also rooted in generous funding from the city, county and state for the services described, as well as in a strong sense of community, collaboration and cooperation between the organizations dealing with this difficult issue; and

Whereas, Local and state political leaders and legislative bodies should support such a program with adequate funding to help ensure its success. We are dealing with a pay-now or pay-more-later situation. Premature death of an individual from an opioid overdose has economic consequences in the millions of dollars per individual, as well as stress and psychological effects on the family. There is also an increase in costs due to more crime, policing, court cases and incarcerations; therefore be it

RESOLVED, That our American Medical Association review the following opioid mitigation strategies based on their effectiveness in Huntington, WV, and Clark County, IN, and provide feedback concerning their utility in dealing with opioids:

(1) The creation of an opioid overdose team that decreases the risk of future overdose and overdose death, increases access to opioid-related services and increases the likelihood that an individual will pursue drug rehabilitation.

(2) A needle exchange program that is open multiple days a week and is mobile offers not only a source for needles but also Narcan, other supplies, health care and information.

(3) The creation of a drug court that allows a judge to have greater flexibility in determining the legal consequences of an arrest for an opioid-related crime. It also allows for the judicial patience necessary to deal with the recidivism of this population.

(4) Offering more acute-care inpatient drug rehab beds, although those ready for treatment need to be willing to travel significant distances to get to a treatment bed.

(5) Make available Narcan intranasal spray OTC through pharmacies and the syringe exchange, overdose team, etc.

(6) Encourage prevention education in K-12 programs that uses multiple media with anti-drug messaging delivered in the school system but also in the home. (Directive to Take Action)

Fiscal Note: Estimated cost to implement resolution is $130K.

Received: 10/09/18

RELEVANT AMA POLICY

https://policysearch.ama-assn.org/policyfinder/search/opioids/relevant/1/

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 920
(I-18)

Introduced by: Michigan

Subject: Continued Support for Federal Vaccination Funding

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, The “CDC estimates that vaccination of children born between 1994 and 2013 will prevent 322 million illnesses; will help avoid 732,000 deaths; and will save nearly $1.4 trillion in total societal costs;” and

Whereas, Section 317 of the Public Health Service Act provides federal funding to cover vaccines for uninsured and underinsured individuals as well as those with insurance during times of emergency outbreaks; and

Whereas, The federal funding through the Section 317 program also serves a crucial role in vaccine development and improvement, conducting community outreach and education, and leading the responses to disease outbreaks; and

Whereas, The Section 317 program is different from the Vaccines for Children program in that Section 317 funded vaccines can be given to under-insured individuals receiving vaccines at a health care institution that is not a Federally Qualified Health Center nor deputized; and

Whereas, An independent study demonstrated that an increase in Section 317 funding by $10 per individual resulted in a 1.6 percent increase in vaccination coverage between 1997 and 2003; and

Whereas, In the Fiscal Year 2018 President’s Budget Proposal and House of Representatives Appropriations, $521,000,000 and $557,000,000, respectively, is appropriated for funding for the Section 317 Immunization program, a decrease from $607,000,000 allocated in Fiscal Year 2017; and

Whereas, While it is important for funding to remain, at minimum, the same; ideally, it would increase to support public health efforts at vaccination and safety during times of outbreaks across individual states and the country; therefore be it

RESOLVED, That our American Medical Association release a public statement of support for federal vaccination funding efforts such as Section 317, and actively advocate for sustained funding. (Directive to Take Action)

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

Received: 10/10/18

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RELEVANT AMA POLICY

Financing of Adult Vaccines: Recommendations for Action H-440.860

1. Our AMA supports the concepts to improve adult immunization as advanced in the Infectious Diseases Society of America's 2007 document "Actions to Strengthen Adult and Adolescent Immunization Coverage in the United States," and support the recommendations as advanced by the National Vaccine Advisory Committee's 2008 white paper on pediatric vaccine financing.

2. Our AMA will advocate for the following actions to address the inadequate financing of adult vaccination in the United States:

Provider-related
a. Develop a data-driven rationale for improved vaccine administration fees.
b. Identify and explore new methods of providing financial relief for adult immunization providers through, for example, vaccine company replacement systems/deferred payment/funding for physician inventories, buyback for unused inventory, and patient assistance programs.
c, Encourage and facilitate adult immunization at all appropriate points of patient contact; e.g., hospitals, visitors to long-term care facilities, etc.
d. Encourage counseling of adults on the importance of immunization by creating a mechanism through which immunization counseling alone can be reimbursed, even when a vaccine is not given.

Federal-related
a. Increase federal resources for adult immunization to: (i) Improve Section 317 funding so that the program can meet its purpose of improving adult immunizations; (ii) Provide universal coverage for adult vaccines and minimally, uninsured adults should be covered; (iii) Fund an adequate universal reimbursement rate for all federal and state immunization programs.
b. Optimize use of existing federal resources by, for example: (i) Vaccinating eligible adolescents before they turn 19 years of age to capitalize on VFC funding; (ii) Capitalizing on public health preparedness funding.
c. Ease federally imposed immunization burdens by, for example: (i) Providing coverage for Medicare-eligible individuals for all vaccines, including new vaccines, under Medicare Part B; (ii) Creating web-based billing mechanisms for physicians to assess coverage of the patient in real time and handle the claim, eliminating out-of-pocket expenses for the patient; (iii) Simplifying the reimbursement process to eliminate payment-related barriers to immunization.

d. The Centers for Medicare & Medicaid Services should raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations.

State-related
a. State Medicaid programs should increase state resources for funding vaccines by, for example: (i) Raising and funding the maximum Medicaid reimbursement rate for vaccine administration fees; (ii) Establishing and requiring payment of a minimum reimbursement rate for administration fees; (iii) Increasing state contributions to vaccination costs; and (iv) Exploring the possibility of mandating immunization coverage by third party payers.
b. Strengthen support for adult vaccination and appropriate budgets accordingly.

Insurance-related
1. Provide assistance to providers in creating efficiencies in vaccine management by: (i) Providing model vaccine coverage contracts for purchasers of health insurance; (ii) Creating simplified rules for eligibility verification, billing, and reimbursement; (iii) Providing vouchers to patients to clarify eligibility and coverage for patients and providers; and (iv) Eliminating provider/public confusion over insurance payment of vaccines by universally covering all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines.
b. Increase resources for funding vaccines by providing first-dollar coverage for immunizations.
c. Improve accountability by adopting performance measurements.
d. Work with businesses that purchase private insurance to include all ACIP-recommended immunizations as part of the health plan.
e. Provide incentives to encourage providers to begin immunizing by, for example: (i) Including start up costs (freezer, back up alarms/power supply, reminder-recall systems, etc.) in the formula for reimbursing the provision of immunizations; (ii) Simplifying payment to and encouraging immunization by nontraditional providers; (iii) Facilitating coverage of vaccines administered in complementary locations (e.g., relatives visiting a resident of a long-term care facility).

Manufacturer-related
Market stability for adult vaccines is essential. Thus: (i) Solutions to the adult vaccine financing problem should not deter research and development of new vaccines; (ii) Solutions should consider the maintenance of vibrant public and private sector adult vaccine markets; (iii) Liability protection for manufacturers should be assured by including Vaccine Injury Compensation Program coverage for all ACIP-recommended adult vaccines; (iv) Educational outreach to both providers and the public is needed to improve acceptance of adult immunization.

3. Our AMA will conduct a survey of small- and middle-sized medical practices, hospitals, and other medical facilities to identify the impact on the adult vaccine supply (including influenza vaccine) that results from the large contracts between vaccine manufacturers/distributors and large non-government purchasers, such as national retail health clinics, other medical practices, and group purchasing programs, with particular attention to patient outcomes for clinical preventive services and chronic disease management.

Citation: (CSAPH Rep. 4, I-08; Reaffirmation I-10; Reaffirmation: I-12; Reaffirmation I-14)

Reimbursement for Influenza Vaccine H-440.848
Our AMA: (1) will work with third party payers, including the Centers for Medicare and Medicaid Services, to establish a fair reimbursement price for the flu vaccine; (2) encourage the manufacturers of influenza vaccine to publish the purchase price by June 1st each year; (3) shall seek federal legislation or regulatory relief, or otherwise work with the federal government to increase Medicare reimbursement levels for flu vaccination and other vaccinations.
Citation: (CSAPH Rep. 5, I-12)

Assuring Access to ACIP/AAFP/AAP-Recommended Vaccines H-440.875

1. It is AMA policy that all persons, regardless of economic and insurance status, receive all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines as soon as possible following publication of these recommendations in the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report (MMWR).
2. Our AMA will continue to work with the federal government, Congress, and other stakeholders to improve liability protection for vaccine manufacturers and health care professionals who provide immunization services and to examine and improve compensation mechanisms for patients who were legitimately injured by a vaccine.
3. Our AMA will continue to work with the federal government, Congress, and other appropriate stakeholders to enhance public opinion of vaccines and to monitor and ensure the continued safety of existing and newly approved vaccines (including providing adequate resources for post-approval surveillance) so as to maintain and improve public confidence in the safety of vaccines.
4. Our AMA will work with appropriate stakeholders, including vaccine manufacturers, vaccine distributors, the federal government, medical specialty societies, and third party payers, to guarantee a robust vaccine delivery infrastructure (including but not limited to, the research and development of new vaccines, the ability to track the real-time supply status of ACIP-recommended vaccines, and the timely distribution of ACIP-recommended vaccines to providers).
5. Our AMA will work with appropriate federal and state agencies and private sector entities to ensure that state Medicaid agencies and private insurance plans pay health care professionals at least the approved Relative Value Unit (RVU) administration Medicare rates for payment when they administer ACIP-recommended vaccines.
6. Our AMA will work with the Centers for Medicare and Medicaid Services (CMS) to address barriers associated with Medicare recipients receiving live zoster vaccine and the routine boosters Td and Tdap in physicians' offices.
7. Our AMA will work through appropriate state entities to ensure all health insurance plans rapidly include newly ACIP-recommended vaccines in their list of covered benefits, and to pay health care professionals fairly for the purchase and administration of ACIP-recommended vaccines.
8. Our AMA will urge Medicare to include Tdap (Tetanus, Diphtheria, Acellular Pertussis) under Medicare Part B as a national public health measure to help prevent the spread of Pertussis.
9. Until compliance of AMA Policy H-440.875(6) is actualized to the AMA's satisfaction regarding the tetanus vaccine, our AMA will aggressively petition CMS to include tetanus and Tdap at both the "Welcome to Medicare" and Annual Medicare Wellness visits, and other clinically appropriate encounters, as additional "triggering event codes" (using the AT or another modifier) that allow for coverage and payment of vaccines to Medicare recipients.
10. Our AMA will aggressively petition CMS to include coverage and payment for any vaccinations administered to Medicare patients that are recommended by the ACIP, the US Preventive Services Task Force (USPSTF), or based on prevailing preventive clinical health guidelines.

Citation: BOT Action in response to referred for decision Res. 524, A-06; Reaffirmation A-07; Appended: Res. 531, A-07; Reaffirmation A-09; Reaffirmed: Res. 501, A-09; Reaffirmation I-10; Reaffirmation A-11; Reaffirmed in lieu of Res. 422, A-11: BOT action in response to referred for decision Res. 422, A-11; Reaffirmation: I-12; Appended: Res. 227, I-12; Appended: Res. 824, I-14; Reaffirmed: Res. 411, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 921
(I-18)

Introduced by: Michigan

Subject: Food Environments and Challenges Accessing Healthy Food

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, Over 29.7 million Americans live at or below 200 percent of the federal poverty level; and

Whereas, Food security, diversity, and accessibility significantly impact individual and community health; and

Whereas, A food desert is defined by the United States Department of Agriculture as a low-income census tract where a significant number or share of residents have low access to a full-service supermarket or grocery store, where low access is defined as residing more than 1 mile from a full-service grocery store in urban areas and more than 10 miles from a full-service grocery store in rural areas; and

Whereas, A food swamp can be characterized as areas where large relative amounts of energy-dense snack foods inundate healthy food options or geographic areas with disproportionate access to energy-dense, nutrient-poor foods; and

Whereas, A food mirage is a food environment distinct from food deserts in that healthy foods may be available, but prices are beyond the means of those living nearby, making them functionally equivalent to food deserts in that long journeys are needed to obtain food; and

Whereas, Food mirages are often invisible to conventional food desert assessment criteria due to their proximity to healthy food options and thereby causing an illusion of access; and

Whereas, Conventional food desert assessments can inaccurately assume that grocery store prices are reasonably similar, and that any full-service grocery store can serve consumers equally well as points of access to healthy foods; and

Whereas, Though grocery store food can be relatively affordable compared to those of other stores, it does not equate to being affordable for low-income residents who may be struggling to consistently put food on the table; and

Whereas, Not only is price at times the strongest motivator for deciding where one shops or if one is even able to shop, consideration for whether their choice stores accept federal assistance dollars further sways their decisions; and

Whereas, A food outlet's choice of inventory and impact on a community's food diversity are influenced heavily by community interest and consumer financial capability, and

Whereas, A food oasis is best described as “any place where people have the best possible access to healthy options and eating environments” where “access includes financial and physical access to healthy foods and drinks that are high quality, affordable, culturally acceptable, and meet the nutritional needs of the people in the community;” and

Whereas, Previous studies examining food oases effectively consider them the gold standard for communities to strive for; and

Whereas, American Medical Association (AMA) policies such as D-150.978 and 150.034MSS provide no guidance on identification of food oases, which makes it more difficult to differentiate between communities that may or may not have access to healthy, affordable food alternatives; and

Whereas, Although these AMA policies aim to address disparities secondary to functional access to food including cost, ethnic preferences, and education, these alone are unlikely to resolve the distinct challenges faced by food swamps and food mirages; and

Whereas, By accounting only for food deserts, which are measured in literature and policy by physical proximity to healthy foods, and omitting consideration of consumer socioeconomic or cultural factors, “food environment literature takes on a singular narrative and a narrow conceptual representation of the barriers people face to accessing food”; therefore be it

RESOLVED, That our American Medical Association work with appropriate stakeholders to advocate for the study of the national prevalence and impact of food mirages, food swamps, and food oases as food environments distinct from food deserts. (Directive to Take Action)

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

Received: 10/10/18

RELEVANT AMA POLICY

Sustainable Food D-150.978
Our AMA: (1) supports practices and policies in medical schools, hospitals, and other health care facilities that support and model a healthy and ecologically sustainable food system, which provides food and beverages of naturally high nutritional quality; (2) encourages the development of a healthier food system through tax incentive programs, community-level initiatives and federal legislation; and (3) will consider working with other health care and public health organizations to educate the health care community and the public about the importance of healthy and ecologically sustainable food systems.
Citation: (CSAPH Rep. 8, A-09; Reaffirmed in lieu of Res. 411, A-11; Reaffirmation A-12; Reaffirmed in lieu of Res. 205, A-12; Modified: Res. 204, A-13; Reaffirmation A-15)

Reform the US Farm Bill to Improve US Public Health and Food Sustainability H-150.932
Reform the US Farm Bill to Improve US Public Health and Food SustainabilityOur AMA supports the creation of a new advisory board to review and recommend US Farm Bill budget allocations to ensure any government subsidies are only used to help produce healthy food choices and sustainable foods, and that advisory committee members include physicians, public health officials and other public health stakeholders.
Citation: (Res. 215, A-13)

National Nutritional Guidelines for Food Banks and Pantries H-150.930
Our AMA: (1) supports the use of existing national nutritional guidelines for food banks and food pantries and (2) will promote sustainable sourcing of healthier food options and the dissemination of user-friendly resources and education on healthier eating for food banks and food pantries.
Citation: Res. 413, A-14; Appended: Res. 415, A-17

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 958
(I-18)

Introduced by: California

Subject: National Health Service Corps Eligibility

Referred to: Reference Committee C
(Peter C. Amadio, MD, Chair)

Whereas, The National Health Service Corps (NHSC) provides scholarships and loan repayment for primary care physicians serving in health professional shortage areas (HPSAs); and

Whereas, The NHSC's purpose is to strengthen and grow the primary care workforce to improve access to care in medically underserved areas; and

Whereas, There are severe physician shortages in rural areas across the country; and

Whereas, Many primary care physicians provide care as inpatient hospitalists; and

Whereas, NHSC approved sites provide outpatient, ambulatory primary health care services in health professional shortage areas; and

Whereas, Many primary care physicians seeking to participate in the NHSC would like to participate as hospitalists; therefore be it

RESOLVED, That our American Medical Association consider eligibility criteria changes for the National Health Service Corps Program to increase the pool of eligible physicians, such as allowing participation from primary care physicians providing in-patient hospitalist care in health professional shortage areas. (Directive to Take Action)

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

Received: 10/11/18

RELEVANT AMA POLICY

Long-Term Solutions to Medical Student Debt D-305.975
Our AMA will: (1) encourage medical schools and state medical societies to consider the creation of self-managed, low-interest loan programs for medical students, and collect and disseminate information on such programs; (2) advocate for increased funding for the National Health Service Corps Loan Repayment Program to assure adequate funding of primary care within the National Health Service Corps, as well as to permit: (a) inclusion of all medical specialties in need, and (b) service in clinical settings that care for the underserved but are not necessarily located in health professions shortage areas; (3) work with state medical societies to advocate for the creation of either tuition caps or, if caps are not feasible, pre-defined tuition increases, so that medical students will be aware of their tuition and fee costs for the total period of their enrollment; (4) collect and disseminate information on medical school programs that cap medical education debt, including the types of debt management education that are provided; and (5) encourage the National Health Services Corps to have repayment policies that are

consistent with other federal loan forgiveness programs, thereby decreasing the amount of loans in default and increasing the number of physicians practicing in underserved areas.
Citation: (CME Rep. 3, I-04; Reaffirmation I-06; Appended: Res. 321, A-12; Reaffirmation A-13; Modified: CCB/CLRPD Rep. 2, A-14; Reaffirmation I-14)

Educational Strategies for Meeting Rural Health Physician Shortage H-465.988
In light of the data available from the current literature as well as ongoing studies being conducted by staff, the AMA recommends that: (1) Our AMA encourage medical schools and residency programs to develop educationally sound rural clinical preceptorships and rotations consistent with educational and training requirements, and to provide early and continuing exposure to those programs for medical students and residents.
(2) Our AMA encourage medical schools to develop educationally sound primary care residencies in smaller communities with the goal of educating and recruiting more rural physicians.
(3) Our AMA encourage state and county medical societies to support state legislative efforts toward developing scholarship and loan programs for future rural physicians.
(4) Our AMA encourage state and county medical societies and local medical schools to develop outreach and recruitment programs in rural counties to attract promising high school and college students to medicine and the other health professions.
(5) Our AMA urge continued federal and state legislative support for funding of Area Health Education Centers (AHECs) for rural and other underserved areas.
(6) Our AMA continue to support full appropriation for the National Health Service Corps Scholarship Program, with the proviso that medical schools serving states with large rural underserved populations have a priority and significant voice in the selection of recipients for those scholarships.
(7) Our AMA support full funding of the new federal National Health Service Corps loan repayment program.
(8) Our AMA encourage continued legislative support of the research studies being conducted by the Rural Health Research Centers funded by the National Office of Rural Health in the Department of Health and Human Services.
(9) Our AMA continue its research investigation into the impact of educational programs on the supply of rural physicians.
(10) Our AMA continue to conduct research and monitor other progress in development of educational strategies for alleviating rural physician shortages.
(11) Our AMA reaffirm its support for legislation making interest payments on student debt tax deductible.
(12) Our AMA encourage state and county medical societies to develop programs to enhance work opportunities and social support systems for spouses of rural practitioners.
Citation: CME Rep. C, I-90; Reaffirmation A-00; Reaffirmation A-01; Reaffirmation I-01; Reaffirmed: CME Rep. 1, I-08; Reaffirmed: CEJA Rep. 06, A-18

Effectiveness of Strategies to Promote Physician Practice in Underserved Areas D-200.980
1. Our AMA, in collaboration with relevant medical specialty societies, will continue to advocate for the following: (a) Continued federal and state support for scholarship and loan repayment programs, including the National Health Service Corps, designed to encourage physician practice in underserved areas and with underserved populations. (b) Permanent reauthorization and expansion of the Conrad State 30 J-1 visa waiver program. (c) Adequate funding (up to at least FY 2005 levels) for programs under Title VII of the Health Professions Education Assistance Act that support educational experiences for medical students and resident physicians in underserved areas.
2. Our AMA encourages medical schools and their associated teaching hospitals, as well as state medical societies and other private sector groups, to develop or enhance loan repayment or scholarship programs for medical students or physicians who agree to practice in underserved areas or with underserved populations.
3. Our AMA will advocate to states in support of the introduction or expansion of tax credits and other practice-related financial incentive programs aimed at encouraging physician practice in underserved areas.
4. Our AMA will advocate for the creation of a national repository of innovations and experiments, both successful and unsuccessful, in improving access to and distribution of physician services to government-insured patients (National Access Toolbox).
5. Our AMA supports elimination of the tax liability when employers provide the funds to repay student loans for physicians who agree to work in an underserved area.
Citation: CME Rep. 1, I-08; Modified: CME Rep. 4, A-10; Reaffirmation I-11; Appended: Res. 110, A-12; Reaffirmation A-13; Reaffirmation A-14; Appended: Res. 312, I-16; Appended: Res 312, I-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 959
(I-18)

Introduced by: Indiana

Subject: Physician and Medical Student Mental Health and Suicide

Referred to: Reference Committee C
(Peter C. Amadio, MD, Chair)

Whereas, The suicide rate of physicians and medical students is more than double that of the general population, making it the profession with the highest suicide rate of any profession in the United States; and

Whereas, One million U.S. patients lose one of their physicians each year due to physician suicide; and

Whereas, Physicians and medical students are reluctant to report mental health issues and suicidal thoughts because of fear of losing their medical privileges and/or medical license; and

Whereas, Physicians and medical students report rising stress and falling satisfaction from their career choice; and

Whereas, Suicidal deaths and mental health issues are increasing with about 400 deaths in 2018 and in previous years; and

Whereas, Productivity and quality of patient care are negatively affected by physician and medical student mental health issues; and

Whereas, Physicians and medical students are less likely to seek help and more likely to self-medicate for mood disturbances; and

Whereas, Physician and medical student knowledge of physiology and pharmacology coupled with access to lethal drugs, devices and techniques increases the risk of successful suicide; and

Whereas, Physician and medical student death by suicide is a tragedy for family, friends, patients and the community; and

Whereas, Physician and medical student death by suicide exacerbates growing physician shortages; and

Whereas, AMA policy on physician and medical student mental health and suicide are extensive and are reviewed by the Council on Science and Public Health (CSAPH); and

Whereas, Current AMA policy is inadequate because the suicide rate among physicians and medical students is increasing; therefore be it

RESOLVED, That our American Medical Association create a new Physician and Medical Student Suicide Prevention Committee with the goal of addressing suicides and mental health disease in physicians and medical students. This committee will be charged with:

1) Developing novel policies to decrease physician and medical trainee stress and improve professional satisfaction.

2) Vociferous, repeated and widespread messaging to physicians and medical students encouraging those with mood disorders to seek help.

3) Working with state medical licensing boards and hospitals to help remove any stigma of mental health disease and to alleviate physician and medical student fears about the consequences of mental illness and their medical license and hospital privileges.

4) Establishing a 24-hour mental health hotline staffed by mental health professionals whereby a troubled physician or medical student can seek anonymous advice. Communication via the 24-hour help line should remain anonymous. This service can be directly provided by the AMA or could be arranged through a third party, although volunteer physician counselors may be an option for this 24-hour phone service. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/09/18

The topic of this resolution is currently under study by the Council on Medical Education.

RELEVANT AMA POLICY

Study of Medical Student, Resident, and Physician Suicide D-345.984
Our AMA will determine the most efficient and accurate mechanism to study the actual incidence of medical student, resident, and physician suicide, and report back at the 2018 Interim Meeting of the House of Delegates with recommendations for action.
Citation: Res. 019, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 960
(I-18)

Introduced by: Indiana

Subject: Inadequate Residency Slots

Referred to: Reference Committee C
(Peter C. Amadio, MD, Chair)

Whereas, The annual residency match this year resulted in 8,063 medical school graduates (37,103 applicants with 29,040 matched and about 1000 more matches through the SOAP [Supplemental Offer and Acceptance Program]) failing to find a residency program. This group included U.S. medical school graduates, as well as international medical school graduates; and

Whereas, The AMA and ISMA both have policies on postgraduate medical education position adequacy; and

Whereas, It is estimated that it costs up to $0.5 million or more to produce one medical school graduate in the United States. Students make a great investment of money, time and effort in their training. For a medical school graduate to fail to become a duly licensed medical practitioner is truly a tragedy, as well as a significant loss to the community. It is also a great waste of public and private funds when the situation arises; and

Whereas, These graduates typically have debt that is equivalent to a home mortgage with interest rates that are significant. Commonly, loan payments are set to begin shortly after medical school graduation if the individual is not in a postgraduate program; and

Whereas, Some of these individuals are never able to complete their residencies and are burdened with significant debt, and yet are not able to practice as a physician except in states that have assistant physician programs. These programs typically are in medically underserved communities offering a collaborating physician relationship; therefore be it

RESOLVED, That our American Medical Association adopt policy to establish parity between the number of medical school graduates and the number of match positions and withhold support for any further increase in medical school enrollment, unless there is a corresponding increase in residency positions(New HOD Policy); and be it further

RESOLVED, That our AMA lobby the federal government for increased funding for residency spots, to investigate other sustainable models for residency position funding and to advocate for loan repayment waivers for individuals who fail to match. (Directive to Take Action)

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

Received: 10/09/18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 961
(I-18)

Introduced by: Michigan

Subject: Protect Physician-Led Medical Education

Referred to: Reference Committee C
(Peter C. Amadio, MD, Chair)

Whereas, High quality education of our next generation of physicians is the most important legacy we can provide our patients and profession; and

Whereas, Education, supervision, and evaluation of training physicians by physicians has been a defining characteristic of our medical profession for thousands of years; and

Whereas, The rules for education, supervision, and evaluation of training physicians are determined by the Liaison Committee on Medical Education (LCME) and Accreditation Council for Graduate Medical Education (ACGME); and

Whereas, The member organizations of the LCME and ACGME include physician organizations, as well as hospital organizations and hospital systems; and

Whereas, The economics and politics of health care have produced an unprecedented proliferation of non-physicians providing highly specialized care in hospital systems without graduating from LCME-approved medical school or ACGME-approved residency or fellowship training; and

Whereas, The economics and politics of health care have produced an unprecedented proliferation of hospital system employed physicians who may not be in a position to stand up for themselves or their trainees; and

Whereas, Medical students, residents, and fellows are increasingly finding themselves trained, supervised, and evaluated by non-physicians, in addition to losing valuable procedural experience to non-physicians, with little understanding of their rights or how to report such violations; and

Whereas, Non-physician members of the health care team can provide valuable education to medical students, residents, and fellows within their scope of non-physician care as part of a physician-led health care team, but this should not replace physician-led training, supervision and evaluation of physician trainees; therefore be it

RESOLVED, That our American Medical Association, in their role as a member organization of the Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education, strongly advocate for the rights of medical students, residents, and fellows to be trained, supervised, and evaluated by licensed physicians (Directive to Take Action); and be it further

RESOLVED, That our AMA provide medical students, residents, and fellows a clear online resource outlining their rights, as per Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education guidelines, to physician-led education and a means to report violations without fear of retaliation. (Directive to Take Action)

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

Received: 10/10/18

RELEVANT AMA POLICY

Communication and Clinical Teaching Curricula D-295.329
Our AMA will:
1. encourage the Liaison Committee on Medical Education to continue to enforce accreditation standards requiring that faculty members and resident physicians are prepared for and evaluated on their teaching effectiveness;
2. encourage the Accreditation Council for Graduate Medical Education to create institutional-level standards related to assuring the quality of faculty teaching;
3. encourage medical schools and institutions sponsoring graduate medical education programs to offer faculty development for faculty and resident physicians in time-efficient modalities, such as online programs, and/or to support faculty and resident participation in off-site programs;
4. encourage medical educators to develop and utilize valid and reliable measures for teaching effectiveness; and
5. encourage medical schools to recognize participation in faculty development for purposes of faculty retention and promotion.
Citation: (CME Rep. 9, A-09)

Recommendations for Future Directions for Medical Education H-295.995
Our AMA supports the following recommendations relating to the future directions for medical education:
(1) The medical profession and those responsible for medical education should strengthen the general or broad components of both undergraduate and graduate medical education. All medical students and resident physicians should have general knowledge of the whole field of medicine regardless of their projected choice of specialty.
(2) Schools of medicine should accept the principle and should state in their requirements for admission that a broad cultural education in the arts, humanities, and social sciences, as well as in the biological and physical sciences, is desirable.
(3) Medical schools should make their goals and objectives known to prospective students and premedical counselors in order that applicants may apply to medical schools whose programs are most in accord with their career goals.
(4) Medical schools should state explicitly in publications their admission requirements and the methods they employ in the selection of students.
(5) Medical schools should require their admissions committees to make every effort to determine that the students admitted possess integrity as well as the ability to acquire the knowledge and skills required of a physician.
(6) Although the results of standardized admission testing may be an important predictor of the ability of students to complete courses in the preclinical sciences successfully, medical schools should utilize such tests as only one of several criteria for the selection of students. Continuing review of admission tests is encouraged because the subject content of such examinations has an influence on premedical education and counseling.
(7) Medical schools should improve their liaison with college counselors so that potential medical students can be given early and effective advice. The resources of regional and national organizations can be useful in developing this communication.
(8) Medical schools are chartered for the unique purpose of educating students to become physicians and should not assume obligations that would significantly compromise this purpose.
(9) Medical schools should inform the public that, although they have a unique capability to identify the changing medical needs of society and to propose responses to them, they are only one of the elements

of society that may be involved in responding. Medical schools should continue to identify social problems related to health and should continue to recommend solutions.
(10) Medical school faculties should continue to exercise prudent judgment in adjusting educational programs in response to social change and societal needs.
(11) Faculties should continue to evaluate curricula periodically as a means of insuring that graduates will have the capability to recognize the diverse nature of disease, and the potential to provide preventive and comprehensive medical care. Medical schools, within the framework of their respective institutional goals and regardless of the organizational structure of the faculty, should provide a broad general education in both basic sciences and the art and science of clinical medicine.
(12) The curriculum of a medical school should be designed to provide students with experience in clinical medicine ranging from primary to tertiary care in a variety of inpatient and outpatient settings, such as university hospitals, community hospitals, and other health care facilities. Medical schools should establish standards and apply them to all components of the clinical educational program regardless of where they are conducted. Regular evaluation of the quality of each experience and its contribution to the total program should be conducted.
(13) Faculties of medical schools have the responsibility to evaluate the cognitive abilities of their students. Extramural examinations may be used for this purpose, but never as the sole criterion for promotion or graduation of a student.
(14) As part of the responsibility for granting the MD degree, faculties of medical schools have the obligation to evaluate as thoroughly as possible the non-cognitive abilities of their medical students.
(15) Medical schools and residency programs should continue to recognize that the instruction provided by volunteer and part-time members of the faculty and the use of facilities in which they practice make important contributions to the education of medical students and resident physicians. Development of means by which the volunteer and part-time faculty can express their professional viewpoints regarding the educational environment and curriculum should be encouraged.
(16) Each medical school should establish, or review already established, criteria for the initial appointment, continuation of appointment, and promotion of all categories of faculty. Regular evaluation of the contribution of all faculty members should be conducted in accordance with institutional policy and practice.
(17a) Faculties of medical schools should reevaluate the current elements of their fourth or final year with the intent of increasing the breadth of clinical experience through a more formal structure and improved faculty counseling. An appropriate number of electives or selected options should be included. (17b) Counseling of medical students by faculty and others should be directed toward increasing the breadth of clinical experience. Students should be encouraged to choose experience in disciplines that will not be an integral part of their projected graduate medical education.
(18) Directors of residency programs should not permit medical students to make commitments to a residency program prior to the final year of medical school.
(19) The first year of postdoctoral medical education for all graduates should consist of a broad year of general training. (a) For physicians entering residencies in internal medicine, pediatrics, and general surgery, postdoctoral medical education should include at least four months of training in a specialty or specialties other than the one in which the resident has been appointed. (A residency in family practice provides a broad education in medicine because it includes training in several fields.) (b) For physicians entering residencies in specialties other than internal medicine, pediatrics, general surgery, and family practice, the first postdoctoral year of medical education should be devoted to one of the four above-named specialties or to a program following the general requirements of a transitional year stipulated in the "General Requirements" section of the "Essentials of Accredited Residencies." (c) A program for the transitional year should be planned, designed, administered, conducted, and evaluated as an entity by the sponsoring institution rather than one or more departments. Responsibility for the executive direction of the program should be assigned to one physician whose responsibility is the administration of the program. Educational programs for a transitional year should be subjected to thorough surveillance by the appropriate accrediting body as a means of assuring that the content, conduct, and internal evaluation of the educational program conform to national standards. The impact of the transitional year should not be deleterious to the educational programs of the specialty disciplines.
(20) The ACGME, individual specialty boards, and respective residency review committees should improve communication with directors of residency programs because of their shared responsibility for programs in graduate medical education.
(21) Specialty boards should be aware of and concerned with the impact that the requirements for certification and the content of the examination have upon the content and structure of graduate medical

education. Requirements for certification should not be so specific that they inhibit program directors from exercising judgment and flexibility in the design and operation of their programs.
(22) An essential goal of a specialty board should be to determine that the standards that it has set for certification continue to assure that successful candidates possess the knowledge, skills, and the commitment to upgrade continually the quality of medical care.
(23) Specialty boards should endeavor to develop a consensus concerning the significance of certification by specialty and publicize it so that the purposes and limitations of certification can be clearly understood by the profession and the public.
(24) The importance of certification by specialty boards requires that communication be improved between the specialty boards and the medical profession as a whole, particularly between the boards and their sponsoring, nominating, or constituent organizations and also between the boards and their diplomates.
(25) Specialty boards should consider having members of the public participate in appropriate board activities.
(26) Specialty boards should consider having physicians and other professionals from related disciplines participate in board activities.
(27) The AMA recommends to state licensing authorities that they require individual applicants, to be eligible to be licensed to practice medicine, to possess the degree of Doctor of Medicine or its equivalent from a school or program that meets the standards of the LCME or accredited by the American Osteopathic Association, or to demonstrate as individuals, comparable academic and personal achievements. All applicants for full and unrestricted licensure should provide evidence of the satisfactory completion of at least one year of an accredited program of graduate medical education in the US. Satisfactory completion should be based upon an assessment of the applicant's knowledge, problem-solving ability, and clinical skills in the general field of medicine. The AMA recommends to legislatures and governmental regulatory authorities that they not impose requirements for licensure that are so specific that they restrict the responsibility of medical educators to determine the content of undergraduate and graduate medical education.
(28) The medical profession should continue to encourage participation in continuing medical education related to the physician's professional needs and activities. Efforts to evaluate the effectiveness of such education should be continued.
(29) The medical profession and the public should recognize the difficulties related to an objective and valid assessment of clinical performance. Research efforts to improve existing methods of evaluation and to develop new methods having an acceptable degree of reliability and validity should be supported.
(30) Methods currently being used to evaluate the readiness of graduates of foreign medical schools to enter accredited programs in graduate medical education in this country should be critically reviewed and modified as necessary. No graduate of any medical school should be admitted to or continued in a residency program if his or her participation can reasonably be expected to affect adversely the quality of patient care or to jeopardize the quality of the educational experiences of other residents or of students in educational programs within the hospital.
(31) The Educational Commission for Foreign Medical Graduates should be encouraged to study the feasibility of including in its procedures for certification of graduates of foreign medical schools a period of observation adequate for the evaluation of clinical skills and the application of knowledge to clinical problems.
(32) The AMA, in cooperation with others, supports continued efforts to review and define standards for medical education at all levels. The AMA supports continued participation in the evaluation and accreditation of medical education at all levels.
(33) The AMA, when appropriate, supports the use of selected consultants from the public and from the professions for consideration of special issues related to medical education.
(34) The AMA encourages entities that profile physicians to provide them with feedback on their performance and with access to education to assist them in meeting norms of practice; and supports the creation of experiences across the continuum of medical education designed to teach about the process of physician profiling and about the principles of utilization review/quality assurance.
(35) Our AMA encourages the accrediting bodies for MD- and DO-granting medical schools to review, on an ongoing basis, their accreditation standards to assure that they protect the quality and integrity of medical education in the context of the emergence of new models of medical school organization and governance.
Citation: CME Rep. B, A-82; Amended: CLRPD Rep. A, I-92; Res. 331, I-95; Reaffirmed by Res. 322, A-97; Reaffirmation I-03; Modified: CME Rep. 7, A-05; Modified: CME Rep. 2, I-05; Appended: CME Rep. 5, A-11; Reaffirmed: CME Rep. 3, A-11; Modified: CME Rep. 01, I-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 962
(I-18)

Introduced by: Michigan

Subject: Improve Physician Health Programs

Referred to: Reference Committee C
(Peter C. Amadio, MD, Chair)

Whereas, In 2007, thirteen state Medical Boards indicated that the diagnosis of mental illness in and of itself was sufficient for sanctioning physicians; and

Whereas, A Physician Health Program (PHP) is defined as a “confidential resource for physicians, other licensed healthcare professionals, or those in training suffering from addictive, psychiatric, medical, behavioral or other potentially impairing conditions;” and

Whereas, While PHPs operate in 47 states and the District of Columbia, there are no formal programs in California, Nevada, and Wisconsin; and

Whereas, PHPs were created with the intention to rehabilitate and monitor physicians with mental illness, physical illness, and substance use disorders; and

Whereas, PHPs are charged with oversight of licensees who are deemed to be in need of evaluation and/or treatment (namely, those with illnesses that have the potential to interfere with the safe practice of medicine); and

Whereas, Documentation of untreated “mental illness” is enough to require an evaluation; and

Whereas, Many psychiatric disorders (including personality disorders or gender identity disorders) do not have a well-defined treatment and may not impact the physician's’ ability to carry out their health care obligations; and

Whereas, PHPs insist that the selection of evaluator(s), whether an individual clinician or a multidisciplinary center should be the responsibility of the PHP, although, if possible the licensee may be allowed to select an evaluator(s) from a PHP-approved list; and

Whereas, Physicians can be referred to a PHP by their employer, a colleague, a family member, or even themselves; and

Whereas, PHPs do not provide treatment services, but instead offer long-term case management and monitoring to ensure that physicians follow the program mandated for them; and

Whereas, Substance use disorder treatment recommended by PHPs typically mandate participation in 12-step programs; and

Whereas, Despite the fact that physicians with substance use disorder are forced to partake in 12-step programs, research on the efficacy of these programs is mixed and there are other effective programs for substance abuse treatment; and

Whereas, Physicians must agree to cooperate with the PHP and adhere to any recommendations it makes (including specific treatment type) to avoid disciplinary action and remain in practice; and

Whereas, PHPs must report to the state licensing board any physician suffering from serious psychiatric illness, drug or alcohol dependence, or any condition it deems to be potentially impairing and may place the public at risk who refuses their recommendation for treatment; and

Whereas, A recent survey of medical students found they would avoid seeking help for psychological problems for various reasons, including loss of confidentiality (37 percent) and fear of a negative impact on their career (23 percent); and

Whereas, Two states - North Carolina and Michigan - have already been asked to investigate many of the issues raised by PHP critics; and

Whereas, The North Carolina audit found that, “physicians may be vulnerable to intimidation because failure to comply with Program directives can result in referral to the North Carolina Medical Board (Medical Board) and the loss of the physician’s medical license;” and

Whereas, The same audit found that the North Carolina PHP had a lack of objective and independent due process procedures, which prevented physicians from successfully appealing against potentially erroneous accusations and evaluations, and in effect were operating outside of the law, a concern echoed in other state PHPs; and

Whereas, Many of the evaluation and treatment centers to which PHPs refer their clients also sponsor PHP meetings, resulting in a significant potential for conflicts of interest; and

Whereas, A recent publication in the *Journal of Addiction Medicine* called for national standards for the day-to-day operation of PHPs and for PHPs to be routinely audited to ensure soundness and fairness of practice; and

Whereas, Due to a lack of consistent funding, participating physicians are forced to pay at least a portion of treatment costs in about half of the available treatment centers; and

Whereas, 30 of the 43 PHPs in a 2009 survey received a substantial portion of their funding from their state licensing boards, which creates a potential conflict of interest as these PHPs may become beholden to licensing boards rather than risk loss of financial support or closure; and

Whereas, Although multiple studies show high success rates for PHPs in substance use disorders, they often appear to calculate these success rates by only including patients who a) initially agreed to adhere to the treatment program and b) who were compliant throughout the program - a practice that results in elevated and misleading success rates; and

Whereas, ‘Substantive non-compliance’ is considered to be a pattern of non-compliance or dishonesty, or simply an episode of non-compliance (including relapse) which could place patients at risk and result in dismissal from the treatment program; therefore be it

RESOLVED, That our American Medical Association amend policy D-405.990, "Educating Physicians About Physician Health Programs," by addition to read as follows:

1) Our AMA will work closely with the Federation of State Physician Health Programs (FSPHP) to educate our members as to the availability and services of state physician health programs to continue to create opportunities to help ensure physicians and medical students are fully knowledgeable about the purpose of physician health programs and the relationship that exists between the physician health program and the licensing authority in their state or territory; 2) Our AMA will continue to collaborate with relevant organizations on activities that address physician health and wellness; 3) Our AMA will, in conjunction with the FSPHP, develop state legislative guidelines addressing the design and implementation of physician health programs; ~~and~~ 4) Our AMA will work with FSPHP to develop messaging for all Federation members to consider regarding elimination of stigmatization of mental illness and illness in general in physicians and physicians in training; 5) Our AMA will advocate for more independent oversight and regulation of Physician Health Programs (PHPs), by physician groups without any conflict of interest with the participating PHPs; and 6) Our AMA advocate for Physician Health Programs that allow physicians to access more than one type of treatment program. (Modify Current HOD Policy)

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

Received: 10/10/18

RELEVANT AMA POLICY

Educating Physicians About Physician Health Programs D-405.990
1) Our AMA will work closely with the Federation of State Physician Health Programs (FSPHP) to educate our members as to the availability and services of state physician health programs to continue to create opportunities to help ensure physicians and medical students are fully knowledgeable about the purpose of physician health programs and the relationship that exists between the physician health program and the licensing authority in their state or territory; 2) Our AMA will continue to collaborate with relevant organizations on activities that address physician health and wellness; 3) Our AMA will, in conjunction with the FSPHP, develop state legislative guidelines addressing the design and implementation of physician health programs; and 4) Our AMA will work with FSPHP to develop messaging for all Federation members to consider regarding elimination of stigmatization of mental illness and illness in general in physicians and physicians in training.
Citation: (Res. 402, A-09; Modified: CSAPH Rep. 2, A-11; Reaffirmed in lieu of Res. 412, A-12; Appended: BOT action in response to referred for decision Res. 403, A-12)

Impaired Physicians Practice Act H-275.964
Our AMA encourages state medical societies that do not have effectively functioning impaired physicians programs to improve their programs and to urge their states to adopt the AMA 1985 Model Impaired Physician Treatment Act, as necessary.
Citation: (Sub. Res. 7, A-89; Reaffirmed: BOT Action in response to referred for decision Res. 215, I-97; Reaffirmed: BOT Rep. 17, I-99; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10)

Confidentiality of Enrollment in Physicians (Professional) Health Programs D-405.984
1. Our American Medical Association will work with other medical professional organizations, the Federation of State Medical Boards, the American Board of Medical Specialties, and the Federation of State Physician Health Programs, to seek and/or support rules and regulations or legislation to provide for confidentiality of fully compliant participants in physician (and similar) health programs or their recovery programs in responding to questions on medical practice or licensure applications.
2. Our AMA will work with The Joint Commission, national hospital associations, national health insurer organizations, and the Centers for Medicare and Medicaid Services to avoid questions on their applications that would jeopardize the confidentiality of applicants who are compliant with treatment within professional health programs and who do not constitute a current threat to the care of themselves or their patients.
Citation: (Res. 4, A-15)

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