

REPORTS OF THE BOARD OF TRUSTEES

The following reports, 1–12, were presented by Patrice A. Harris, MD, MA, Chair:

1. 2016 AMA ADVOCACY EFFORTS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Policy G-640.005, “AMA Advocacy Analysis,” calls on the Board of Trustees (BOT) to provide a report to the House of Delegates (HOD) at each Interim Meeting highlighting the year’s advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The BOT has prepared the following report to provide an update on 2016 American Medical Association (AMA) advocacy activities.

DISCUSSION OF 2016 ADVOCACY EFFORTS

MACRA Implementation

With the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) behind us, our attention turned immediately to MACRA implementation through the regulatory process where numerous key decisions will be made. MACRA is a complex law, and the proposed regulations to implement it are long and complicated. Compared to the current Medicare physician payment framework, the MACRA law and proposed/final regulations provide significant improvements. Changes to the proposed rule are still needed, and we are advocating forcefully to achieve them in order to reduce regulatory burdens on physicians and to create greater flexibility and choice so physician practices can thrive.

To help guide our MACRA implementation efforts, the AMA established a MACRA Task Force comprised of national medical specialty societies, state medical associations, the American Osteopathic Association, and the Medical Group Management Association to develop strategic approaches and consistent messaging.^{1,2} We also set up staff workgroups on two key MACRA components – the Merit-based Incentive Payment System (MIPS) and alternative payment models (APMs) to help inform our activities.^{3,4} We have also organized Centers for Medicare & Medicaid Services (CMS) listening sessions with representatives of national medical organizations and state medical associations to improve understanding of MACRA and offer feedback to CMS from across the Federation. Further, we have met regularly with key officials at CMS and the White House on MACRA, and we are keeping Congress apprised of regulatory developments. In addition, the AMA’s 2016 Physician Practice Benchmark Survey will include questions to measure physicians’ awareness of MACRA and intended pathways for participation.

Earlier this year in April, CMS released the first MACRA proposed rule. In response, the AMA filed extensive comments that would lead to a better final rule. (The AMA’s full comments to CMS are available at ama-assn.org/go/medicarepayment.) There are some positive developments in the proposed rule:

- The proposed rule attempts to align three previously disparate and highly burdensome federal reporting programs tied to Medicare payment (Meaningful Use [MU], Physician Quality Reporting System [PQRS], and the Value-based Modifier [VBM]).
- For the MIPS quality component, the proposed rule reduces the number of quality measures, grants more flexible reporting, and allows for partial credit.
- In Advancing Care Information (the replacement for the MU program), the proposed rule modifies the 100 percent pass/fail approach and reduces the number of required measures.
- The proposed rule creates exemptions for physicians whose practices have under \$10,000 in Medicare claims and fewer than 100 patients.
- It establishes a pathway for physicians to participate in APMs and receive five percent bonus payments from 2019-2024.

In our comments to the propose rule, we highlighted our top priorities for improvements in the final rule:

- A more realistic start date is needed for reporting requirements under the MIPS program, specifically July 1, 2017 rather than January 1, 2017.
- Further accommodations are needed for small and rural practices including increasing the low-volume threshold to under \$30,000 in Medicare claims or fewer than 100 patients which AMA estimates will exempt about 29 percent of physicians from MIPS reporting requirements.
- The four components of the MIPS program are still too complex for physician practices, so further enhancements and streamlining are needed.
- The APM requirements are too stringent and will lead to too few APM options for physicians, so further flexibility, a more reasonable risk standard, and a more diverse set of models are needed.

Our comments also discussed other provisions in the proposed rule where refinements are needed.

In response to advocacy efforts by the AMA and other physician organizations, CMS Acting Administrator Andy Slavitt announced on September 8 in the CMS Blog that the agency was making significant changes to the physician reporting requirements under MACRA for 2017. According to the blog post, the only physicians who risk any negative payment adjustment in 2019 will be those who opt not to report at all under MACRA in 2017. Those who do choose to report will have three options with no risk of penalties. Physicians who report for the full year, beginning on January 1, 2017, will be eligible for an unspecified “modest positive payment adjustment.” Under a second option, those who report for part of the calendar year will be eligible for an unspecified “small positive payment adjustment.” Finally, physicians who submit a small amount of data during the year under a “test” option will avoid any negative payment adjustments. Qualified physicians who participate in an Advanced Alternative Payment Model in 2017 will remain eligible for a 5 percent incentive payment in 2019.

Knowing that this is a complicated and confusing time for physicians as they prepare to adapt their practices to MIPS or seek to participate in an APM, AMA staff from Professional Satisfaction and Practice Sustainability, Advocacy, and Enterprise Communications and Marketing collaborated to develop tools and resources for physicians to assist them with these decisions (ama-assn.org/go/medicarepayment). The Payment Model Evaluator (also available at ama-assn.org/go/medicarepayment) was released in September and is a tool for physicians to assess the impact of MACRA on their practices and obtain implementation resources to maximize their success. The AMA also produced a “[MACRA Checklist](#)” to help physicians prepare for the new payment system. The AMA’s STEPS Forward™ program has been recognized by CMS as eligible for Clinical Practice Improvement credit under MACRA. In addition, the AMA is a Support and Alignment Network under the CMS Transforming Clinical Practice Initiative and is providing MACRA education to independent and small practices via Practice Transformation Networks across the country. Additional resources for practices are in development.

The final MACRA rule is expected to be released prior to the Interim Meeting. With this report being prepared for the HOD in September, it does not include information on the final rule. Please watch for alerts from the AMA and information on our website. Further information will be available at the Interim Meeting as well assuming that the final rule has been released.

Insurer Mergers

The Federation and the AMA achieved a major accomplishment when the US Department of Justice (DOJ) and a number of state attorneys general (AGs) filed suit to block the Anthem-Cigna and Aetna-Humana mergers. By working together, the AMA and the state medical associations rang the alarm nationally about the potential negative effects that these mergers could have for patients and physicians. Our collaborative work was instrumental in convincing the DOJ and many state AGs that the proposed mega-mergers should not proceed. The AMA will continue to oppose these mergers aggressively as they enter the litigation phase.

For over a decade, the AMA has produced research highlighting that health insurance markets in most geographic areas are highly concentrated, and thus provide health insurers with anticompetitive contracting leverage in these markets. This is detrimental to patients and physicians. The 2015 edition of *Competition in Health Insurance: A Comprehensive Study of US Markets* was publicized widely in the media and highlighted to policymakers and antitrust regulators such as DOJ and AGs. The AMA also conducted special analyses of states and metropolitan areas, to identify the states and metropolitan areas that would be most negatively affected by one or both of the proposed mergers.

The AMA showcased this research in testimony before federal and state lawmakers several times. AMA President Andrew W. Gurman, MD, and AMA Trustee Barbara L. McAneny, MD, testified at congressional hearings to discuss our research and express our concerns about health insurance market concentration. We testified and wrote letters to legislators, AGs, and insurance commissioners in several states as well.

We also regularly convened those state medical associations most likely to be negatively affected by the mergers, to facilitate the exchange of information and strategy, and to ensure that the AMA was providing optimal support to those associations in their merger advocacy. We also had discussions with national groups such as the National Association of Attorneys General (NAAG) and select state insurance regulators. For example, AMA worked very successfully with the Missouri State Medical Association and the California Medical Association to convince their respective insurance regulators to oppose the mergers. AMA filed comments in a number of states, including Florida, Missouri, California, Indiana, Georgia and New York – and worked with a number of others behind the scenes. We brought in economists and legal experts to bolster our case. We worked closely with consumer groups too. The AMA also prepared a member survey for states to gauge the effect of the proposed mergers in their physician communities and passed the results on to the DOJ, as well as state AGs and insurance regulators.

We expect the health insurers to defend the mergers vigorously, but we will continue to oppose them and continue to build strong coalitions that will challenge them at the federal level, the state level, in the courts, and in public opinion.

Opioid Misuse

With over 78 deaths per day, the opioid epidemic remains one of the biggest health challenges facing our nation. The AMA is continuing our advocacy and communications efforts through the AMA Task Force to Reduce Opioid Abuse (Task Force), which is comprised of more than 25 physician organizations including the AMA, American Osteopathic Association, American Dental Association, national medical specialty societies and state medical associations.⁵ The Task Force has coalesced around pursuing five clear actions:

- Increasing physicians' registration and use of effective prescription drug monitoring programs;
- Enhancing physicians' education on safe, effective and evidence-based prescribing of opioids;
- Reducing the stigma of pain and promoting comprehensive assessment and treatment;
- Reducing the stigma of substance use disorder and enhancing access to treatment; and
- Supporting overdose prevention efforts by expanding access to naloxone and providing Good Samaritan protections.

The severity of the epidemic led to an [open letter](#) from AMA Immediate Past President Steven J. Stack, MD, to physicians on the responsibilities and roles they must play to reduce the opioid epidemic and to make sure physicians are trained in safe prescribing practices.

At the state level, there were more than 1,000 individual pieces of legislation concerning prescription drug misuse, overdose and death in 2016 – nearly double from 2015. The AMA worked with states individually on pressing bills, and helped more than 10 states secure victories on issues ranging from prescription drug monitoring programs (PDMPs) to increased access to naloxone. We also continued our work with national groups such as the National Governors Association (NGA) which led to a major accomplishment when the AMA and the NGA issued a national joint statement on key recommendations that physician leaders and governors could mutually support. This was the first time that the AMA and NGA had issued such a statement - which included all of the Task Force recommendations. AMA Chair Patrice A. Harris, MD, MA, testified at the NGA's Winter Meeting in support of the recommendations. Furthermore, the Task Force recommendations were emphasized in more than 10 published op-eds and letters to the editor, many of which were joint efforts with state medical associations.

At the federal level, the AMA expressed support for the recently enacted Comprehensive Addiction and Recovery Act (CARA). The final version of CARA authorizes numerous grant programs focused on prevention of opioid addiction, alternatives to incarceration, increasing the availability of naloxone, supporting PDMPs, promoting medication-assisted therapy and expanding drug take-back programs. The legislation also included other AMA-supported proposals, such as the reauthorization of the National All Schedules Prescription Electronic Reporting Act, which supports state PDMPs, and allows partial fills of Schedule II drugs. While CARA authorizes hundreds of

millions of dollars in funding for these programs, Congress must still appropriate the funds in order to fulfill its promise. The AMA will continue to urge Congress to take this critical next step.

Also at the federal level, a proposed rule issued in July regarding Medicare hospital outpatient and ambulatory surgical center payments in 2017 includes a provision to eliminate the current pain management questions in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience care survey from performance scores beginning in 2018. This was done in response to advocacy by the AMA and others expressing concern that the link between scoring well on the survey and higher facility payments interferes with efforts to curb over-prescribing of opioids. CMS is developing alternative questions for the pain management dimension to address these concerns.

Telemedicine

States saw a flurry of activity on telemedicine in 2016, with dozens of laws and regulations proposed to address telemedicine licensure, reimbursement, and practice standards. Many of these laws were based on the AMA “Telemedicine Act,” which addresses these and other issues related to telemedicine. This year, five bills based on this AMA model bill were signed into law.

While most attention was given to debates over how to establish a patient-physician relationship via telemedicine—in person, using two-way interactive audio-video technology or over the phone—states continued to make gains in passage of coverage parity laws, ensuring that physicians will be compensated for treating their patients via telemedicine. AMA advocacy was instrumental in many of these victories. The AMA is already working towards 2017 legislation with many medical associations from states that lack coverage parity, using the AMA “Telemedicine Act” as a guide. States also continue to advance the “Interstate Medical Licensure Compact,” with 17 states now having enacted it. The Compact facilitates interstate licensure for telemedicine services.

There has also been significant activity around telemedicine at the federal level. Our AMA continues to advance several major priorities to accelerate the integration of telemedicine into regular clinical practice, including expanding coverage in federal health care programs for telemedicine services, building the evidence base through federal funding for research, and supporting widely supported standards. We are also strongly advocating against efforts by some telecommunications groups to undermine existing state licensure laws, including proposals to create a national licensure scheme or change the site of practice from the state where the patient is located to the state where the physician is located for the purpose of providing telemedicine services to Medicare, the Veterans Health Administration (VA), or DOD TRICARE patients. On the coverage front, the AMA is working with telemedicine stakeholders to draft comments in support of expanded coverage of telehealth services in the Medicare program in response to the proposed 2017 Medicare Physician Fee Schedule, and convening national medical specialty societies to support and urge acceleration of initiatives that grow the evidence base, increase national specialty clinical practice guidelines, and other strategic engagements that ensure physicians have the information and tools to support implementation.

Electronic Health Records (EHR) Meaningful Use (MU)

In October 2015, CMS announced that the 2015 MU reporting period would be reduced from 365 to 90 days. The AMA has consistently urged CMS to implement a shorter reporting period for MU, due to the program’s pass-fail nature and the unforeseeable reporting disruptions that occur due to system failures, the adoption of new vendor products, and other factors beyond a physician’s control. Physicians had until March 15, 2016, to apply for a hardship exemption from three percent MU financial penalties in effect for the 2015 program year. In direct response to AMA advocacy, CMS announced that it would broadly grant hardship exemptions as a result of the delayed publication of the final regulations that announced the policy change, since physicians were left with insufficient time to report that year under the modified program requirements. This inclusive approach to allowing hardship exemptions is a result of the “Patient Access and Medicare Protection Act,” passed just before Congress adjourned for the 2015 holidays, [which directed CMS to make AMA-supported changes](#) to the previously limited exemption process.

In July, CMS proposed to implement a 90-day MU reporting period for 2016, as well. The announcement was made in draft regulations pertaining to Medicare hospital outpatient and ambulatory surgical center payment systems for

2017. The AMA has urged CMS to finalize its proposal promptly, to avoid the extraordinary measures that were needed for the 2015 exemptions process due to tardy publication of the regulations.

Finally, in the MACRA draft regulations, CMS proposed 2017 as the first performance period for MIPS. As it happens, 2017 is also the last year that first-time participants in the MU program may attest to avoid penalties in 2018. Therefore, a new MU participant would be required to participate in both the MU program and the new Advancing Care Information performance category of MIPS in 2017 to avoid any payment adjustment, despite the significant overlap of these two programs. Following AMA advocacy efforts, the proposed rule on Medicare outpatient hospital and ambulatory surgical center payments for 2017 offered a change in this approach, and would allow physicians who have not previously demonstrated MU to apply for a significant hardship exemption from the 2018 payment adjustment and so avoid the duplicative reporting requirements.

Insurer Networks/Balance Billing

In late 2015, the National Association of Insurance Commissioners (NAIC) finalized its network adequacy model bill, prompting insurance commissioners across the country to push for its adoption by their legislatures. The AMA was heavily involved in the NAIC's process of drafting the model legislation, and as a result of AMA and medicine's advocacy, many important provisions that would improve access to care for patients were included in the final bill. Unfortunately, also included were provisions that threaten access to care and the ability of physicians to negotiate fair contracts with insurers. The AMA offers a detailed, edited version of the NAIC model bill for states to use. As states, such as Connecticut and Maryland, took up the NAIC model this year, medical societies, with assistance from the AMA, worked off of the AMA's version to amend their legislation to better serve patients and physicians and were highly successful in doing so. It is very likely that more states will be proposing versions of the NAIC model next year, and the Federation is already working with insurance commissioners and legislators to propose changes to their version of the legislation.

When legislators tackle network adequacy issues, balance billing discussions arise as well. In 2016, many states engaged in difficult debates over what should happen when a patient receives a bill from an out-of-network physician while at an in-network facility. With AMA assistance, state medical associations worked hard to accurately frame the issue as a symptom of the larger problems with provider networks and unfair contracting practices. The AMA is working with several coalitions including a work group that we convened with several specialty and state medical associations to find workable solutions.

Pharmaceutical Costs

In response to a call for action by the HOD at I-15, the AMA convened a Task Force on Pharmaceutical Costs,⁶ chaired by AMA Chair-Elect Gerald E. Harmon, MD, to develop principles to guide grassroots efforts aimed at addressing pharmaceutical costs and improving patient access. Board of Trustees Report 10-I-16, "AMA Initiatives on Pharmaceutical Costs," contains a full update on this issue, but to provide a snapshot, the Task Force recommended that increasing transparency among pharmaceutical companies, health plans and pharmacy benefit managers (PBMs) should be the focus of Phase I of the HOD-directed grassroots campaign. The AMA launched and is promoting an online petition that calls on Congress to demand that these companies introduce a basic level of transparency to the general public. The petition is being featured on cause-oriented websites frequented by online activists on both sides of the political spectrum (e.g., standunited.org), as well as specifically promoted to the AMA's Patient's Action Network. This fall, a campaign-specific microsite focused on drug pricing transparency will be launched in order to build on the initial interest generated by the online petition and related promotional activities. Following the November elections, additional public opinion research and message testing will be conducted to help provide further guidance on how to best advocate on this topic.

Zika Prevention Funding

On May 26, 2016, the AMA wrote the bipartisan leadership of Congress, urging "immediate action to make available the necessary resources to prepare our nation to address the growing threat of the Zika virus." The AMA has also joined the efforts of a broad coalition of organizations, including the March of Dimes, the American Congress of Obstetricians and Gynecologists, and the American Academy of Pediatrics in continuing to advocate for congressional action. Though Congress recessed for the summer without taking final action on funding, AMA

continues to press for a resolution to the funding dispute as soon as possible. The AMA is also working with the coalition on state strategies to combat the spread of Zika.

Proposed Medicare Fee Schedule

The annual proposed rule on the Medicare physician payment schedule, issued in July, included both favorable and unfavorable policy proposals. Policies in the proposed rule that the AMA will support in its comments include:

- Following up on an announcement earlier this year, the draft regulation proposes to expand the duration/scope of the Diabetes Prevention Program (DPP) model. Under the new program, to be known as the Medicare Diabetes Prevention Program (MDPP), providers could deliver services either in-person or via remote technologies.
- Several policy updates were made for primary care services, including improved payments for chronic care management services and a separate payment for behavioral health integration models.
- Despite statements made earlier in the year by former CMS officials, the agency did not propose to revise existing policies and will continue to exclude industry support for independent continuing medical education in the Open Payments Program (Sunshine Act) reporting data base.

Other policies outlined in the proposed rule are more problematic:

- As part of a data collection effort on the frequency of and inputs involved in providing global surgical services, CMS is proposing to require comprehensive claims-based reporting on the number and level of pre- and post-operative services furnished during 10- and 90-day global periods. This would require physicians to report a set of time-based G-codes (in 10-minute increments) that distinguish between the setting of care and whether the services are provided by a physician or their clinical staff. The extraordinary administrative burden would be imposed during the first MACRA reporting year – on January 1, 2017 – when physicians are already adapting to broad regulatory changes. The AMA is working with a coalition of specialty organizations to stop this proposal and replace it with a data collection effort more in line with congressional intent.
- CMS is proposing an add-on code that could be billed with an evaluation and management service for physicians treating patients with mobility-related impairments. Payments for this add-on code would be funded through an across-the-board cut in Medicare payment rates in 2017. The AMA is exploring alternative approaches to recommend for improving access to care for these patients.

Tobacco Regulation

In August, the US Food and Drug Administration (FDA) released its [final rule](#) regulating e-cigarettes, cigars, hookah and other previously unregulated tobacco products. The new rules are sweeping in scope, and for the first time, extend federal regulatory authority to e-cigarettes, banning their sale to minors under the age of 18 and requiring health warnings.

Also required under the rules:

- Adults under the age of 26 must show a photo identification to buy these tobacco products.
- Producers must register with the FDA and provide a detailed accounting of the ingredients in their products and their manufacturing processes.
- Manufacturers are prohibited from making unproven health claims.
- Manufacturers must apply to the FDA for permission to sell their products.

As recommended by the AMA and other public health stakeholders, the FDA extended the rules to all cigars, rejecting proposals to exempt so-called “premium cigars.” The AMA has long called for e-cigarettes to be subject to the same regulations and oversight that the FDA applies to tobacco and nicotine products, and supports the final rule as an important step in protecting the public’s health, especially that of minors. However, the AMA believes further regulation is necessary with regard to marketing e-cigarettes and banning flavored e-cigarettes, which are particularly enticing to minors.

The AMA is also assisting state medical associations with efforts to raise the minimum age for purchasing tobacco and electronic smoking devices. For example, with AMA support, California raised the age to purchase tobacco products to 21 this year, making it the second state to do so.

Medical Liability Reform

The AMA and the Federation continue to promote and defend medical liability reform (MLR). Most of the activity is occurring at the state level in recent years. In 2016, states considered bills that promoted a variety of reforms, including expert witness guidelines, affidavit of merit requirements, collateral source reform and bills that established structures such as pretrial screening panels or health court systems. Most of these bills did not progress to enactment. A handful of states had to engage in defensive efforts as they faced attempts to raise caps on non-economic damages. Most efforts to defeat cap bills were successful, while at the eleventh hour, the Indiana legislature passed a long-pending bill to raise the state's 18-year old cap from \$1.25 million to \$1.65 million in 2017 and \$1.8 million in 2019.

Team-based Care/Scope of Practice

In 2016, the AMA continued to promote physician-led teams at the state level and to fight inappropriate scope of practice legislation. State legislatures considered over 500 bills seeking to eliminate team-based care models of health care delivery and/or expand the scope of practice of non-physician health care professionals. The AMA expects this high level of legislative activity to continue in 2017.

Though tough fights in all cases, most bills that threatened passage were defeated with the support of the AMA, in close coordination with state and specialty medical associations. For example, bills pursuing independent practice of advanced practice nurses were defeated in 12 states. In two of those states – Arizona and Ohio – grants from the Scope of Practice Partnership (SOPP) played a key role in supporting efforts to defeat independent practice bills from nurse anesthetists and nurse practitioners, respectively. AMA advocacy and SOPP support also helped to defeat bills to allow psychologists to prescribe psychotropic medication. To date, the SOPP has granted nearly \$1.4 million to state and specialty medical societies in support of scope of practice, truth in advertising, and physician-led team advocacy efforts.

Nurse Practitioners in the Veterans Health Administration

The Veterans Health Administration (VA) published a [proposed rule](#) in May that would give full practice authority to four categories of advanced practice registered nurses (APRN): certified nurse practitioner, certified registered nurse anesthetist, clinical nurse specialist, and certified nurse-midwife. The proposal would allow APRNs working within the scope of VA employment to provide services without the clinical oversight of a physician, regardless of state or local law restrictions on that authority. Efforts at the VA to permit independent nursing practice go back several years but gained momentum when significant staffing shortages and long patient wait times were uncovered in 2014.

In addition to meetings of AMA Trustees with VA officials on this subject, the AMA submitted comments opposing the proposed rule and urged members of the Federation to do the same. The AMA submitted a [sign-on letter](#) on behalf of 98 specialty and state medical societies urging the VA not to move forward with the proposal.

Prior Authorization

The AMA is conducting a major research project on prior authorization (see “New Advocacy Research” section that follows) and has formed a work group with Federation groups and other stakeholders to address this issue. In 2016, the AMA worked with several states to propose new legislative ideas on this problematic issue. Delaware enacted legislation based on the AMA model prior authorization bill that requires reporting of prior authorization statistics by insurers or benefit managers to a state database. The data is likely to prove invaluable in studying the impact and utility of prior authorization. Additionally, Ohio and Delaware were able to include AMA model provisions in their new laws that make prior authorizations valid for a year and prevent retroactive denials. They were also both able to include a transition to electronic prior authorization (ePA) to automate the prior authorization process, a major priority of the AMA.

2016 GRASSROOTS/GRASSTOPS ACTIVITIES

In order to provide both patient and physician advocates with the best tools and resources, the AMA Patient's Action Network and Physicians' Grassroots Network recently made changes to their online advocacy platforms. On the patient side, this included: an updated website design for [PatientsActionNetwork.org](#); a new call to action on freeing up regulations that affect electronic health records and interfere with the patient-physician relationship; even more resources to help enhance advocacy efforts; an interactive "share your story" feature; and, stronger social media tools to make it easier to connect with fellow advocates. For physicians, changes focused on broadening the scope of [BreaktheRedTape.org](#) to include new issues important to medicine such as the opioid misuse crisis, MACRA, telemedicine, and drug pricing transparency. New action-taking tools and online resources will be available to physicians as well, enabling them to communicate with lawmakers on these important issues through social media channels and new, interactive video-sharing technologies.

In conjunction with the Medical Student Advocacy and Region Conference held earlier this year, the AMA has also launched an updated version of [SaveGME.org](#). The updates include new resources and content, including video submissions from medical students and a call to action on the Public Service Loan Forgiveness Program. In addition, new videos and social media outreach expected to be unveiled in the fall will be focused on expanding the SaveGME campaign's mission to focus on raising awareness with the general public on the urgent need to preserve adequate funding for graduate medical education.

2016 AMPAC ACTIVITIES

AMPAC has once again worked closely with its state medical association PAC partners this election cycle on contribution support decisions for candidates running for the US House of Representatives and Senate. A report summarizing AMPAC activities will be distributed at the Interim Meeting in Orlando.

FEATURED ADVOCACY RESOURCES

The AMA has also produced new resources to assist physicians:

- [Guide to Physician-focused Alternative Payment Models](#): The AMA worked with Harold Miller at the Center for Healthcare Quality and Payment Reform, a member of the newly appointed Physician-Focused Payment Models Technical Advisory Committee to the federal government, to develop a guide to help physicians understand the various types of APMs and how their practice may be able to participate in a new model.
- [HIPAA podcast](#): The AMA and the Healthcare Information and Management Systems Society (HIMSS) produced this podcast to answer questions about providing patients access to their health information, as required by the Health Insurance Portability and Accountability Act (HIPAA).
- [AMA Health Workforce Mapper](#): The AMA launched an update of the AMA Health Workforce Mapper, an interactive online resource that illustrates the distribution of physicians and non-physician clinicians by specialty, state, county, or metropolitan areas. The AMA Health Workforce Mapper provides a useful visual tool to demonstrate to law- or policymakers the geographic distribution of the health care workforce in a given state or nationally, to assist them in making appropriate, evidence-based decisions. The updated Health Workforce Mapper now integrates CDC data on morbidity, mortality, health care access and quality, health behavior demographics and social environments, further helping to ensure that patients have access to the care they need.
- [Workers' Compensation and Auto Injury Toolkit](#): The AMA recently updated its Workers' Compensation and Auto Injury Toolkit. This resource offers a primer on property and casualty billing, as well as provides valuable practice tips for transitioning from manual to electronic processes for these business lines.

NEW ADVOCACY RESEARCH

The AMA has also produced the following studies to assist in our efforts:

- [Policy Research Perspective - Payment and Delivery in 2014: The Prevalence of New Models Reported by Physicians](#): This publication presents a national view of physician participation in new payment and delivery models by specialty, practice type and practice ownership. Based on the 2014 Physician Practice Benchmark Survey, it concludes that although the majority (59.0 percent) of physicians worked in practices that received

revenue from at least one alternative payment model, fee-for-service payment was still the dominant payment method used by insurers to pay physician practices. An average of 71.9 percent of practice revenue came from fee for service. A 2016 edition of this study is forthcoming in 2017.

- Competition in Health Insurance: A Comprehensive Study of US Markets: In this report, the AMA produces the largest, most complete picture of competition in the commercial health insurance markets across the US. It is a valuable resource for physicians, policymakers, regulators, researchers, and patients. It has been a vital component of our campaign to halt the proposed insurance mergers.
- Prior Authorization: The AMA is partnering with the University of Southern California Schaeffer Center for Health Policy & Economics in an ambitious research project focused on prior authorization. Through rigorous analysis of claims and clinical data, this study will assess the impact of prior authorization on resource utilization, costs (both for a particular service and overall health care expenditures), and patient outcomes. While health plans endorse prior authorization as a mechanism to control costs, the more holistic analysis proposed for this study may show an overall lack of value for the health care system. Results from the study will be targeted for publication in a peer-reviewed journal in 2017 and will provide valuable support to the AMA's evidence-based advocacy on this issue.
- Narrow Network Regulation: Recent research conducted by the Georgetown University Health Policy Institute (Georgetown), commissioned by the AMA, presents important findings regarding the regulation of narrow networks, specifically with regard to consideration of quality as a component of regulation. As highlighted by Georgetown researchers, state regulators generally do not define or regulate "narrow networks" or "tiered networks" any differently than standard networks. Additionally, when the Georgetown researchers drilled down on the issue of quality and asked state regulators and other stakeholders whether state provider network rules should incorporate the concept of quality, especially when assembling narrow networks, they found little to no focus on quality in network design, even in the narrowest of networks. At the time of this writing, the research, along with a supplemental AMA discussion document, is set to be released in September to complement and enhance the AMA's state advocacy on network adequacy and physician profiling issues.
- National survey: Physician perceptions and practices on opioid prescribing, education, barriers to care, naloxone: The AMA released the findings of a national physician survey that showed strong support for key policies and recommendations to help reverse the nation's opioid epidemic, including ways to improve prescription drug monitoring programs, enhance physician education as well as remove barriers to care. The survey found, among other things, that PDMPs need improvement to integrate with electronic health records, provide real-time data and other key features that would make them even more useful. The survey also found that a majority of respondents have taken continuing medical education (CME) on safe opioid prescribing and strong support for increasing access to naloxone.

CONCLUSION

As shown by this report, the AMA continues to advocate for physicians and patients on numerous, vital health care issues, and we continue to have a positive impact. In 2017, our advocacy efforts will focus on MACRA implementation (with a particular emphasis on assisting small practices); the opioid crisis; health insurer mergers; pharmaceutical pricing; health insurer networks; public health topics; and other issues that arise. We are gearing up for a new Administration and Congress and will be ready to move forward once our new federal and state officials assume office. We appreciate the collaboration with the Federation in 2016, and look forward to further work and success in 2017 at the federal and state levels.

REFERENCES

1. National Medical Specialty Societies – American Academy of Family Physicians, American Academy of Ophthalmology, American Association of Neurological Surgeons, American Association of Orthopaedic Surgeons, American College of Cardiology, American College of Emergency Physicians, American College of Physicians, American College of Surgeons, American Psychiatric Association, and American Society of Clinical Oncology.
2. State Medical Associations – Illinois State Medical Society, Massachusetts Medical Society, North Carolina Medical Society, Ohio State Medical Association, Texas Medical Association, Washington State Medical Association, and Wisconsin Medical Society.
3. MIPS workgroup – American Association for Clinical Endocrinology, American Association of Neurological Surgeons, American College of Cardiology, American College of Radiology, American Osteopathic Association, AMDA (The Society for Post-Acute and Long-Term Care Medicine), American Society of Cataract and Refractive Surgery, American Society of Gastrointestinal Endoscopy, Illinois State Medical Society, Maine Medical Association, Medical Group Management Association, North Carolina Medical Society, Society of Gynecologic Oncology, and Texas Medical Association.

4. APM workgroup – American Academy of Otolaryngology-Head and Neck Surgery, American College of Emergency Physicians, American College of Physicians, American College of Surgeons, American Psychiatric Association, American Gastroenterological Society, American Society of Clinical Oncology, American Society for Therapeutic Radiology and Oncology, American Urological Association, American Uro-gynecologic Society, California Medical Association, Massachusetts Medical Society, Society of Gynecologic Oncology, Society of Thoracic Surgeons, Washington State Medical Association, and Wisconsin Medical Society.
5. AMA Task Force to Reduce Opioid Abuse (Task Force) – American Academy of Addiction Psychiatry, American Academy of Family Physicians, American Academy of Hospice and Palliative Medicine, American Academy of Orthopaedic Surgeons, American Academy of Neurology, American Academy of Pain Medicine, American Academy of Pediatrics, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American College of Emergency Physicians, American College of Occupational and Environmental Medicine, American College of Physicians, American College of Rheumatology, American Congress of Obstetricians and Gynecologists, American Dental Association, American Medical Association, American Osteopathic Association, American Psychiatric Association, American Society of Addiction Medicine, American Society of Anesthesiologists, Arkansas Medical Society, Massachusetts Medical Society, Medical Society of the State of New York, New Mexico Medical Society, Ohio State Medical Association, Oregon Medical Association, and Utah Medical Association.
6. AMA Task Force on Pharmaceutical Costs – AMA Council on Legislation, AMA Council on Medical Service, AMA Council on Science and Public Health, Medical Association of the State of Alabama, California Medical Association, Massachusetts Medical Society, Minnesota Medical Association, American Academy of Dermatology, American Academy of Pediatrics, American College of Cardiology, American College of Physicians, and American Society of Clinical Oncology.

**2. AMA SUPPORT FOR STATE MEDICAL SOCIETIES' EFFORTS TO
IMPLEMENT MICRA-TYPE LEGISLATION
(RESOLUTION 214-I-15)**

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 214-I-15
REMAINDER OF REPORT FILED**
See Policies H-435.943 and H-435.967

INTRODUCTION

Resolution 214-I-15, which was introduced by the Tennessee Delegation and referred to the Board of Trustees, asked “that our American Medical Association continue to support state medical societies’ efforts to implement MICRA-type legislation,” and “that our AMA engage its leadership and staff, those of the national medical specialty societies, and other stakeholder organizations to provide resources and technical assistance to efforts throughout the Federation to defeat no fault medical liability legislation.” This report summarizes no-fault medical liability legislation and analyzes available evidence pertaining to such legislation, and recommends new policy and reaffirmation of existing policy.

BACKGROUND

No-fault liability or Patient Compensation Systems (PCS) propose compensating patients for any suboptimal medical outcome, regardless of whether negligence has occurred. Essentially, PCS proposals would replace the current medical liability system in a state with a system modeled on workers’ compensation programs or more limited systems like neurologic birth injury funds.

While individual proposals differ from state to state, generally, a PCS would operate as follows. Patients dissatisfied with their medical care would file a claim to a panel including individuals such as physicians, patient advocates, hospital administrators, and attorneys. Based on interviews and a medical record review, the panel would make a *prima facie* determination of whether a medical injury occurred. The panel would not be required to make a determination of whether medical negligence occurred. If the panel finds that a medical injury occurred, the claim will go to a compensation department for the determination of compensation based on a fee schedule for each type of injury and the severity of the injury. Appeals could be made based only on the process itself and not the size of the award.

PCS proponents claim that the system will “dramatically reduce the practice of defensive medicine, thereby reducing health care costs, increasing the number of physicians practicing in a state, improving patient safety, and providing patients fair and timely compensation without the expense and delay of the court system.”¹

PCS opponents question these claims, including the assumptions made about the impact on defensive medicine, and counter that the PCS system will compensate patients where no negligence has occurred, increase the number of claims filed, increase reporting to the National Practitioner Data Bank (NPDB), increase costs for physicians and other clinicians, and otherwise undermine medical liability reforms at the state and federal levels.

PATIENT COMPENSATION SYSTEM LEGISLATION

To date, PCS bills have been filed in about half a dozen states. To date, none of these bills has passed the respective state legislature. This report will focus on legislation filed in one state – Georgia – as representative of other state experiences.

Georgia Senate Bill 141 (2013) and subsequent bills

During the 2013 – 2014 legislative session, the Georgia General Assembly considered Senate Bill (S.B.) 141 and its companion bill, House Bill (H.B.) 662, both called the “Patient Injury Act.” Neither bill passed out of committee. The following is a summary of the PCS structure the bills proposed.

PCS administration and governance

The PCS would have been governed by an 11-member board representing the medical, legal, patient, and business communities, and would be appointed by the governor, the lieutenant governor, and the speaker of the House of Representatives. The Board would employ staff including an executive director, advocacy director, chief compensation officer, chief financial officer, chief medical officer, and chief quality officer. The chief medical officer’s office would manage medical review, with the authority to administer oaths, take depositions, issue subpoenas, compel the attendance of witnesses and the production of evidence, and obtain patient records pursuant to the patient’s release of protected health information.

The board would also establish committees, including a medical review committee composed of two physicians and one other board member, with the authority to convene an independent medical review panel to evaluate whether an application constitutes a medical injury. The panel would be composed of an odd number of at least three panelists chosen from a list of panelists recommended by the medical review committee and approved by the board.

The board would also establish a compensation committee responsible for recommending a compensation schedule for damage payments to the board.

Health care professionals included in a PCS

The following health care professionals and entities would have been included in a PCS pursuant to S.B. 141:

- Hospitals and health care facilities, including nursing homes and skilled nursing facilities
- Pharmacists and pharmacies
- Chiropractors
- Professional counselors, social workers, and marriage and family therapists
- Dentists, dental hygienists, and dental assistants
- Dieticians
- Nurses, including advanced practice nurses
- Nursing home administrators
- Occupational therapists
- Optometrists
- Physical Therapists
- Physicians
- Acupuncturists
- Physician assistants

- Cancer and glaucoma treatment practitioners, respiratory care, clinical perfusionists, and orthotics and prosthetic practitioners
- Podiatrists
- Psychologists
- Speech language pathologists and audiologists

Other versions of PCS bills have applied to:

- Physicians, hospitals, health systems or persons licensed or otherwise authorized to provide health care services²
- Only physicians³
- Only primary care physicians⁴

Notably, after facing opposition from many of the categories of health care professionals included, more recent versions of Georgia's PCS legislation – now coined the “Patient Compensation Act” – were pared down to apply only to physicians.

Provider taxes

According to S.B. 141, the PCS would be administered by the Department of Community Health, with an independent budget not controlled by the Department. The PCS' administrative costs would be supported by a tax on health professionals. The following are a sample of the taxes proposed.

- Dentists, dental hygienists, dental assistants, and nurses (except nurse anesthetists): \$100 per licensee
- Hospitals and ambulatory surgery centers: \$200 per bed
- Physician assistants and nurse anesthetists: \$250 per licensee
- Physicians and chiropractors: \$500 per licensee
- Other providers: \$2,500 per registration or license

A report by Aon Risk Solutions, prepared for Patients for Fair Compensation, the main proponent of the PCS system, estimated that the total contribution for a PCS more expansive than that proposed by S.B. 141 could be \$43.9 million annually from hospitals, nursing homes and assisted care facilities, medical and osteopathic practice, nurses, dentistry/dental hygiene/dental labs and other providers.⁵ Physician contributions from PCS taxes would account for approximately \$8.7 million of this total estimate.⁵

Notably, this estimate was taken from a longer list of health care professionals⁶ than was included in S.B. 141. The estimated tax on physicians from S.B. 141 is not known. Further, while subsequent PCS legislation significantly narrowed the list of health professionals potentially subject to the system, as is noted above, the Board is not aware of an estimate of what the tax on physicians would be with these more limited bills.

What is a medical injury?

S.B. 141 defines a medical injury as “a personal injury or wrongful death due to medical treatment, including a missed diagnosis, which reasonably could have been avoided: (i) with care provided by an individual practitioner, under the care of an experienced specialist or by an experienced general practitioner practicing under the same or similar circumstances, or (ii) with care provided in a system of care, if rendered within an optimal system of care under the same or similar circumstances.”

Consideration of whether a medical injury could have been avoided shall only, per S.B. 141, include “consideration of an alternate course of treatment if the injury could have been avoided through a different but equally effective manner with respect to the treatment of the underlying condition.” This consideration shall also only include “consideration of information that would have been known to an experienced specialist or readily available to an optimal system of care at the time of treatment.”

A medical injury, as defined by S.B. 141, does not include “an injury or wrongful death caused by a product defect in a drug or device.”

More recent versions of PCS legislation⁷ in Georgia have defined medical injury as follows: A personal injury or wrongful death due to medical treatment, including a missed diagnosis, where all the following criteria exist:

- The provider performed a medical treatment on the applicant;
- The applicant suffered a medical injury with damages;
- The medical treatment was the proximate cause of the damages; and
- Based on the facts at the time of medical treatment, one or more of the following:
 - An accepted method of medical services was not used for treatment; or
 - An accepted method of medical services was used for treatment, but executed in a substandard fashion.

The definition still excludes an injury or wrongful death caused by a product defect in a drug or device.⁷

Process

To obtain compensation for a medical injury, a patient or his or her legal representative would file an application with the PCS, including a brief statement of the facts and circumstances surrounding the medical injury that gave rise to the application, as well as an authorization for the release of protected health information potentially relevant to the application. Within 10 days of receipt of the application, the office of medical review would determine whether the application on its face constitutes a medical injury.

If the office determines that the application *does not*, on its face, constitute a medical injury, the office must send a rejection to the applicant that informs the applicant of a right of appeal.

If the office determines that the application *does*, on its face, constitute a medical injury, the office must notify each provider named in the application and his or her insurer. The provider then has 15 days to “support the application” or elect not to support the application. It is unclear from the plain language of S.B. 141 what “supporting the application” would entail.

If the provider does support the application, and the office of medical review finds that the application is valid, then the office of compensation shall determine a compensation award in accordance with a compensation schedule, and offset by any past and future collateral source payments. Periodic payment would be allowed.

If the provider does not support the application, the office then undertakes a 60-day investigation conducted by a “multidisciplinary team with relevant clinical experience.” This investigation can include document review and interviews. If the review panel determines that a medical injury has occurred, the office of compensation must determine a compensation award in accordance with the compensation schedule and the panel’s findings.

Both provider and patient have the opportunity to appeal the office’s determinations to an administrative law judge, though the judge’s determinations are limited to whether the requirements and rules of the PCS system were followed.

RESEARCH ON NO-FAULT MEDICAL LIABILITY PROPOSALS

A 2012 analysis by Aon Risk Solutions,⁸ prepared for Patients for Fair Compensation, estimates the claims cost impact of a change from the fault-based liability system in Georgia to a PCS. Based on the Aon work, claims cost (measured by indemnity payments and adjusted loss expenses) would increase by 13 percent.

A subsequent independent actuarial analysis⁹ by TowersWatson of the Aon estimates suggests that the cost increase could be much larger than 13 percent. TowersWatson finds that small changes in Aon’s assumptions have a large impact on cost.

These two analyses being the primary evidence of the potential impact of PCS proposals on the medical liability system, they are worth reviewing in more detail.

Aon calculations

In order to better understand Aon’s estimate it is important to look at the steps involved in their analysis and the assumptions that they made.

- As a first step in estimating the additional claims cost of a PCS, Aon needed to know how many claims are indemnified (paid) under the current system. Aon estimates that 864 claims are paid annually in Georgia. Because state-level claims data are not publically available in the state, Aon bases this estimate (864 claims annually) on an internal database.
- Also important is the total number of patients in Georgia who seek indemnification (file claims) in the current system. This metric is important because it forms the basis for the number of claims that would be brought under a PCS. Again, because of a lack of data, Aon had to estimate that number. Using the previous estimate of 864 paid claims, and an assumption that 30 percent of patients who seek indemnification receive payment, Aon estimates that 2,880 ($864 / 0.30$) patients per year file claims in Georgia under the current system.
- A key point of consideration in changing from a fault-based system to a PCS is the effect on the number of patients who seek indemnification. Aon assumes the number who seek indemnification would increase by 67 percent, with almost all of that increase occurring for lower-cost claims: for example, Aon assumes there would be a 1,000 percent increase in the number of patients seeking indemnity for insignificant injury under a PCS, from 133 patients annually to 1,468 patients annually. Taken together, Aon estimates that the number of patient claims will increase from 2,880 to roughly 4,800 ($2,800 \times 1.67$) annually under a PCS.
- Aon also had to make an assumption about how many of those patients would be indemnified under the PCS. Aon assumes that 40 percent of the 4,880 (about 1,920) would receive payment under a Georgia PCS.
- Finally, Aon assumes that average indemnity payments in Georgia within each of the nine injury severity categories would be 6.3 percent lower under the PCS than under the current system.

Aon combines those estimates and assumptions with data on claim costs from an internal database and data from PIAA. Aon's work suggests that in Georgia, claims cost would increase from \$423 million to \$478 million—a 13 percent increase. Further, the number of paid claims would more than double, and for some categories of injury, increase even more dramatically—up to 1,730 percent for insignificant injury.

Further, an individual analysis by TowersWatson demonstrates that the Aon estimates are subject to a greater deal of uncertainty than is present in usual actuarial calculations. As demonstrated below, small changes in each of the assumptions have a large impact on the estimated cost impact.

TowersWatson analysis

Changing the assumption about the indemnification ratio in the current system

As discussed, one concern with moving to a PCS is that the number of patients filing claims would greatly increase. Complicating the estimation process is that in many states there is not a good measure of how many patients file claims in the current system, including in Georgia. Aon estimates that 2,880 patients per year seek payment under the current system. They arrive at this estimate using the 864 paid claims and an assumption that 30 percent of patients seeking indemnity under the current system receive payment ($864 / 0.30 = 2,880$).

TowersWatson explored the cost impact if a 25 percent indemnification ratio were used instead of 30 percent. With 864 paid claims and an indemnification ratio of 25 percent, the number of patients seeking indemnification would be higher ($864 / 0.25 = 3455$). Keeping the other assumptions that Aon made the same, this modification would yield a claims cost increase of 35 percent rather than 13 percent.

Changing the assumption about the increase in the number of patients seeking indemnification

TowersWatson also analyzed the effect of the cost increase if more patients were to seek indemnification under the PCS than Aon estimates. Aon assumes the number of patients filing claims would increase by 67 percent, with almost all of that increase occurring in the lower-cost injury categories. TowersWatson modifies that assumption to an increase of 105 percent of patients filing claims, and allows more of that increase to occur within the higher-cost categories. With that modification—and using the 25 percent rather than the 30 percent indemnification ratio in the current system—the cost increase is 68 percent rather than the 13 percent given by the Aon analysis.

Changing the assumption about the indemnification ratio in the PCS

TowersWatson also calculated the effect on costs, were the PCS to indemnify far more patients than Aon assumed. Aon assumes that the indemnification ratio would be 40 percent under a PCS. When TowersWatson modifies this to

50 percent (resulting in more claims paid) on top of the changes to the other assumptions, the cost increase is 108 percent.

With these assumptions, the cost of a PCS would be more than twice that of the current system.

RELEVANT AMA POLICY

The AMA remains fully committed to the enactment of proven MLR laws, such as those modeled after the California Medical Injury Compensation Reform Act of 1975 (MICRA) (Policy H-435.967, “Report of the Special Task Force and the Advisory Panel on Professional Liability”). Caps on non-economic damages, such as those enacted in California and Texas, have proven to be successful at maintaining a stable state liability climate. A large and growing body of research shows that caps on non-economic damages lead to improved access to care for patients, lower medical liability premiums and lower health care costs. In addition to the cap on non-economic damages, the other reforms contained in MICRA (attorney contingency fee limits, collateral source reform and periodic payment of future damages), have helped to stabilize premiums in California and to stabilize California’s medical liability climate as whole. As such, the AMA continues to press for relief from the current medical liability system for physicians at both the federal and state levels through the enactment of these traditional reforms.

At the same time, the AMA generally calls for the implementation and evaluation of innovative reforms to see if they are able to improve the nation’s medical liability climate. These reforms could either complement traditional MLR provisions, such as caps, or they may be able to improve the liability climate in a state that is not able to enact traditional MLR provisions for political or judicial reasons.

The AMA has called for federal funding for pilot projects to test such concepts as health courts, liability safe harbors for the practice of evidence-based medicine, early disclosure and compensation models, expert witness guidelines and affidavits of merit, to name some of the more promising options.

The AMA Principles for Health Courts, which the AMA House of Delegates adopted in 2007, are particularly relevant here (Policy H-435.951, “Health Court Principles”). These principles are particularly relevant because the AMA believes that administrative liability systems such as those established by hospitals or insurers – or in this case, the state – should include many of the same requirements that the AMA supports for a health court established within a jurisdiction’s standard judicial system (Policy H-435.951, “Health Court Principles”). Reasoning dictates that the PCS should similarly include many of these requirements. However, a close examination of the PCS demonstrates that many key facets are not aligned with AMA policy and principles.

Standard of proof

The PCS would lower the standard of proof required for a judgment against a physician. To prove medical liability based on negligence, a plaintiff must establish four elements: (1) a duty by the physician to act according to the applicable standard of care; (2) a breach of that standard of care; (3) injury or harm to the plaintiff; and (4) a causal connection between the breach of the standard of care and the injury or harm. The PCS would skip step (2) and find judgment against a physician by focusing only on step (3)–injury or harm to the patient–and not requiring a determination of whether the physician breached the standard of care, and whether that breach of the standard of care caused the injury or harm. Recent PCS proposals focus on “whether an accepted method of medical treatment” was used, while earlier proposals focus simply on whether the injury could have been avoided.

In other alternative medical liability reform systems such as health courts, the AMA has insisted that negligence must be proven for a patient to recover (Policy H-435.951, “Health Court Principles”). A PCS system would lower this standard of proof, and thus, is contrary to AMA policy.

Expert witnesses and judges

AMA principles recommend that health court judges have specialized training in the delivery of medical care that qualifies them for serving on a health court. In addition, qualified experts should be utilized to assist a health court in reaching a judgment (Policy H-435.951, “Health Court Principles”). AMA policy provides guidance on what the standards for those experts should be. At minimum, statutory requirement for qualification as an expert witness in medical liability cases should provide that the witness have:

- Comparable education, training, and occupational experience in the same field as the defendant or specialty expertise in the disease process or procedure performed in the case;
- Occupational experience that includes active medical practice or teaching experience in the same field as the defendant;
- Active medical practice or teaching experience within five years of the date of the occurrence giving rise to the claim; and
- Certification by a board recognized by the American Board of Medical Specialties or the American Osteopathic Association or by a board with equivalent standards (Policy H-265.994, “Expert Witness Testimony”).

In cases brought before health courts, AMA policy further recommends that:

- The health court task force maintain a list of qualified medical experts who meet the same qualifications as the medical experts who testify on behalf of the party in the lawsuit, from which a judge may select to help clarify or interpret medical testimony; and
- Party expert witnesses be a doctor of medicine or osteopathy who meets the same requirements outlined in AMA policy on expert witnesses (Policy H-435.951, “Health Court Principles”).

PCS cases would be decided by a panel of “individuals with relevant clinical expertise,” though what that expertise consists of is not specified. There is no requirement that the medical experts have the same or similar expertise, training, qualifications, or specialty certification as the defendant. Moreover, there is no standard at which to hold those experts who testify to the appropriateness of care provided. For these reasons, the PCS lowers – or at minimum, does not specify – standards for expert witnesses and decision makers, and goes against the high standards AMA policy expects for expert witnesses in medical liability cases.

Damages

AMA policy supports a fee structure system for damage awards based on type or severity of injury, or to have non-economic damages linked to the amount of economic damages included in the judgment. The underlying principle is that consistent injuries should result in consistent non-economic damage awards based on the schedule. At the same time, economic damages should not be limited; injured parties should be fully compensated for their economic losses. Punitive damages, if allowed, should not be awarded unless the party alleging such damages meets the burden of producing clear and convincing evidence of oppression, fraud, malice, or the opposing party’s intent to do harm (Policy H-435.951, “Health Court Principles”). With these considerations in mind, the fee structure system the PCS proposes is aligned with AMA policy.

National Practitioner Data Bank

PCS legislation commonly includes a provision stating that a physician who is the subject of an application shall not be found to have committed medical negligence and shall not be automatically reported to the state medical board. The PCS will only share with the medical board for disciplinary action information from those applications in which the department has determined that the provider represents an imminent risk of harm to the public. However, the plain language of PCS bills does not specify what standard the department should use to make this determination of risk of harm to the public.

Further, while PCS proponents commonly claim that PCS systems will not trigger reporting to the National Practitioner Data Bank (NPDB), the Board believes this assertion is debatable.

According to the NPDB Guidebook, “[e]ach entity that makes a payment for the benefit of a health care practitioner in settlement of or, in satisfaction in whole or in part of, a written claim or judgment for medical malpractice against that practitioner must report the payment information to the NPDB.... Medical malpractice payments are limited to exchanges of money and must be the result of a written complaint or claim demanding monetary payment for damages. The written complaint or claim must be based on a practitioner’s provision of or failure to provide health care services. A written complaint or claim can include, but is not limited to, the filing of a cause of action based on the law of tort in any State or Federal court or other adjudicative body, such as a claims arbitration board.”¹⁰

The NPDB interprets the written claim requirement “to include any form of writing, including pre-litigation communications.”¹⁰ The NPDB, not any other entity, determines whether a written claim has occurred for purposes of

filing a report. Unless the PCS system is to be entirely verbal, it seems possible that the NPDB would consider payments made as a result of a PCS system judgment to be reportable events. The issue whether a “medical malpractice” payment, for the purposes of the NPDB, requires wrongful conduct by the physician.

Given the findings of the Aon and TowersWatson estimates that claims made to the PCS system would dramatically increase in comparison to the current liability system, it is possible that reports to the NPDB would increase dramatically as well.

AMA policy opposes legislative or administrative efforts to expand the NPDB reporting requirements for physicians, such as the reporting of a physician who is dismissed from a medical liability lawsuit without any payment made on his or her behalf, or to expand the entities permitted to query the NPDB such as public and private third party payers for purposes of credentialing or reimbursement (Policy H-355.975, “Opposition to the National Practitioner Data Bank”).

Because of the potential for the PCS to dramatically increase claims to the NPDB – including claims in which there has been no finding of negligence – the PCS system goes against longstanding AMA policy regarding reporting to the NPDB.

DISTINGUISHING PCS PROPOSALS FROM NEUROLOGIC INJURY FUNDS

Several states, including Florida and Virginia, have funds established to pay for the care of infants born with certain neurological injuries. While these systems share the no-fault nature of PCS proposals, they differ in that utilization of neurologic injury programs is an exclusive remedy, providing absolute immunity from medical liability for participating health care professionals. Because injury claims adjudicated by neurologic injury tribunals do not depend upon medical liability, decisions do not need to be reported to the NPDB. Similarly, standard of care and expert witness considerations are not present with neurologic injury funds as they are with PCS proposals. Even so, neurologic injury programs continue to be a subject of debate.

CONCLUSION

Medical liability remains a continuing concern for physicians. It affects both how and where they practice. The ramifications of the current liability system are wide-ranging, from patients who now have limited access to health care to the financial implications on the health care system as a whole. The AMA remains at the forefront on this issue by advocating at both the federal and state levels and conducting research to improve the liability system. The AMA remains committed to advocating for proven reforms – such as caps on non-economic damages – to fix the problem. At the same time, the AMA will continue advocating for innovative reforms, such as health courts, safe harbors for the practice of evidence-based medicine and early disclosure and compensation models, as a way to complement traditional reforms and to solve this issue for both physicians and patients.

Though some aspects of PCS proposals are consistent with AMA policy, significant aspects of the proposals to date are inconsistent with AMA Health Court Principles and AMA medical liability reform policy, including policies on the standard of care for medical liability cases, expert witness requirements, and reporting to the NPDB. Moreover, analyses of PCS proposals – even those prepared on behalf of PCS advocates – demonstrate the potential for a PCS to vastly increase the cost of a state’s medical liability system. These shortcomings are deeply concerning to the Board of Trustees.

Given the AMA’s in-house expertise and the ongoing MLR-related advocacy, the Board of Trustees believes that support for a Patient Compensation System is not warranted.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 214-I-15 and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy H-435.967, “Report of the Special Task Force and the Advisory Panel on Professional Liability.”

2. That our AMA support state medical associations in their opposition to proposals to replace a state medical liability system with a no-fault liability or Patient Compensation System, unless those proposals are consistent with AMA policy.

REFERENCES

1. Georgia Senate Bill 141 (2013-2014 Regular Session).
2. Maine L.D. 1311 (127th Legis. 2015).
3. Florida Senate Bill 1308 (2016 Session).
4. Vermont House 35 (2013-2014 Regular Session).
5. Aon Risk Solutions. Georgia Rating Model for the Implementation of a Patients Compensation System. Prepared for Patients for Fair Compensation. June 21, 2012.
6. Abortion clinics, acupuncture, assisted care facilities, athletic trainers, chiropractic medicine, clinical laboratories, clinical laboratory personnel, dentistry, dental hygiene, dental laboratories, dietetics, nutritional practice, electrolysis, HMOs, hospitals, maternal and child health, medical practice, medical transportation service – EMT, midwifery, multiphasic health testing, naturopathic, nursing, nursing home administration, nursing homes and related health care, occupational therapy, optometry, orthotics, prosthetics, pedorthics, osteopathic medicine, pharmacy, physical therapy, podiatric medicine, radiological, respiratory therapy, speech language pathology, and audiology.
7. Georgia Senate Bill 86 (2015-2016 Regular Session)
8. Aon Risk Solutions. An Evaluation of the Impact to Direct Medical Malpractice Costs in the State of Georgia Related to the Implementation of a Patients Compensation System. Prepared for Patients for Fair Compensation. October 10, 2012.
9. TowersWatson analysis of 2012 Aon Risk Solutions reports for Patients for Fair Compensation. August 9, 2013.
10. U.S. Department of Health and Human Resources, Health Resources and Services Administration. NPDB Guidebook. Rockville, Maryland. U.S. Department of Health and Human Services, 2015. A payment made as a result of a suit or claim solely against an entity (for example, a hospital, clinic, or group practice) that does not identify an individual practitioner should not be reported to the NPDB. See also, Wakefield memo to Sebelius regarding Appropriate Medical Malpractice Payment Reporting to the National Practitioner Data Bank (NPDB) in Light of Recent Medical Malpractice Reforms in Massachusetts and Oregon (May 20, 2014).

3. MODEL STATE LEGISLATION PROMOTING THE USE OF ELECTRONIC TOOLS TO MITIGATE RISK WITH PRESCRIPTION OPIOID PRESCRIBING (RESOLUTION 222-I-15)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 222-I-15
REMAINDER OF REPORT FILED**

See Policies H-95.928, D-478.972, D-478.994 and D-478.996

INTRODUCTION

At the 2015 Interim Meeting, the House of Delegates referred Resolution 222-I-15, “Model State Legislation Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid Prescribing,” introduced by the Virginia Delegation, which asked:

That our American Medical Association develop model state legislation that improves workflow for using state based prescription monitoring programs by enhancing information available including automated alert notification of doctor shopping, real time EHR-PMP integration, and e-prescribing of schedule II and III drugs which should be essential parts of a state based risk mitigation strategy with identification and correction of any workflow or technological barriers a high priority; and

That Stage 3 of the federal government’s meaningful use program should be delayed until the following are accomplished: a) real time integration of EHRs and state based PMPs, and b) electronic prescribing of schedule II and III drugs are available for meaningful use certified EHRs in the United States.

Reference committee testimony broadly supported the concept of prescription drug monitoring program (PDMP) integration with electronic health records (EHRs). There was concern, however, about how well PDMPs and EHRs are integrated in actual practice. Testimony noted that in clinical situations where PDMPs and EHRs work well

together, there are positive benefits to data retrieval and information that can help with clinical decision making. On the other hand, testimony also noted that not all PDMPs currently have the ability to provide real-time data or are effectively integrated into clinical workflow systems. In addition, testimony noted that EHR integration into PDMPs varies greatly, and there are considerable technological and practical challenges to such integration.

The reference committee cited work being done by several medical societies as well as the AMA Task Force to Reduce Opioid Abuse in support of physicians registering for and using PDMPs. When PDMPs contain relevant, real-time data that can be accessed as part of a physician's workflow, physicians often have important information that can help improve patient care and make more informed prescribing decisions. This report will discuss issues surrounding automated alerts of so-called "doctor shopping," which raise several questions, including who should receive the alerts and what action(s) should be taken based on those alerts. In addition, it is not clear how state legislation, by itself, could improve the technological functionality of a PDMP, but such legislation could be a factor in requirements of using PDMPs. This includes tying such requirements to when PDMPs and EHRs may be, in fact, integrated. In addition, this report will provide a brief update on electronic prescribing of controlled substances and an update on relevant issues concerning Stage 3 of the federal government's Meaningful Use program.

This report will recommend that existing policy be reaffirmed and recommends new policies be adopted to guide AMA advocacy.

AUTOMATED ALERTS IN A PRESCRIPTION DRUG MONITORING PROGRAM

Proponents of automated alerts to prescribers using PDMPs frequently cite the ability of such alerts to provide information about "doctor shopping." While not a legal term of art or clinical description, "doctor shopping" generally—and often pejoratively—seeks to define individuals who seek to fraudulently obtain a prescription¹ or who seek multiple prescriptions for controlled substances from multiple prescribers and/or pharmacies in a short time frame. State laws and regulation define the parameters differently. Being deemed a "doctor shopper" typically means that the patient has received one or more prescriptions for a controlled substance from 3-5 prescribers and filled it at 3-5 pharmacies within a 30-90 day time frame. This also is referred to as a Multiple Prescription Event (MPE). Many states and other stakeholders have touted their PDMPs as being able to reduce the number of MPEs. Commonly cited examples are New York and Tennessee, which have reported significant reductions in MPEs.²

The Board supports efforts to identify individuals who use fraudulent means to obtain controlled substances from prescribers and dispensers either for their own use or for diversion to others. It is not a straightforward issue, however, to separate: (1) patients who unintentionally receive multiple prescriptions that may represent dangerous drug combinations from; (2) patients with substance use disorders who are seeking more controlled substance prescriptions than would generally be prescribed for their medical condition; or from (3) individuals who misrepresent their health conditions in order to obtain controlled substance prescriptions for purposes of misuse or diversion. For this reason, the broad application of criteria for identifying MPEs may not meet the goal of reducing opioid misuse, overdose or diversion. For example, if a patient sees multiple physicians for multiple conditions, and each physician prescribes a controlled substance—and the patient fills each prescription at a different pharmacy, then technically that patient may be flagged as a "doctor shopper." The automated alert in the PDMP may be set to highlight that patient in yellow, red or some other distinctive color. The technology and functionality for communicating these types of alerts vary by state, but there is little discussion about what the physician is supposed to do when the PDMP identifies a patient as having an MPE.

If it becomes clear that an individual is fraudulently seeking prescriptions for nonmedical use or diversion, these efforts should be resisted and denied and potentially referred to law enforcement. Patients seeking more controlled substances than their health condition warrants may need to be screened, assessed for a possible opioid use disorder, and counseled and/or referred for treatment.

Patients who are unintentionally receiving dangerous drug quantities or combinations need better care coordination. If, for example, the patient is receiving an opioid analgesic, a benzodiazepine and a muscle relaxant from three different physicians, the combination could be deadly. Depending on how the PDMP allows a physician to set up an alert—or if the PDMP default is to flag such an MPE—when a patient is flagged as a potential doctor shopper, what should the physician do in such a situation?

As stated by E-10.01, “Fundamental Elements of the Patient-Physician Relationship,” “the physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient.” Yet, to prescribe a controlled substance to this patient raises the practical concern whether that prescription will be seen by regulatory bodies, law enforcement or others as contributing to further MPEs. Even if the physician documents the reasons why the patient is not a “doctor shopper,” it is unlikely that the PDMP has the sophistication to distinguish between patients. All the PDMP (and others who have access to the PDMP) know is that the physician continued to prescribe controlled substances to an alleged “doctor shopper.”

Ethical policy E-10.01 further states that “the physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care.” In an MPE situation, physicians and pharmacists are under intense pressure to reduce the number of MPEs. The balance is ensuring that the PDMP alert does not create a barrier to care. Therefore, the Board recommends that the AMA advocate to key stakeholders, including the National Association of State Controlled Substances Authorities, the National Association of Boards of Pharmacy, and the National Governors Association, to ensure that efforts to reduce MPEs are done in a manner that supports continuity of care and does not adversely affect the patient-physician relationship.

INTEGRATION OF PDMPs AND EHRs

There are many benefits to integrating PDMP data into EHRs in a seamless manner. A seamless integration process would allow physicians to have a patient’s prescription history as part of the medical record, eliminate having to sign in to separate systems, improve workflow, and other benefits that could improve patient care.

The AMA supports this type of technological improvement. For example, Policy H-95.945, “Prescription Drug Diversion, Misuse and Addiction,” provides a recommendation “that PDMPs be designed such that data is immediately available when clinicians query the database and are considering a decision to prescribe a controlled substance.” PDMPs, while they vary on whether data is input by pharmacists from within 24 hours to a week or more, arguably contain helpful information for physicians and other health care professionals about a patient’s controlled substances prescription history.

In addition, a 2016 AMA national survey found that, when asked “what would make PDMPs more effective and useful,” the number one response (66 percent of respondents) was “integration with EHR/EMR.”³ Such integration, moreover, has been studied in several pilot programs by the federal Office of the National Coordinator across multiple states and in clinical settings ranging from the emergency department to ambulatory settings to pharmacies and opioid treatment programs.⁴ This is consistent with AMA policy and its considerable support for the interoperability of EHRs and other systems. This includes D-478.972, “EHR Interoperability,” D-478.994, “Health Information Technology,” and D-478.996, “Information Technology Standards and Costs.”

UPDATE ON EPCS AND MEANINGFUL USE

Electronic prescribing of controlled substances (EPCS) has not become a major component of the U.S. health care system. Although all states allow for EPCS, according to Sure Scripts, approximately 6.0 percent of physicians and other health care providers are enabled for EPCS.⁵ New York has the highest percentage (37 percent)—almost certainly due to the fact that as of March 27, 2016, New York requires mandatory electronic prescribing for all prescriptions.⁶

As the AMA wrote to the U.S. Drug Enforcement Administration in 2015, “a well-designed electronic medication prescription (eRx) system adds value to [physicians’] practice of medicine and supports better patient care. We believe expanding the utility of EPCS to match that of current eRx capabilities will benefit physicians and patients alike.”⁷

A number of reasons continue to limit the ability of those physicians, however, who would like to prescribe controlled substances electronically, including the DEA “two-factor authentication” requirement, verification requirements, vendor incompatibility and readiness, technological and workflow barriers and other reasons, whose full discussion are beyond the scope of this report. If these issues can be resolved, however, then it is hopeful that EPCS can truly become a helpful component of risk mitigation strategies at the clinical, systems-wide and state-based levels.

Yet, significant barriers remain. With CMS' release of the Stage 3 Meaningful Use proposed rule in 2015, CMS signaled their intent to increase the complexity of the program and to further physicians' burden on the interoperability of electronic health information. While the majority of the Stage 3 objectives and measures were recycled from Stage 2, the proposed rule increased the bar for physician success and set a high initial threshold for all new objectives. Many health care systems and state and medical associations, including the AMA, provided CMS detailed comments focused on reducing the physician reporting burden and methods to increase flexibility in the program.

Specifically relating to the electronic prescription of medications, the AMA asked CMS to allow physicians the option to include or exclude controlled substances in the calculation of Meaningful Use electronic prescribing measure. In the final Stage 3 rule CMS accepted AMA's comments, stating:

After consideration of the public comments received, we are finalizing changes to the language to continue to allow providers the option to include or exclude controlled substances in the denominator where such medications can be electronically prescribed. For the purposes of this objective, we are adopting that prescriptions for controlled substances may be included in the definition of permissible prescriptions where the electronic prescription of a specific medication or schedule of medications is permissible under state and federal law.⁸

While a number of suggested changes by the AMA were adopted, CMS stated that further program adjustments could be made in future rulemaking. For many in the industry, the forthcoming MACRA proposed rule in early 2016 was seen as an opportunity for CMS to rethink Stage 3 requirements.

Health IT development is largely guided by federal certification and reporting requirements. Prior to commenting on CMS' Stage 3 proposed rule, the AMA provided detailed comments to ONC on their 2015 Edition Health IT Certification—with a focus on improving EHR interoperability and usability. By taking a two-pronged approach of reducing prescriptive federal reporting demands while seeking a more focused health IT certification, the AMA, along with many other organizations, believes physician EHR satisfaction and participation in new payment models will increase. However, due to the EHR development timeline, even before a Stage 3 final rule was released, health IT developers began working on new EHRs. Although the MACRA proposed rule incorporated many aspects of Meaningful Use through the Advancing Care Information (ACI) component of MIPS, CMS has acknowledged health IT must improve and adapt to the needs of physicians and patients.⁹

The AMA views MACRA as an opportunity to align the development of health IT with the evolving demands of health care. Value-based reimbursement models will require physicians to have at their disposal a robust health IT toolbox. While the EHR will still play a major role going forward, physicians and patients must have the ability to optimize care using both certified and non-certified technology. CMS has already identified 2015 Edition health IT products as one component for successful participation in MIPS; however, requirements on the use of EHRs will not be finalized until late 2016.

Additionally, CMS has proposed a flexible approach to the use of EHRs in APMs. The AMA views the proposed APM requirements as a logical starting point for MIPS. The AMA has supplied detailed and constructive feedback outlining how physicians can optimize the use of EHRs while achieving success in multiple MIPS components.¹⁰ This holistic approach to CMS' quality payment program provides the flexibility physicians will need to successfully participate in MIPS, and may also act as a glide path for those who wish to migrate to APMs. Furthermore, because this approach focuses less on the process and more on patient outcomes, health IT developers will benefit by increased development freedom—focusing less on federal reporting demands and creating tools that better integrate with physician workflows.

2015 Edition EHRs are already in development and some have already been certified. Many health IT developers will have products in the market by mid-2017. Advanced functionality like real-time integration between EHRs and PDMPs is not included in certification, nor are EHR vendors incentivized to focus on this type of functionality. Furthermore, there are no national standards for EHR-PDMP communication, and each state has established their own requirements around PDMP interoperability. While this capability is highly desirable by physicians, health IT developers are driven to meet federal certification requirements before developing other functionality.

Going forward, CMS and ONC must create a way to better incorporate feedback from physicians into the development of their programs. By restructuring CMS programs to focus on outcomes and focusing ONC certification on testing for product safety, security, usability, and interoperability—including with PDMPs—a physician will encounter greater choice and better functioning products in health IT going forward.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 222-I-15, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the ability of prescription drug monitoring programs (PDMPs) to have the capability for physicians to know when their patients have received a prescription for controlled substances from multiple prescribers or multiple pharmacies within a short time frame;
2. That our AMA advocate to key stakeholders, including the National Association of State Controlled Substances Authorities, the National Association of Boards of Pharmacy, and the National Governors Association, to ensure that efforts to reduce Multiple Provider Events (MPEs) are done in a manner that supports continuity of care;
3. That our AMA work with the Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA) and other relevant federal agencies, to better understand the factors that lead to MPEs and develop medically and ethically appropriate strategies for reducing them;
4. That our AMA advocate for the interoperability of state PDMPs with electronic health records (EHRs);
5. That Policies D-478.972, “EHR Interoperability,” D-478.994, “Health Information Technology,” and D-478.996, “Information Technology Standards and Costs,” be reaffirmed;
6. That our AMA advocate for the Centers for Medicaid and Medicare Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) to better incorporate feedback from physicians to focus on outcomes and focusing ONC certification on testing for product safety, security, usability, and interoperability.

REFERENCES

1. For a good discussion of statutory and regulatory requirements related to fraud, misrepresentation and other illicit means of obtaining a prescription, see “Doctor Shopping Laws” from the Public Health Law Program in the Office for State, Tribal, Local and Territorial Support at the Centers for Disease Control and Prevention. Available at <https://www.cdc.gov/phlp/docs/menu-shoppinglaws.pdf>
2. Mandating PDMP participation by medical providers: current status and experience in selected states Prescription Drug Monitoring Program Center of Excellence at Brandeis COE Briefing states States, Prescription Drug Monitoring Program Center of Excellence at Brandeis COE Briefing. Revision 1, February 2014. Available at http://www.pdmpexcellence.org/sites/all/pdfs/COE%20briefing%20on%20mandates%20revised_a.pdf
3. Physician perceptions and practices on opioid prescribing, education, barriers to care, naloxone. AMA national survey conducted by TNS Global Research, Nov. 13–23, 2015. The survey had 2,130 respondents who are practicing U.S. physicians who provide a minimum of 20 hours per week in direct patient care, have a current DEA license to prescribe Schedule II controlled substances, and prescribe opioids on a weekly, or more frequent, basis. See more at <http://www.ama-assn.org/ama/pub/news/news/2016/2016-02-18-barriers-non-opioid-therapy.page>
4. See “Connecting for Impact: Linking Potential Prescription Drug Monitoring Programs (PDMPs) to Patient Care Using Health IT,” available at <https://www.healthit.gov/PDMP>
5. EPCS Provider Enablement by State. <http://surescripts.com/products-and-services/e-prescribing-of-controlled-substances>
6. See New York State Department of Health website: http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/ which also lists exceptions to the mandate.
7. August 11, 2015 letter from AMA CEO James L. Madara, MD, to Barbara J. Boockholdt, Chief, Regulatory Section, U.S. Drug Enforcement Administration Office of Diversion Control. <http://www.ama-assn.org/resources/doc/washington-x-pub/2015-8-11-ama-letter-dea-epcs.PDF>
8. CMS. Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017. October 2015. Accessed August 2016 from: <https://www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications>

9. Acting CMS Administrator Andy Slavitt. Remarks by Andy Slavitt, CMS Acting Administrator before the American Medical Association 2016 Annual Meeting Chicago, IL. June 2016. Accessed August 2016 from: <https://blog.cms.gov/2016/06/13/remarks-by-andy-slavitt-cms-acting-administrator-before-the-american-medical-association-2016-annual-meeting-chicago-il/>
10. AMA comments to CMS on the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS-5517-P). June 2016. Accessed August 2016 from: <https://download.ama-assn.org/resources/doc/washington/ama-macra-comments-27june2016.pdf>

4. REDEFINING THE AMA'S POSITION ON THE ACA AND HEALTH CARE REFORM - UPDATE

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

At the 2013 Annual Meeting of the House of Delegates (HOD), the HOD adopted Policy D 165.938, "Redefining AMA's Position on ACA and Healthcare Reform," which called on our American Medical Association (AMA) to "develop a policy statement clearly outlining this organization's policies" on a number of specific issues related to the Affordable Care Act (ACA) and health care reform. The adopted policy went on to call for our AMA to report back at each meeting of the HOD. Board of Trustees (BOT) Report 6-I-13 accomplished the original intent of the policy. This report serves as an update on the issues and related developments occurring since the most recent meeting of the HOD.

REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR

As previously reported, the repeal of the Sustainable Growth Rate (SGR) was accomplished with the enactment of the "Medicare Access and CHIP Reauthorization Act of 2015" (MACRA) on April 16, 2015.

On April 28, 2016, the Centers for Medicare & Medicaid Services (CMS) released proposed implementing regulations [Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models; Proposed Rule (CMS-5517-P)]. Following consultation with state and national medical specialty societies, the AMA responded with extensive comments¹ on June 27, 2016. Our AMA and 118 state and national medical specialty societies sent a separate comment letter² on June 24, 2016 outlining areas of broad agreement among physician organizations.

PAY-FOR-PERFORMANCE

Inherent in the implementation of MACRA is the opportunity to reshape current pay-for-performance programs. As stated in AMA comments to CMS, "the intent of MACRA was not to merely move the current incentive programs into MIPS but to improve and simplify these programs into a single more unified approach." AMA comments on the proposed regulations are lengthy and may be accessed at: ama-assn.org/go/medicarepayment. In the most general terms, our AMA has called on CMS to create a transition reporting period so that physicians may prepare for a successful implementation, provide additional flexibility for solo and small group practices, and provide more timely and actionable feedback in a usable and clear format. More specifically, our AMA made 13 high-level recommendations:

- Establish a transitional period to allow for sufficient time to prepare physicians to have a successful launch of MACRA.
- Provide more flexibility for solo physicians and small group practices, including raising the low volume threshold.
- Provide physicians with more timely and actionable feedback in a more usable and clear format.
- Align the different components of MIPS so that it operates as a single program rather than four separate parts, such as creating a common definition for small practices.
- Simplify reporting burdens and improve chances of success by creating more opportunities for partial credit and fewer required measures within MIPS.
- Reduce the thresholds for reporting on quality measures.

- Reward reporting of outcome or cross-cutting measures under a bonus point structure rather than a requirement in order to achieve the maximum quality score.
- Improve risk adjustment and attribution methods before moving forward with the resource use category.
- Replace current cost measures that were developed for hospital-level measurement and refine and test new episode measures prior to widespread adoption.
- Permit proposals for more relevant measures, rather than keeping the current MU Stage 3 requirements.
- Remove the pass-fail component of the Advancing Care Information (ACI) score.
- Reduce the number of required Clinical Practice Improvement Activities (CPIAs) and allow more activities to count as “high-weighted.”
- Simplify and lower financial risk standards for Advanced APMs.

Though final regulations are not expected until autumn, our AMA continues to encourage all physicians to prepare for the transition. Numerous resources have been made available on the AMA MACRA webpage (ama-assn.org/go/medicarepayment), including an action kit (download.ama-assn.org/resources/doc/washington/16-0384-advocacy-macra-action-kit.pdf) detailing steps that practices should take now as well as explanatory material on the two options for participating, the Merit-based Incentive Payment System and Alternative Payment Models. Additionally, the AMA’s STEPS Forward™ practice improvement initiatives provide a step-by-step process to help prepare practices for value-based care.

REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

As noted in BOT Report 7-A-16, the House of Representatives has passed H.R. 1190, the “Protecting Seniors’ Access to Medicare Act of 2015,” repealing the IPAB. While the AMA supported the passage of the House bill, the funding provisions, specifically cuts to the ACA Prevention and Public Health Fund, are contrary to AMA policy. Our AMA continues to explore possible pathways for consideration of the Senate-introduced bill though no action has been scheduled at this time.

SUPPORT FOR MEDICAL SAVINGS ACCOUNTS, FLEXIBLE SPENDING ACCOUNTS, AND THE MEDICARE PATIENT EMPOWERMENT ACT

H.R. 1270, the “Restoring Access to Medication Act of 2015” was passed by the House on July 6, 2016 by a vote of 243-164. The legislation would repeal a provision of the Affordable Care Act that prohibited the use of Flexible Spending Accounts for the purchase of over the counter medications without a prescription and increase allowable contributions to Health Savings Accounts. The White House has announced that the President would veto the measure if it were presented for signature. In releasing the White House Statement of Administration Policy, the Office of Management and Budget expressed opposition to provisions in the legislation that would “provide additional tax breaks that disproportionately benefit those with higher incomes” and “increase taxes paid by low- and middle-income families.” This objection refers to the funding provision of the House-passed bill that would pay for increases in HSA contributions by increasing subsidy recapture provisions for those who receive subsidies for the purchase of ACA coverage. The Senate has not scheduled action on the bill.

As previously reported, the “Medicare Patient Empowerment Act” has been reintroduced in the current Congress by Rep. Tom Price, MD, (R-GA) and Sen. Lisa Murkowski (R-AK). The House version, H.R. 1650, currently has 30 cosponsors while the Senate bill, S. 1849, has six cosponsors. Neither bill has been scheduled for consideration at this time.

STEPS TO LOWER HEALTH CARE COSTS

The AMA continues to seek opportunities to advance policies that will lower health care costs. Central to these efforts is the AMA’s work on Improving Health Outcomes. One key component of the work of our AMA on improving health outcomes is the expansion of coverage for the Diabetes Prevention Program (DPP). As part of the CY 2017 Medicare Physician Fee Schedule Proposed Rule published on July 15, 2016, CMS proposes to expand the duration and scope of the DPP model test, and refer to the new program as the Medicare Diabetes Prevention Program (MDPP). The proposed rule provides a basic framework for the MDPP, and CMS notes that if finalized, they will engage in additional rulemaking within the next year to establish specific MDPP requirements. This development represents a significant step forward in efforts to expand coverage for DPP.

REPEAL NON-PHYSICIAN PROVIDER NON-DISCRIMINATION PROVISIONS OF THE ACA

Legislation repealing the non-physician provider non-discrimination provisions of the ACA has not been introduced in the current Congress to date.

CONCLUSION

AMA Policy D-165.938 calls for updates at each meeting of the HOD on a number of specific policies related to the ACA. Our AMA continues to pursue these issues. Other key advocacy issues will continue to be addressed in the annual Advocacy report at each Interim Meeting of the House.

REFERENCES

1. <https://download.ama-assn.org/resources/doc/washington/ama-macra-comments-27june2016.pdf>
2. <https://download.ama-assn.org/resources/doc/washington/macra-state-speciality-sign-on-letter.pdf>

5. IOM “DYING IN AMERICA” REPORT (RESOLUTION 6-I-15)

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 6-I-15 REMAINDER OF REPORT FILED

See Policies H-70.915, H-85.955, H-85.956, H-85.957, H-140.845, H-140.966, H-140.970, H-140.989, H-275.924, H-275.997, H-295.875, H-295.981, H-480.953, D-140.968, D-295.969, D-478.994, D-478.995 and D-478.996

At its 2015 Interim Meeting, the American Medical Association (AMA) House of Delegates referred to the Board of Trustees Resolution 6-I-15, “IOM ‘Dying in America’ Report,” introduced by the Medical Association of Georgia. Resolution 6 asked our AMA to “support and advocate for the recommendations of the Institute of Medicine ‘Dying in America’ report, which will improve the quality of end-of-life care received by all patients.”

Testimony for this resolution supported the spirit of the IOM report in light of the recognized need to improve quality of care at the end of life. However, testimony noted that the AMA had not had the opportunity to vet the report thoroughly in light of existing AMA policies on relevant issues and noted that endorsing the report in its entirety could have unintended consequences for AMA.

BACKGROUND

The overarching goal of *Dying in America* is to ensure that all patients “with advanced serious illness who are nearing the end of life” have round-the-clock access to comprehensive care provided by appropriately trained personnel in appropriate settings, in keeping with individuals’ values, goals, and preferences.

The report identifies five key domains in which action is needed: financing for comprehensive care; quality measurement; professional education, licensure, and credentialing; interoperable electronic health records; and public education about end-of-life care and advance care planning. In each of these areas, the report recommends specific activities and defines accountability among key stakeholders. (See Appendix A.)

Financing for Comprehensive Care

Dying in America calls for public and private payers to cover provision of comprehensive, high-quality consistently accessible care that is “patient centered and family oriented”; consistent with individuals’ values, goals, and preferences; and delivered by appropriately trained personnel (Recommendation 1). Such care should include access to interdisciplinary palliative care. The report further recommends that federal, state, and private insurance and health care delivery programs “integrate the financing of medical and social services,” by supporting coordination of

care and use of financial incentives to decrease use of inappropriate emergency department or acute care services, among other initiatives (Recommendation 4).

Quality Measurement

Dying in America recommends that organizations that deliver health care publicly report aggregate measures of quality and cost for the full range of end-of-life care (Recommendation 1). The report urges professional societies and other organizations to establish, and payers and health care systems to adopt, quality standards specifically relating to patient-clinician communication and advance care planning, toward the goal of ensuring that all individuals have an opportunity to participate in decisions about their care and receive services consistent with their values, goals, and preferences (Recommendation 2). It further calls on the federal government to require public reporting of quality measures, outcomes and costs, for all programs it funds or administers, and to encourage all other payment and delivery systems to do so as well (Recommendation 4).

Professional Education, Licensure and Credentialing

Dying in America recommends that all clinicians who provide care for patients with advanced serious illness should be competent in basic palliative care and that educational institutions and professional societies provide opportunities for lifelong learning in this area (Recommendation 3). Accrediting organizations, certifying bodies, health systems, and regulatory agencies should include training in palliative care in licensure requirements for health care professionals who provide care for patients nearing the end of life, and resources should be committed to increase the number of available training positions for specialty-level training in palliative care.

Interoperable Electronic Health Records

Dying in America identifies the need for “coordinated, efficient, interoperable” transfer of information among all providers and settings of care to support high quality, integrated, comprehensive care (Recommendation 1). It further calls for electronic health records that document advance care planning to improve communication across providers and settings over time, including providing for documentation of designation of a surrogate; patient values, goals, and preferences; the patient’s advance directive (when the patient has one); and medical orders for life-sustaining treatment (Recommendation 4). The report also urges states to develop and implement Physician Orders for Life-Sustaining Treatment (POLST) programs “in accordance with nationally standardized requirements.”

Public Education about End of Life and Advance Care Planning

Finally, *Dying in America* urges civic leaders, government entities, health care professionals, and other stakeholders to collaborate in developing and disseminating evidence-based information about care and the end of life and advance care planning to counter misinformation and encourage meaningful dialogue (Recommendation 5). The report calls on stakeholders to support research to assess public perceptions and actions, developing and testing effective messaging tailored to target audiences, and measuring progress and results.

AMA POLICY

AMA has extensive policy relevant to end-of-life care and to support the ultimate goals of the *Dying in America* report in all of the domains noted above. (See Appendix B.)

The AMA *Code of Medical Ethics* has strong, well-established guidance that recognizes the importance of engaging patients in advance care planning so that patients’ values, goals, and preferences can inform care planning (Opinions 5.1, 5.2). The *Code* calls on physicians to respect patients’ decisions about care at the end of life, including decisions to forgo or withdraw life-sustaining interventions (Opinions 5.3, 5.4). The *Code* encourages physicians to engage pediatric patients (Opinion 2.2.1) and adult patients with compromised decision-making capacity to participate in treatment decisions to the extent possible, and recognizes the important role that surrogate decision makers play when patients lack decision-making capacity (Opinion 2.1.2). The *Code* further provides for the use of sedation to unconsciousness as an intervention of last resort for terminally ill patients when distressing symptoms are refractory to appropriate, symptom-specific palliative care (Opinion 5.6).

Policies of the AMA House of Delegates similarly promote advance care planning and patient-centered decision making at the end of life (H-85.956, H-85.957, H-140.845, H-140.966, H-140.970, H-140.989, D-140.968). House policies also encourage palliative care and hospice for patients nearing the end of life and support education across the professional lifespan in these areas (H-70.915, H-85.955, H-295.875), as well as in areas of medical specialization in which end-of-life decision making can play a central role, such as geriatrics (H-295.981, D-295.969).

In addition, the AMA has adopted policy calling for affordable, interoperable electronic medical records and medical devices to promote more effective coordination of care (D-478.994, D-478.995, D-478.996), as well as policy that addresses essential frameworks for physician maintenance of licensure and maintenance of certification (H-275.917, H-275.924). However, AMA policy opposes tying physician licensure to mandated, content-specific continuing medical education (H-275.973, H-295.921, H-300.953).

AMA PROGRAMS & ACTIVITIES

In addition to extensive policy, the AMA is (or has been) involved in numerous activities and programs designed to improve care at the end of life consistent with the broad recommendations of *Dying in America*. For example, the AMA was instrumental in the development of Education in Palliative and End-of-Life Care (EPEC), a program designed to educate practicing physicians from all specialties in palliative care, which is now offered by Northwestern University Feinberg School of Medicine ([EPEC](#)). Journals in the [JAMANetwork](#) offer a variety of online CME modules in palliative care and pain management and live educational events at AMA meetings in recent years have addressed communicating with patients for advance care planning [1].

Through its participation in the Liaison Committee on Medical Education (LCME) and Accreditation Committee for Graduate Medical Education (ACGME), the AMA works to promote comprehensive education for physician trainees to ensure that they acquire the knowledge and skills to provide high quality, patient-centered care for a diverse patient population [2, 3]. Through the Physician Consortium for Performance Improvement ([PCPI](#)), the AMA has contributed to efforts to define and measure quality in end of life care.

With the American Bar Association, the American Hospital Association, the American Academy of Hospice and Palliative Medicine and numerous other medical specialty societies, the AMA annually supports [National Health Decisions Day](#), an initiative to provide information and resources on advance care planning for both patients and health care professionals.

The AMA has argued for legal recognition of patients' right to control decisions about their care at the end of life, including the right to refuse unwanted life-sustaining treatment [4]. The AMA has advocated for legislative support of advance care planning and advance directives. The AMA's efforts were instrumental in the decision by the Centers for Medicare & Medicaid Services to include payment for AMA-developed CPT codes for advance care planning services in the [2016 Medicare Physician Fee Schedule \(PFS\) Final Rule](#).

The AMA's innovative STEPS Forward program of interactive, online educational modules recently launched a new module, [Planning for End-of-Life Decisions with Your Patients](#), to help physicians help patients convey their wishes about end of life care. The AMA is also a strong advocate for improving the usability of electronic health records, and is collaborating with key stakeholders in digital health to this end ([Digital Health](#)).

RECOMMENDATION

The Board of Trustees recommends that the following be adopted in lieu of Resolution 6-I-15 and the remainder of this report be filed:

That our AMA reaffirm the following policies, which collectively promote high-quality, patient-centered care for all patients at the end of life:

- H-70.915, Good Palliative Care
- H-85.955, Hospice Care
- H-85.956, Educating Physicians About Advance Care Planning
- H-85.957, Encouraging Standardized Advance Directive Forms within States

- H-140.845, Encouraging the Use of Advance Directives and Health Care Powers of Attorney
- H-140.966, Decisions Near the End of Life
- H-140.970, Decisions to Forgo Life-Sustaining Treatment for Incompetent Patients
- H-140.989, Informed Consent and Decision-Making in Health Care
- H-275.924, Maintenance of Certification
- H-275.997, Licensure by Specialty
- H-295.875, Palliative Care and End-of-Life Care
- H-295.981, Geriatric Medicine
- H-480.953, Interoperability of Medical Devices
- D-140.968, Standardized Advanced Directives
- D-295.969, Geriatric and Palliative Training for Physicians
- D-478.994, Health Information Technology
- D-478.995, National Health Information Technology
- D-478.996, Information Technology Standards and Costs

REFERENCES

1. Council on Ethical and Judicial Affairs. *Resources in Advance Care Planning*. November 2010.
2. Liaison Committee on Medical Education. *Functions and Structure of a Medical School: Standards for Accreditation of Medical Education Programs Leading to the MD Degree*. March 2016.
3. Accreditation Committee for Graduate Medical Education. *Requirements for Graduate Medical Education in Hospice and Palliative Medicine*. February 2015.
4. Brief for the Am. Med. Ass'n et al. as Amici Curiae Supporting Petitioner, Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990) (No. 88-1503).

APPENDIX A¹ - Recommendations of the Institute of Medicine

Recommendation 1. Government health insurers and care delivery programs as well as private health insurers should cover the provision of comprehensive care for individuals with advanced serious illness who are nearing the end of life.

Comprehensive care should

- be seamless, high-quality, integrated, patient-centered, family-oriented, and consistently accessible around the clock;
- consider the evolving physical, emotional, social, and spiritual needs of individuals approaching the end of life, as well as those of their family and/or caregivers;
- be competently delivered by professionals with appropriate expertise and training;
- include coordinated, efficient, and interoperable information transfer across all providers and all settings; and
- be consistent with individuals' values, goals, and informed preferences.

Health care delivery organizations should take the following steps to provide comprehensive care:

- All people with advanced serious illness should have access to skilled palliative care or, when appropriate, hospice care in all settings where they receive care (including health care facilities, the home, and the community).
- Palliative care should encompass access to an interdisciplinary palliative care team, including board-certified hospice and palliative medicine physicians, nurses, social workers, and chaplains, together with other health professionals as needed (including geriatricians). Depending on local resources, access to this team may be on site, via virtual consultation, or by transfer to a setting with these resources and this expertise.
- The full range of care that is delivered should be characterized by transparency and accountability through public reporting of aggregate quality and cost measures for all aspects of the health care system related to end-of-life care. The committee believes that informed individual choices should be honored, including the right to decline medical or social services.

Recommendation 2. Professional societies and other organizations that establish quality standards should develop standards for clinician-patient communication and advance care planning that are measurable, actionable, and evidence-based. These standards should change as needed to reflect the evolving population and health system needs and be consistent with emerging evidence, methods, and technologies. Payers and health care delivery organizations should adopt these standards and their supporting processes, and integrate them into assessments, care plans, and the reporting of health care quality. Payers should tie such standards to reimbursement, and professional societies should adopt policies that facilitate tying the standards to reimbursement, licensing, and credentialing to encourage

¹ Institute of Medicine. *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life*. Washington, DC: National Academies Press; 2015.

- all individuals, including children with the capacity to do so, to have the opportunity to participate actively in their health care decision making throughout their lives and as they approach death, and receive medical and related social services consistent with their values, goals, and informed preferences;
- clinicians to initiate high-quality conversations about advance care planning, integrate the results of these conversations into the ongoing care plans of patients, and communicate with other clinicians as requested by the patient; and
- clinicians to continue to revisit advance care planning discussions with their patients because individuals' preferences and circumstances may change over time.

Recommendation 3. Educational institutions, credentialing bodies, accrediting boards, state regulatory agencies, and health care delivery organizations should establish the appropriate training, certification, and/or licensure requirements to strengthen the palliative care knowledge and skills of all clinicians who care for individuals with advanced serious illness who are nearing the end of life.

Specifically,

- all clinicians across disciplines and specialties who care for people with advanced serious illness should be competent in basic palliative care, including communication skills, interprofessional collaboration, and symptom management;
- educational institutions and professional societies should provide training in palliative care domains throughout the professional's career;
- accrediting organizations, such as the Accreditation Council for Graduate Medical Education, should require palliative care education and clinical experience in programs for all specialties responsible
- for managing advanced serious illness (including primary care clinicians);
- certifying bodies, such as the medical, nursing, and social work specialty boards, and health systems should require knowledge, skills, and competency in palliative care; state regulatory agencies should include education and training in palliative care in licensure requirements for physicians, nurses, chaplains, social workers, and others who provide health care to those nearing the end of life;
- entities that certify specialty-level health care providers should create pathways to certification that increase the number of health care professionals who pursue specialty-level palliative care training; and
- entities such as health care delivery organizations, academic medical centers, and teaching hospitals that sponsor specialty-level training positions should commit institutional resources to increasing the number of available training positions for specialty-level palliative care.

Recommendation 4. Federal, state, and private insurance and health care delivery programs should integrate the financing of medical and social services to support the provision of quality care consistent with the values, goals, and informed preferences of people with advanced serious illness nearing the end of life. To the extent that additional legislation is necessary to implement this recommendation, the administration should seek and Congress should enact such legislation. In addition, the federal government should require public reporting on quality measures, outcomes, and costs regarding care near the end of life (e.g., in the last year of life) for programs it funds or administers (e.g., Medicare, Medicaid, the U.S. Department of Veterans Affairs).

The federal government should encourage all other payment and health care delivery systems to do the same.

Specifically, actions should

- provide financial incentives for
 - medical and social support services that decrease the need for emergency room and acute care services,
 - coordination of care across settings and providers (from hospital to ambulatory settings as well as home and community), and
 - improved shared decision making and advance care planning that reduces the utilization of unnecessary medical services and those not consistent with a patient's goals for care;
- require the use of interoperable electronic health records that incorporate advance care planning to improve communication of individuals' wishes across time, settings, and providers, documenting (1) the designation of a surrogate/decision maker, (2) patient values and beliefs and goals for care, (3) the presence of an advance directive, and (4) the presence of medical orders for life-sustaining treatment for appropriate populations; and
- encourage states to develop and implement a Physician Orders for Life-Sustaining Treatment (POLST) paradigm program in accordance with nationally standardized core requirements.

Medical and social services provided should accord with a person's values, goals, informed preferences, condition, circumstances, and needs, with the expectation that individual service needs and intensity will change over time. High-quality, comprehensive, person-centered, and family-oriented care will help reduce preventable crises that lead to repeated use of 911 calls, emergency department visits, and hospital admissions, and if implemented appropriately, should contribute to stabilizing aggregate societal expenditures for medical and related social services and potentially lowering them over time.

Recommendation 5. Civic leaders, public health and other governmental agencies, community-based organizations, faith-based organizations, consumer groups, health care delivery organizations, payers, employers, and professional societies should engage their constituents and provide fact-based information about care of people with advanced serious illness to encourage advance care planning and informed choice based on the needs and values of individuals.

Specifically, these organizations and groups should

- use appropriate media and other channels to reach their audiences, including underserved populations;
- provide evidence-based information about care options and informed decision making regarding treatment and care;
- encourage meaningful dialogue among individuals and their families and caregivers, clergy, and clinicians about values, care goals, and preferences related to advanced serious illness; and
- dispel misinformation that may impede informed decision making and public support for health system and policy reform regarding care near the end of life.

In addition,

- health care delivery organizations should provide information and materials about care near the end of life as part of their practices to facilitate clinicians' ongoing dialogue with patients, families, and caregivers;
- government agencies and payers should undertake, support, and share communication and behavioral research aimed at assessing public perceptions and actions with respect to end-of-life care, developing and testing effective messages and tailoring them to appropriate audience segments, and measuring progress and results; and
- health care professional societies should prepare educational materials and encourage their members to engage patients and their caregivers and families in advance care planning, including end-of-life discussions and decisions.

All of the above groups should work collaboratively, sharing successful strategies and promising practices across organizations.

APPENDIX B - AMA Policies Relating to End-of-Life and Palliative Care

Policy	Issued
<i>Advance Care Planning</i>	
E-2.191 Advance Care Planning	2011
E-2.225 Optimal Use of Orders-Not-to-Intervene and Advance Directives	1998 ¹
D-140.968 Standardized Advanced Directives	2007 ¹
H-85.957 Encouraging Standardized Advance Directive Forms within States	2011 ²
H-140.845 Encouraging the Use of Advance Directives and Health Care Powers of Attorney	2014 ²
H-330.891 Payment and Coverage for Voluntary Discussions of End-of-Life Issues	2011
<i>Decisions Regarding Life-Sustaining Treatment</i>	
E-2.20 Withholding or Withdrawing Life-Sustaining Medical Treatment	1984 ³
E-2.201 Sedation to Unconsciousness in End-of-Life Care	2008
E-2.22 Do-Not-Resuscitate Orders	1992 ⁴
E-8.081 Surrogate Decision Making	2001
E-10.016 Pediatric Decision Making	2008 ⁵
H-140.966 Decisions Near the End of Life	1991 ⁶
H-140.970 Decisions to Forgo Life-Sustaining Treatment for Incompetent Patients	1991 ⁷
H-280.968 Do Not Hospitalize Orders	1993 ⁸
<i>Symptom Management, Palliative Care & Hospice</i>	
H-55.999 Symptomatic and Supportive Care for Patients with Cancer	1978 ⁹
H-70.915 Good Palliative Care	2014
H-85.955 Hospice Care	2014
H-85.966 Hospice Coverage and Underutilization	1994 ¹⁰
H-165.834 National Pain Care	2010
H-295.875 Palliative Care and End-of-Life Care	2006 ¹¹
<i>Physician Education</i>	
D-295.969 Geriatric and Palliative Training for Physicians	2002 ¹²
H-85.956 Educating Physicians About Advance Care Planning	2014
H-295.981 Geriatric Medicine	1985 ¹³
H-295.995 Recommendations for Future Directions for Medical Education	1982 ¹⁴
<i>Physician Licensure & Certification</i>	
H-275.997 Licensure by Specialty	1980 ¹⁵
H-275.917 An Updated on Maintenance of Licensure	2015
H-275.924 Maintenance of Certification	2009 ¹⁶
<i>Health Information Technologies</i>	
D-478.994 Health Information Technology	2005 ¹⁷
D-478.995 National Health Information Technology	2004 ¹⁸
D-478.996 Information Technology Standards and Costs	2004 ¹⁹
H-480.953 Interoperability of Medical Devices	2009 ²⁰

Quality Measures

<u>H-450.958</u>	Support for Development of Measures of Quality	1997 ²¹
<u>H-450.966</u>	Quality Management	1994 ²²

1	Reaffirmed 2015
2	Reaffirmed 2015
3	Updated 1996
4	Updated 2005
5	Updated 2010
6	Reaffirmed 2013
7	Reaffirmed 2009
8	Reaffirmed 2010
9	Updated 2010
10	Updated 2014
11	Amended, Res 322 A-14
12	Reaffirmed 2012
13	Amended, Res 301 A-10
14	Reaffirmed 2011
15	Reaffirmed 2010
16	Updated 2015
17	Reaffirmed 2014
18	Reaffirmed 2015
19	Reaffirmed 2014
20	Reaffirmed 2015
21	Reaffirmed 2007
22	Reaffirmed 2015

6. DESIGNATION OF SPECIALTY SOCIETIES FOR REPRESENTATION IN THE HOUSE OF DELEGATES

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policy G-600.027

At the American Medical Association's (AMA) 2007 Annual Meeting, Policy G-600.135 (see Appendix A for policies cited in report) was adopted, establishing a mechanism by which specialty society representation in the House of Delegates (HOD) would be determined. The mechanism for specialty society delegate allocation is based on a formula that looks at a society's AMA membership and the number of ballots cast for representation in each specialty (Appendix B). The specialty ballot is available online at www.ama-assn.org/go/ballot. The goal was to determine appropriate allocation of specialty society delegates. However, this system does not work as it relies on members making an active selection of a specialty society to represent them, and despite efforts by both our AMA and the specialty societies, few members make a choice, likely because the value of doing so is not well understood by the average member.

Since 2007, there have been a number of reports put forth attempting to improve the specialty delegate allocation process (Policies included in Appendix A). Previous reports have all attempted to present solutions to the challenge of fair allocation of specialty society delegates. The most recent report was at the 2016 Annual Meeting and as with previous reports, was referred back for further development. From the debate at A-16 two critical issues have been identified; the HOD wants parity in representation; and there is a desire for a simple method of allocation that is applied to both the constituent associations and the specialty societies. (AMA Bylaws define constituent associations as recognized medical associations of states, commonwealths, districts, or territories of the United States.)

This report seeks to address these issues and offer a solution. The Board of Trustees (BOT), with input from the Specialty and Service Society (SSS), believes that the following is a reasonable and equitable solution.

In order to establish parity the number of constituent delegates and specialty delegates should be equal. Under the theory that every AMA member should be represented by both a constituent association and a specialty society in

the HOD—the stated goal since 1996—the number of constituent and specialty delegates should be equal. The total AMA membership figure that determines the number of constituent delegates should also be used to determine the number of specialty delegates.

Constituent delegate allocation will continue to be based on the address for each AMA member, without respect to constituent society membership. Specialty delegate allocation is slightly more challenging because while one can only reside in one state, a member may belong to more than one specialty society.

Specialty society delegate allocation should be determined using data that is submitted by each specialty society every five years to determine their eligibility to remain in the HOD. While the membership numbers may fluctuate over five years, this will be the most reliable mark of AMA membership for each specialty.

Under AMA bylaws delegates are apportioned for the coming year each January, after the prior year's membership figures have been finalized. Current policy allows for one AMA delegate for every 1,000 AMA members or fraction thereof an organization has. The same standard should apply to both the constituent association and specialty society delegate allocation.

Once the total number of constituent society delegates allocated for any given year is determined then specialty society delegates would be adjusted up or down so that the total number of specialty society delegates equals the number of constituent society delegates. If the total number of allocated specialty society delegates is fewer than the total number of delegates allocated to constituent societies, additional delegates would be apportioned, one each, to those specialty societies that are numerically closest to qualifying for an additional delegate, until the total number of national specialty society delegates equals the number of constituent society delegates. Conversely, should the total number of allocated specialty society delegates be greater than the number of delegates allocated to constituent societies, then the excess delegates will be removed, one each, from those societies numerically closest to losing a delegate, until the total number of national specialty society delegates equals the number of constituent society delegates. With the adjustment, a few specialty societies will not truly have a 1 to 1,000 or fraction thereof ratio, but no specialty would gain or lose more than one delegate. This method would allow for the adjustment of delegation sizes to achieve parity between constituent society and specialty society representation while still using membership data as the guide.

Organizations with fewer than 1,000 AMA members would remain at one delegate as long as they retain representation in the HOD. Delegate allocation would continue to be adjusted annually based on AMA membership data, and specialty delegates would move annually in concert with the number of state delegates. In addition, as new specialty societies enter or leave the HOD, the delegate allocation of all specialties would be adjusted.

The attached chart (Appendix C) shows the impact implementation of this system would have had in 2016; the membership numbers on the chart are the latest available membership numbers, some of which were collected in preparing BOT Report 15-A-16.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted and the remainder of the report be filed:

1. That the current specialty society delegation allocation system (using a formula that incorporates the ballot) be discontinued; and that specialty society delegate allocation in the House of Delegates be determined so that the total number of national specialty society delegates shall be equal to the total number of delegates apportioned to constituent societies under section 2.1.1 (and subsections thereof) of AMA bylaws, and will be distributed based on the latest available membership data for each society, which is generally from the society's most recent five year review, but may be determined annually at the society's request.
2. That specialty society delegate allocation be determined annually, based on the latest available membership data, using a two-step process:
 - a) First, the number of delegates per specialty society will be calculated as one delegate per 1,000 AMA members in that society, or fraction thereof.

- b) Second, the total number of specialty society delegates will be adjusted up or down to equal the number of delegates allocated to constituent societies.
 - i) Should the calculated total number of specialty society delegates be fewer than the total number of delegates allocated to constituent societies, additional delegates will be apportioned, one each, to those societies that are numerically closest to qualifying for an additional delegate, until the total number of national specialty society delegates equals the number of constituent society delegates.
 - ii) Should the calculated total number of specialty society delegates be greater than the number of delegates allocated to constituent societies, then the excess delegates will be removed, one each, from those societies numerically closest to losing a delegate, until the total number of national specialty society delegates equals the number of constituent society delegates.
 - iii) In the case of a tie, the previous year's data will be used as a tie breaker. In the case of an additional delegate being necessary, the society that was closest to gaining a delegate in the previous year will be awarded the delegate. In the case of a delegate reduction being necessary, the society that was next closest to losing a delegate in the previous year will lose a delegate.

3. That the Council on Constitution and Bylaws investigate the need to change any policy or bylaws needed to implement a new system to apportion national medical specialty society delegates.
4. That this new specialty society delegate apportionment process be implemented at the first Annual Meeting of the House of Delegates following the necessary bylaws revisions.

Appendix A – Bylaws and Policy

Retention of Delegate, B-2.1.1.1.1

If the membership information as recorded by the AMA as of December 31 warrants a decrease in the number of delegates representing a constituent association, the constituent association shall be permitted to retain the same number of delegates, without decrease, for one additional year, if it promptly files with the AMA a written plan of intensified AMA membership development activities among its members. At the end of the one year grace period, any applicable decrease will be implemented.

G-600.021, Specialty Society Representation in our AMA House

The number of AMA delegate positions allocated to the specialty societies in our AMA/Federation House will be determined in the following manner: (1) The number of delegates and alternate delegates allocated to a specialty society will be on the basis of one delegate and one alternate delegate for each 1,000 AMA members, or portion of 1,000 AMA members, who select that a particular specialty society on the annual ballot and return the ballot to our AMA; and (2) Each specialty society that meets the eligibility criteria and is represented in our AMA/Federation House will be assured of at least one delegate and alternate delegate position regardless of the number of AMA members who select the society on the ballot and return the ballot to the AMA. (3) Our AMA will: (a) continue to include the ballot postcard in the Member Welcome Kit; (b) continue to promote the online ballot application to increase specialty society designations; (c) work with all willing specialty societies to solicit additional specialty society designations, using both printed ballots and electronic communications vehicles; and (d) continue to send email ballot solicitations to members who have not yet cast a ballot. (4) The current ballot system will remain in place while the Speakers, working with the Specialty and Service Society, examine other options for ensuring that each member of the American Medical Association is adequately represented by both a state medical association and national medical specialty society.

G-600.023, Designation of Specialty Societies for Representation in the House of Delegates

1. Specialty society delegate allocation in the House of Delegates shall be determined in the same manner as state medical society delegate allocation based on membership numbers allowing one delegate per 1,000 AMA members or fraction thereof.
2. Specialty society membership data shall be submitted annually by all societies with more than one delegate or societies seeking to obtain an additional delegate or delegates as part of a two-year pilot program with a report back at the 2016 Annual Meeting of our AMA House of Delegates.
3. The current specialty delegation allocation system (ballot and formula) will be continued until the pilot program is completed and the 2016 Annual Meeting report is acted upon by the House of Delegates.
4. This system shall be tested with all specialty societies with more than one delegate seated in the House of Delegates.
5. Organizations that would lose or gain one or more delegates through this pilot delegate allocation system shall assist our AMA with documenting the impact. However, no actual changes to delegation allocation other than those which occur through the five-year review and balloting system will be implemented until the data are collected and presented for acceptance to our AMA House of Delegates at the 2016 Annual Meeting.
6. In the future, any system of delegate allocation will continue to be monitored and evaluated for improvements.

G-600.135, Specialty Society Delegate Representation in the House of Delegates

1. Our AMA will continue efforts to expand awareness and use of the designation mechanism for specialty society representation, working wherever possible with relevant members of the Federation. 2. The system of apportioning delegates to specialty societies be enhanced by a systematic allocation of delegates to specialty societies by extrapolating from the current process in which members designate a specialty society for representation. The recommended model will: (a) establish annual targets for the overall proportion of AMA members from whom designations should have been received; (b) adjust actual designations by increasing them proportionately to achieve the overall target level of designations; (c) limit the number of delegates a society can acquire to the number that would be obtained if all the society's AMA members designated it for representation; (d) be initiated with delegate allocations for 2008, following the expiration of the freeze, which ends December 31, 2007; and (e) be implemented over five years because this will result in the least disruption to the House of Delegates and allow the process to unfold naturally. 3. The Board of Trustees will prepare annual reports to the House describing efforts undertaken to solicit designations from members, characterizing progress in collecting designations, and recommending changes in strategies that might be required to implement existing policy on representation of specialty societies. In addition, the Board should, in these or other reports: (a) develop a system for use among direct members to solicit their designations of specialty societies for representation, with an eye on how that system might be expanded or adapted for use among other members; and (b) engage in discussions with specialty societies that will lead to enhanced data sharing so that delegate allocations for both state and specialty societies can be handled in parallel fashion. 4. Our AMA will include in the specialty designation system an option to permit those members who wish to opt out of representation by a specialty society to do so when any automatic allocation system is used to provide representation for specialty societies that are represented in the House of Delegates. 5. If any specialty society loses delegates as a result of the apportionment process, the specialty society shall have a one-year grace period commencing January 1, 2008. At the expiration of this one-year grace period, a phase-in period shall be implemented such that the number of delegate seats lost will be limited to one seat per year for the succeeding three years. In the fourth year, any remaining reduction of seats will be implemented. 6. AMA Bylaw 2.11111 grants state societies a one-year grace period following the freeze expiring December 31, 2007 (per Bylaw 2.121). At the end of the grace period, a phase-in period will be implemented such that the number of delegate seats lost will be limited to one seat per year for the succeeding three years. In the fourth year, any remaining reduction of seats will be implemented.

Appendix B - 2016 Apportionment of Specialty Society Delegates

Board of Trustees Report 17-A-07 implemented the current mechanism for apportioning delegates to specialty societies in the House of Delegates.

The starting point for societies is the number of ballots submitted by AMA members designating a particular specialty society to represent their interests in the House of Delegates. That number is weighted, using the formula developed in BOT Report 17-A-07, and the resulting figure apportions delegates at the rate of one per 1,000 or fraction thereof, subject to a cap based on the number of AMA members in the society.

The weighting factor is directly related to the total AMA membership and inversely related to the proportion of AMA members who have actually designated a society for representation purposes. That is, as AMA membership increases, the weight increases, and as the proportion of members casting a ballot increases, the weight decreases. The weight is limited to 80% of its calculated value, and the same weight applies to every specialty society.

Elements of the formula are (with their 2016 values):

- a. Members eligible to ballot, 4th year student or beyond (198,408)
- b. Actual ballots (54,571, which includes 447 who chose NOT to designate a specialty society)
- c. a/b (54,971/198,408 = 0.27504)
- d. 1/c (1 / 0.27504 = 3.635777)
- e. d * 0.8 (3.635777 * 0.8 = 2.908622)
- f. e * ballots / 1000, with result rounded up to next whole number

The delegate apportionment is subject to the following constraints:

1. Every specialty society seated in the House of Delegates has at least one delegate;
2. The number of delegates cannot exceed the figure that would apply if ALL its AMA members selected that society for representation purposes.

The following example illustrates use of the formula. If at year end 2015 a society had 1,015 ballots and 7,913 AMA members:

$1015 * 2.909 / 1000 \rightarrow 2952.6 / 1000 \rightarrow 2.9 \rightarrow$ rounds up to 3; but if all 7913 AMA members had designated the society, the cap would be 8 delegates ($7913 / 1000 = 7.9 \rightarrow$ rounds up to 8). The society gets the lesser of the calculated number or the cap, or in this case 3 delegates.

Appendix C

The 2016 delegate allocation for the constituent medical societies was 265 delegates. Applying the system outlined in this report would have resulted in the delegate allocation shown in the column labeled adjusted delegate allocation for the specialties.

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
Academy of Physicians in Clinical Research	148	1	1			1
Aerospace Medical Association	173	1	1			1
AMDA - The Society for Post-Acute and Long Term Care Medicine	873	1	1			1
American Academy of Allergy, Asthma and Immunology	361	1	1			1
American Academy of Child and Adolescent Psychiatry	1,446	1	2	446		2
American Academy of Cosmetic Surgery	348	1	1			1
American Academy of Dermatology	2,955	4	3	955		3
American Academy of Facial Plastic and Reconstructive Surgery	365	1	1			1
American Academy of Family Physicians	17,323	18	18	323		18
American Academy of Hospice and Palliative Medicine	700	1	1			1
American Academy of Insurance Medicine	64	1	1			1
American Academy of Neurology	2,207	3	3	207		3
American Academy of Ophthalmology	3,380	4	4	380		4
American Academy of Orthopaedic Surgeons	6,755	5	7	755		7
American Academy of Otolaryngic Allergy Inc.	386	1	1			1
American Academy of Otolaryngology-Head and Neck Surgery	2,895	3	3	895		3
American Academy of Pain Medicine	471	1	1			1
American Academy of Pediatrics	8,160	7	9	160		9
American Academy of Physical Medicine and Rehabilitation	1,838	2	2	838		2
American Academy of Psychiatry and the Law	359	1	1			1
American Academy of Sleep Medicine	1,236	1	2	236		2
American Association for Geriatric Psychiatry	876	1	1			1
American Association for Hand Surgery	266	1	1			1
American Association for Thoracic Surgery	279	1	1			1
American Association of Clinical Endocrinologists	815	1	1			1
American Association of Clinical Urologists,	968	1	1			1
American Association of Gynecologic Laparoscopists	1,264	1	2	264		2

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
American Association of Hip and Knee Surgeons	381	1	1			1
American Association of Neurological Surgeons	902	2	1			1
American Association of Neuromuscular & Electrodiagnostic Medicine	809	1	1			1
American Association of Plastic Surgeons	175	1	1			1
American Association of Public Health Physicians	45	1	1			1
American Clinical Neurophysiology Society	197	1	1			1
American College of Allergy, Asthma and Immunology	555	1	1			1
American College of Cardiology	5,693	4	6	693		6
American College of Chest Physicians	2,552	1	3	552		3
American College of Emergency Physicians	6,705	5	7	705		7
American College of Gastroenterology	1,383	2	2	383		2
American College of Legal Medicine	133	1	1			1
American College of Medical Genetics and Genomics	356	1	1			1
American College of Medical Quality	134	1	1			1
American College of Mohs Surgery	219	1	1			1
American College of Nuclear Medicine	81	1	1			1
American College of Occupational and Environmental Medicine	547	1	1			1
American College of Phlebology	310	1	1			1
American College of Physicians	22,690	13	23	690		23
American College of Preventive Medicine	484	1	1			1
American College of Radiation Oncology	323	1	1			1
American College of Radiology	6,077	7	7	77	-1	6
American College of Rheumatology	1,095	2	2	95	-1	1
American College of Surgeons	12,445	6	13	445		13
American Congress of Obstetricians and Gynecologists	12,000	12	12			12
American Gastroenterological Association	1,709	1	2	709		2
American Geriatrics Society	927	1	1			1
American Institute of Ultrasound in Medicine	1,216	1	2	216		2
American Medical Group Association	2,928	1	3	928		3
American Orthopaedic Association	311	1	1			1
American Orthopaedic Foot and Ankle Society	262	1	1			1
American Psychiatric Association	7,478	8	8	478		8
American Roentgen Ray Society	2,377	1	3	377		3
American Society for Aesthetic Plastic Surgery, Inc.	348	1	1			1

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
American Society for Clinical Pathology	2,127	1	3	127		3
American Society for Dermatologic Surgery	1,016	1	2	16	-1	1
American Society for Gastrointestinal Endoscopy	1,662	1	2			2
American Society for Radiation Oncology	839	1	1			1
American Society for Reproductive Medicine	794	1	1			1
American Society for Surgery of the Hand	666	1	1			1
American Society of Addiction Medicine	623	1	1			1
American Society of Anesthesiologists	6,146	7	7	146		7
American Society of Breast Surgeons	568	1	1			1
American Society of Cataract and Refractive Surgery	1,133	1	2	133		2
American Society of Clinical Oncology	3,227	2	4	227		4
American Society of Colon and Rectal Surgeons	228	1	1			1
American Society of Cytopathology	214	1	1			1
American Society of Dermatopathology	344	0	1			1
American Society of Echocardiography	1,135	1	2	135		2
American Society of General Surgeons	341	1	1			1
American Society of Hematology	861	1	0			0
American Society of Interventional Pain Physicians	544	1	1			1
American Society of Maxillofacial Surgeons	82	1	1			1
American Society of Metabolic and Bariatric Surgery	313	1	1			1
American Society of Neuroimaging	90	1	1			1
American Society of Neuroradiology	478	1	1			1
American Society of Ophthalmic Plastic and Reconstructive Surgery	160	1	1			1
American Society of Plastic Surgeons	919	2	1			1
American Society of Retina Specialists	608	1	1			1
American Thoracic Society	1,307	1	2	307		2
American Urological Association	1,181	2	2	181		2
Association of Military Surgeons of the United States	687	1	1			1
Association of University Radiologists	181	1	1			1
College of American Pathologists	3,294	4	4	294		4
Congress of Neurological Surgeons	983	1	1			1
Contact Lens Association of Ophthalmologists, Inc.	37	1	1			1
The Endocrine Society	1,086	1	2	86	-1	1
Heart Rhythm Society	651	1	1			1

	AMA Membership	Actual 2016 Delegates	1 per 1,000 or Fraction Thereof	Rounding Factor	Adjustment	Adjusted Delegate Allocation
Infectious Diseases Society of America	1,147	1	2	147		2
International Academy of Independent Medical Evaluators	191	1	1			1
International College of Surgeons - US Section	313	1	1			1
International Society for the Advancement of Spine Surgery	134	1	1			1
International Society for Hair Restoration Surgery	91	1	0			0
National Association of Medical Examiners	169	1	1			1
North American Spine Society	1,345	1	2	345		2
Obesity Medical Association	259	1	1			1
Radiological Society of North America	2,446	1	3			3
Renal Physicians Association	586	1	1			1
Spine Intervention Society	542	1	1			1
Society for Cardiovascular Angiography and Interventions	434	1	1			1
Society for Investigative Dermatology, Inc.	207	1	1			1
Society for Vascular Surgery	762	1	1			1
Society of American Gastrointestinal Endoscopic Surgeons	1,131	1	2	131		2
Society of Critical Care Medicine	911	1	1			1
Society of Hospital Medicine	1,556	1	2	556		2
Society of Interventional Radiology	580	1	1			1
Society of Laproendoscopic Surgeons	982	1	1			1
Society of Nuclear Medicine and Molecular Imaging	505	1	1			1
Society of Thoracic Surgeons	1,192	2	2	192		2
The Triological Society	152	1	1			1
Undersea and Hyperbaric Medical Society	186	1	1			1
United States and Canadian Academy of Pathology, Inc.	1,281	1	2	281		2
Total delegates		220	269		-4	265

7. SUPPORTING AUTONOMY FOR PATIENTS WITH DIFFERENCES OF SEX DEVELOPMENT (DSD) (RESOLUTION 3-A-16)

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: REFERRED

At the 2016 Annual Meeting, the American Medical Association (AMA) House of Delegates referred to the Board of Trustees Resolution 3-A-16, “Supporting Autonomy for Patients with Differences of Sex Development (DSD),” introduced by the Medical Student Section. Resolution 3 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 was largely in favor of referral. Those offering testimony understood the key developmental issues surrounding individuals born with DSD. However, testimony revealed gaps in understanding about how to address appropriately surgical and medical options in providing care, necessitating a call for further study.

BACKGROUND

The term “differences of sex development” (DSD) refers to congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical [1]. The frequency of DSDs varies with etiology [2], but overall incidence of DSD is estimated to be one in 5,500 births; some 60 percent of affected children are now diagnosed prenatally [3]. Diagnosis of DSD is complex, encompassing family and prenatal history, physical examination (particularly of genital anatomy), and various laboratory tests, including determination of chromosomal sex. Diagnosis may also involve ultrasound or other imaging studies, hormonal stimulation tests (eg, human chorionic gonadotropin or adrenocorticotropin stimulation), and, in rare cases, laparotomy or laparoscopy [3]. Not all cases of DSD are diagnosed perinatally.

DSD include potentially life-threatening developmental anomalies that may require immediate intervention, for example, hypotension resulting from salt-wasting nephropathy, which occurs in 75 percent of infants born with congenital adrenal hyperplasia. DSD also includes “cosmetic” abnormalities for which elective interventions to normalize appearance can be undertaken at various stages in the child’s life [2,4].

Historically, assigning gender in a newborn with ambiguous genitalia has been viewed as a “medical emergency,” with immediate surgery recommended to match genitalia to the assigned gender, on the rationale that uncertain gender is distressing for the family, may adversely affect the child’s mental health, and can lead to stigmatization [3,5]. This view has been increasingly challenged [2,4,6]. DSD communities and a growing number of health care professionals have condemned such genital “normalizing,” arguing that except in the rare cases in which DSD presents as life-threatening anomalies, genital modification should be postponed until the patient can meaningfully participate in decision making [4,7,8].

In 2006, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) observed the lack of sufficient data to guide decisions about gender assignment and absence of clear guidelines for clinical practice [9]. The NIDDK also noted that there are only limited long-term outcome data on early surgical reconstruction, despite concern about irreversibility and possible sensory damage to the genitalia. Finally, the NIDDK cited a lack of “systematic outcome data about sexual function in individuals with disorders of sexual differentiation [sic]” and of data “pertaining to the association of sexual function with genital appearance and types of genital surgery.” It therefore called for prospective studies of gender identity, reproductive function, and quality of life for patients with DSD “to guide clinicians and families in making decisions about gender assignment and surgical reconstruction.”

Also in 2006, the Intersex Society of North America (ISNA) released its “Clinical Guidelines for the Management of Disorders of Sex Development in Childhood,” gathering perspectives of treating physicians, past patients, and parents who have been involved in the management of DSD [1]. The guidelines address appropriate treatment options for common genital anomalies, focusing on patient- and family-centered care provided by a well-trained multidisciplinary team. The guidelines acknowledge that each patient requires unique attention and resources. Importantly, ISNA guidelines note that gender assignment “is a social and legal process not requiring medical or surgical intervention” (original emphasis) [1].

A small study carried out in 2011-2012 among medical students in Zurich found that how physicians discussed treatment for a child with DSD influenced the choice for or against surgery, despite respondents’ belief that their personal attitudes governed decision making [10]. Participants watched brief counseling videos that offered either a “medicalized” or “demedicalized” approach. That is, the video described DSD as a condition that is static, has an inherent psychosocial component, and requires treatment, and for which predetermined treatment regimens focus on biological function, or as a dynamic disorder characterized by context-dependent impairment for which coping strategies should be fostered, with treatment geared to the individual’s interests and capabilities. Sixty-six percent of participants who viewed the medicalized video said they would choose early surgery for their child, compared to 23 percent of those who viewed the demedicalized video.

CURRENT AMA POLICY

Current AMA policy does not address treatment for patients with DSD directly. Rather, a limited number of ethics and House policies speak to decisions for minors more broadly, as well as to issues pertaining to gender identity, sexual orientation, transgender health, and discrimination toward sexual minority communities:

- [Opinion 2.2.1](#), “Pediatric Decision Making,” encourages involving minor patients in decision making at a developmentally appropriate level, including decisions that involve life-sustaining interventions, and recommends that clinicians work with parents or guardians to simplify complex treatment regimens for children with chronic health conditions.
- [Opinion 2.2.4](#), “Treatment Decisions for Seriously Ill Newborns,” articulates the considerations that must be taken into account when addressing emotionally and ethically challenging cases involving newborns, including: the medical needs of the child; the interests, needs, and resources of the family; available treatment options; and respect for the child’s right to an “open future.” It calls on physicians to inform parents about available therapeutic options and the nature of those options and to discuss the child’s expected prognosis with and without intervention.
- [Opinion 2.2.5](#), “Genetic Testing of Children,” identifies conditions under which physicians may ethically offer genetic testing for minor patients. It observes that testing implicates important concerns about the autonomy and best interests of the minor patient and holds that medical decisions made on behalf of a child should not abrogate the opportunity to choose to know his or her genetic status as an adult.
- [H-525.987](#), “Surgical Modification of Female Genitalia,” opposes medically unnecessary surgical modification of female genitalia and encourages the development of educational programs to address complications and corrective procedures.
- [H-475.992](#), “Definitions of ‘Cosmetic’ and ‘Reconstructive’ Surgery,” distinguishes cosmetic surgery, performed on normal bodily structures to improve patient appearance, from reconstructive surgery, performed on abnormal bodily structures to improve function or approximate normal appearance.

DECISIONS FOR PEDIATRIC PATIENTS

Parents (or guardians) are granted the authority to make health care decisions for their minor children when the child lacks the ability to act independently or does not have the capacity to make medical decisions [11]. Parents are deemed to be in a better position than others to understand their child’s unique needs and interests, as well as their families’, and thus to be able to make appropriate decisions regarding their child’s health care. Historically, the best interest standard has predominated as the appropriate decision-making standard for medical decisions for minors. Current consensus rests on a more nuanced view that encompasses not only the patient’s medical interests, but psychosocial and familial concerns as well [11].

The “harm principle” has been suggested as a further refinement on the decision-making standard, requiring not only that decision makers consider the patient’s best interests, broadly understood, but also that a threshold of harm be identified, below which decisions should not be tolerated [11]. Parents (or guardians) are also recognized to have a responsibility to foster their children’s autonomy and moral growth, a responsibility clinicians share. Providing information in a developmentally appropriate way that respects the minor patient’s cognitive ability, engaging the child in decision making to the extent possible, and seeking the child’s assent to proposed interventions helps to fulfill that responsibility [11].

With respect to DSD specifically, it has been suggested that decisions should seek to foster the well-being both of the current child and the adult he or she will become; respect the rights of patients to participate or make decisions that affect them; and foster family and parent-child relationships [4].

In cases of DSD, decisions about a child’s best interests and appropriate interventions involve sensitive issues of sex, gender, and sexuality, and interventions that may be irreversible. Parents are often concerned about the future well-being of their child with regard to self-identity, relationships, and reproductive capacity [7]. Because of these concerns, they may be quick to want to establish sex and gender identity for their child in order to promote “normalcy” and reduce stigmatization. Moreover, when physicians perceive early intervention to be urgently needed or wholly beneficial, they may not fully recognize that there is a decision to be made, or the complexity of that decision for the family and patient.

A 2013 lawsuit, though unsuccessful, raised constitutional issues with respect to early surgical intervention and sex assignment. In 2013, the adoptive parents of a South Carolina child, MC, born with “ovotesticular DSD” filed suit in the US District Court for the District of South Carolina against physicians who had performed feminizing genitoplasty on the child at age 16 months. At the time of surgery, MC was under the legal custody of the South Carolina Department of Social Services, which authorized the intervention. Despite initially being raised as a girl by his adoptive parents, consistent with his surgically assigned sex, MC identified as a boy and at the time the lawsuit was filed was living as a boy. Because of the surgery, MC is now sterile. Although the action was dismissed on appeal by the US Court of Appeals for the Fourth Circuit (in January 2015) [12], the lower court had denied the defendants’ request for dismissal on the grounds that the defendants may have violated MC’s constitutional right to procreate [13].

RECOMMENDATION

The Board of Trustees recommends that the following be adopted in lieu of Resolution 3-A-16 and the remainder of this report be filed:

That our American Medical Association support optimal management of DSD through individualized, multidisciplinary care that: (1) seeks to foster the well-being of the child and the adult he or she will become; (2) respects the rights of the patient to participate in decisions and, except when life-threatening circumstances require emergency intervention, defers medical or surgical intervention until the child is able to participate in decision making; and (3) provides psychosocial support to promote patient and family well-being.

REFERENCES

1. Lee PA, Houk CP, Ahmed SF, et al. Consensus statement on management of intersex disorders. *Pediatrics*. 2006;118(2):e488–e500. Available at <http://pediatrics.aappublications.org/content/118/2/e488>. Accessed August 12, 2016.
2. Hutcheson J, Snyder HM. Disorders of sex development. *Medscape*. 2014. Available at <http://emedicine.medscape.com/article/1015520-overview>. Accessed August 12, 2016.
3. Kim SK, Kim J. Disorders of sex development. *Korean J Urol*. 2012;53:1–8.
4. Wiesemann C, Ude-Koeller S, Sinnecker GH, Thyen U. Ethical principles and recommendations for the medical management of differences of sex development (DSD)/intersex in children and adolescent. *Eur J Pediatr*. 2010;169:671–679.
5. Creighton S, Chernausek SD, Romao R, et al. Timing and nature of reconstructive surgery for disorders of sex development—introduction. *J Pediatr Urol*. 2012;8:602–610.
6. Dreger AD. “Ambiguous sex”—or ambivalent medicine? Ethical issues in the treatment of intersexuality. *Hastings Cent Rep*. 1998;3:24–35.
7. Tamar-Mattis A, Baratz A, Baratz Dalke K, Karkazis K. Emotionally and cognitively informed consent for clinical care for differences of sex development. *Psychol Sex*. 2014;5(1):44–55.
8. Diamond M, Garland J. Evidence regarding cosmetic and medically unnecessary surgery on infants. *J Pediatr Urol*. 2014;10:2–7.
9. National Institute of Diabetes & Digestive & Kidney Diseases. *Strategic Plan for Pediatric Urology*. February 2006. Available at https://www.niddk.nih.gov/about-niddk/strategic-plans-reports/Documents/pediatric-urology/Pediatric_Urology_Feb_2006_Document.pdf. Accessed August 12, 2016.
10. Streuli JC, Vayena E, Cavicchia-Balmer BA, Huber J. Shaping parents: impact of contrasting professional counseling on parents’ decision making for children with disorders of sex development. *J Sex Med*. 2013;10:1953–1960.
11. American Academy of Pediatrics Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics* 2016;138(2): e20161484. Available at <http://pediatrics.aappublications.org/content/pediatrics/138/2/e20161484.full.pdf>. Accessed August 12, 2016.
12. M.C. v. Aaronson, No. 13-2178 (4th Cir. Jan. 26, 2015).
13. M.C. v. Aaronson, No. 2:13-cv-01303-DCN (D. S.C. Aug. 29, 2013) (order denying motion to dismiss).

8. MEDICAL REPORTING FOR SAFETY-SENSITIVE POSITIONS (RESOLUTION 14-A-16)

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

HOUSE ACTION: REFERRED

At the 2016 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred to the Board of Trustees Resolution 14-A-16, “Medical Reporting for Safety Sensitive Positions,” which was introduced by the Aerospace Medical Association. Resolution 14-A-16 asked:

That our American Medical Association advocate for a uniform national policy on mandatory reporting of significant medical conditions for employees in Safety Sensitive positions to protect public safety, as well as to enhance protection of reporting physicians.

Testimony was supportive of the intent of the resolution, but was concerned about the ambiguity of language in light of the complexity of the issue. Testimony also offered an amendment to use the Department of Transportation’s definition of “Safety-Sensitive Position.” It was expressed that, while addressing this issue as timely and necessary, clarification must be provided before the resolution is recommended for adoption.

BACKGROUND

According to the Department of Transportation (DOT), a safety-sensitive position is a job or position where the employee holding this position has the responsibility for his or her own safety or other people’s safety. Under DOT regulations, this term is currently used to describe positions that are subject to drug and alcohol testing. These regulations cover transportation employees in various capacities, including aviation, trucking, rail, mass transit, pipeline, and maritime professions [1].

The DOT requires that employees in safety-sensitive positions be given approval to work by a certified physician. Qualifications for physician certification are regulated by the various agencies of the DOT. For example, the Federal Aviation Administration (FAA) has regulations for the certification of Aviation Medical Examiners [2]. The Federal Motor Carrier Safety Administration has a registry and certification process for physicians who perform medical exams for truck drivers [3]. Once certified, these physicians grant medical certificates to safety-sensitive employees, allowing them to work. The requirements for safety-sensitive positions depend on the job’s duties and are regulated by the various agencies of the DOT. Employees must be free of certain disqualifying conditions, such as poor vision or hearing, epilepsy, or diabetes [4]. Furthermore, there is no requirement that physicians report to the relevant agencies; rather, if an employee is not eligible for work, the physician is expected not to grant a certificate to work.

Mandatory reporting by physicians is required by states in other contexts in which there is concern for public health or safety, such as certain infectious diseases or neurological conditions (e.g., epilepsy) that may impair the driving ability of individuals who hold noncommercial motor vehicle licenses. Specific reporting requirements vary by state.

Professional organizations also have their own recommendations for reporting when a threat to public safety exists. For example, the Federation of State Physician Health Programs recommends immediate reporting to the licensing authority by the state physician health program (PHP) if a physician enrolled in the PHP has an impairing condition and refuses to cease practice or otherwise presents a threat to public safety. Similarly, the physician must be reported if he or she rejects recommendations for evaluation or treatment or has been directed by the licensing authority to undergo evaluation or treatment. Although the safety of individual patients and the public may be the primary consideration, protecting the confidentiality of the impaired physician is also an important consideration [5].

CURRENT AMA POLICY

AMA policy does not speak to safety-sensitive positions specifically. However, the following address issues of mandatory reporting in the context of public health and safety.

- Opinion 1.2.6, “Work-Related and Independent Medical Examinations,” addresses the unique relationships industry-employed physicians have with patients, often confined to the isolated examination required by the

industry employer. Physicians are encouraged to disclose the limited nature of the patient-physician relationship, and to be forthright with the patient about the physician's contractual role with the employer. The physician must maintain professional standards of confidentiality, and, when necessary, should assist the patient in connecting with a qualified physician or in pursuing follow-up care.

- Opinion 3.2.3, "Confidentiality: Industry-Employed Physicians and Independent Medical Examiners," urges that, when a physician assesses an individual's health or disability for work-related illness or injury, the information must remain confidential unless consent is given by the individual or is required by law. When authorized to release medical information, physicians should only release information that is reasonably relevant to the individual's ability to perform work.
- Opinion 8.2, "Impaired Drivers and Their Physicians," urges a physician to assess at-risk patients for conditions that may affect their driving ability. If such a risk exists, a physician should discuss driving risks with the patient and the patient's family in order to minimize risk. The physician should notify the patient that continued driving against advice to stop will result in reporting to authorities, who will make the final determination on the status of the patient's license. The physician should only disclose the minimum necessary information when reporting.
- Opinion 9.3.2, "Reporting Impaired Colleagues," discusses the situation in which a physician or mental health condition interferes with a physician's ability to engage safely in professional activities, potentially compromising patient care. In such situations, physicians have an ethical obligation to intervene in a timely manner, to report colleagues in keeping with ethical guidance and applicable law, and to work collectively to support impaired physicians through the promotion of physician health and wellness and the creation of mechanisms to assist impaired physicians in ceasing their practice.
- H-15.954, "Older Driver Safety," urges physicians to adhere to their state's reporting statutes for medically at-risk drivers.
- H-15.958, "Fatigue, Sleep Disorders, and Motor Vehicle Crashes," recommends collaboration between DOT and other agencies to study fatigue among truck drivers and operator other commercial vehicles. It recommends that physicians become knowledgeable about sleep-related disorders and inform patients of hazards of driving while fatigued, as well as becoming aware of the laws and regulations concerning drivers in their state.

TARGETING MENTAL FITNESS CONCERNS

DOT regulations directly address mental health issues, such as substance use disorders and depression, through the certification process, as well as through drug and alcohol testing. The DOT also requires screening for other physically impairing conditions such as epilepsy or seizure disorders through the medical certification process. Formal psychiatric examinations, however, are not required [6]. In response to the Germanwings crash of 2015, Resolution 14-A-16 seeks to address any gap in mental health screening among employees in safety-sensitive positions.

Following the Bureau d'Enquêtes et d'Analyse report, which confirmed the Germanwings crash of 2015 was caused by the suicide of a co-pilot known to have major depression with psychosis, agencies around the world are working to improve mental health evaluations and treatment, as well as encourage voluntary reporting of mental health issues. Several commercial airlines already have mechanisms in place that allow pilots in distress to report, seek treatment, and return to work once successfully evaluated [7].

In January of 2016, the Aviation Rulemaking Committee (ARC) of the FAA issued several recommendations to the FAA, airlines, and pilots' unions. Collectively, they agreed to develop programs to reduce mental health stigma and promote resources for treatment, including expanding the use of pilot assistance programs to cover mental health. ARC concluded that routine screening for depression is neither productive nor cost effective and therefore did not recommend it be adopted. They instead advocated for education, outreach, and training in order to encourage self-reporting to employers to enroll in treatment programs [7].

CONSIDERING A NATIONAL MANDATORY REPORTING POLICY

Transportation and safety-sensitive positions are primarily inter-state in nature at this time. Truck drivers, pilots, and railroad workers operate in a capacity that affects the safety of people from many different states. The intent of national mandatory reporting for safety-sensitive positions would be to overcome the variability in state requirements.

However, it is not clear as a practical matter that such a policy would achieve the intended goal. A study among primary care physicians in Canada found that they rarely report unsafe drivers to licensing authorities, even when the reporting laws require it. The study surveyed vehicle crashes and prior doctor visits to see how often doctors reported unsafe drivers before accidents occurred. The study found that reporting was very low even though many of the drivers had been to their physician before their crashes. The authors suggest that these findings are due to ambiguous language in the statute, as well as the difficulty in detecting impairing conditions, such as alcohol abuse, in a primary care context [8].

A national reporting mandate must be robustly structured to avoid unintended consequences, such as damage to the reputation or employability of an individual inappropriately identified as impaired. Among the minimum requirements needed for an effective reporting system would be clearly delineated criteria for identifying individuals who pose a plausible, significant risk to public safety and a clear mechanism for reporting such individuals to authorities in a position to take action to protect the public. Appropriate safeguards to protect the confidentiality of individuals identified as impaired and clear means for referring them for appropriate treatment would also be required.

Whether the possible, but as yet unknown, gain in public safety would offset the additional burdens national mandatory reporting would pose administratively for oversight authorities and for primary care or other physicians who do not routinely screen patients for these purposes is uncertain. A more limited approach may be more effective; for example, focusing on training the physicians who currently carry out evaluation of individuals for safety-sensitive positions, such as Aviation Medical Examiners and other certified physicians to better identify mental health issues during their periodic evaluations of safety-sensitive employees.

CONCLUSION

National standards already exist for employees in safety-sensitive positions for their physical and mental health, which require employees to be cleared for work by DOT-certified physicians. The likely gain in public safety that would be achieved by mandatory reporting is at present undemonstrated, while the burden on physicians who are not DOT-certified and not otherwise required to report impairing conditions could be substantial.

RECOMMENDATION

The Board of Trustees recommends that Resolution 14-A-16, “Medical Reporting for Safety-Sensitive Positions,” not be adopted and the remainder of the report be filed.

REFERENCES

1. Department of Transportation. *What Employees Need to Know about DOT Drug & Alcohol Testing*. Available at <https://www.transportation.gov/odapc/employee-handbook-english>. Accessed June 30, 2016.
2. Federal Aviation Administration. *Guide for Aviation Medical Examiners*. Available at http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/. Accessed July 15, 2016.
3. Federal Motor Carrier Safety Administration. *Fact Sheet CMV Driver*. Available at <https://nationalregistry.fmcsa.dot.gov/NRPublicUI/Drivers.seam>. Accessed August 2, 2016.
4. Federal Motor Carrier Safety Administration. Available at <https://www.fmcsa.dot.gov/faq/what-medical-conditions-disqualify-commercial-bus-or-truck-driver>. Accessed August 2, 2016.
5. Federation of State Physician Health Programs, Inc. *Physician Health Program Guidelines*. Available at <http://www.fsphp.org/resources/guidelines>. Accessed July 15, 2016.
6. Federal Aviation Administration. *Guide for Aviation Medical Examiners*. Available at https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/app_process/exam_tech/item47/et/. Accessed August 4, 2016.
7. Federal Aviation Administration. *Press Release – U.S. Commercial Aviation Community Targets Pilot Mental Fitness*. Available at http://www.faa.gov/news/press_releases/news_story.cfm?newsId=20456&omniRss=press_releasesAoc&cid=102_P_R. Accessed June 13, 2016.
8. Redelmeier DA, Venkatesh V, Stanbrook MB. Mandatory reporting by physicians of patients potentially unfit to drive. *Open Medicine* 2008;2(1):E8-17.

**9. PRODUCT-SPECIFIC DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS
(SECOND RESOLVE, RESOLUTION 927-I-15 AND RESOLUTION 514-A-16)**

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF
THE SECOND RESOLVE OF RESOLUTION 927-I-15 AND RESOLUTION 514-A-16
REMAINDER OF REPORT FILED**
See Policy H-105.988

INTRODUCTION

The second resolve of Substitute Resolution 927-I-15, “Ban Direct-To-Consumer Advertisements of Prescription Drugs and Implantable Medical Devices,” referred for decision by the House of Delegates (HOD), and then directed for a report back by the Board of Trustees asked:

That Policy H-105.988, “Direct-to-Consumer Advertising of Prescription Drugs and Implantable Medical Devices,” be rescinded.

Resolution 514-A-16, “Opposing Tax Deductions for Direct-to-Consumer Advertising,” introduced by the California Delegation and referred by the HOD asked:

That our American Medical Association oppose allowing costs for direct-to-consumer advertising of prescription medications, medical devices, and controlled drugs to be considered deductible business expenses for tax purposes.

AMA Policy H-105.986, “Ban Direct-to-Consumer Advertisements of Prescription Drugs and Implantable Devices,” supports a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices. Policy H-105.988 contains a detailed set of guidelines for establishing what the AMA considers to be acceptable product-specific direct-to-consumer advertisements (DTCA) for prescription drugs and implantable medical devices. Although AMA policy supports a ban on DTCA, it may be reasonable and prudent to maintain a policy that provides a framework to evaluate the appropriateness and/or usefulness of DTCA, based principally on the fact that the Supreme Court has ruled that DTCA is protected commercial free speech and therefore, this practice will likely continue in the future. This report summarizes concerns and findings on the impact of DTCA and whether the AMA should maintain a comprehensive policy on what constitutes acceptable product-specific DTCA. Additionally, this report briefly considers whether establishing policy opposing industry tax credits for DTCA is advisable.

BACKGROUND

Food and Drug Administration Regulation of DTCA

Pharmaceutical companies began marketing prescription drugs directly to consumers in the early 1980s. In 1983, the Food and Drug Administration (FDA) imposed a moratorium on DTCA, to which the industry agreed. Two years later, based on the legal view that DTCA is constitutionally protected free speech, the FDA concluded that it lacked the legal authority to prevent this type of advertising and agreed to allow it as long as DTCA: (1) were not false or misleading; (2) presented a fair balance between benefit and risk information; and (3) revealed all material facts about risks in the form of a so-called “brief summary.” The latter required that ads provide sufficient information about warnings, precautions, and side effects associated with prescription drug products. Based on these substantial informational requirements, most product-specific DTCA in the 1980s and 1990s were largely restricted to print media.

In 1999, the FDA acted to facilitate DTCA via broadcast media by finalizing the Agency’s “Guidance for Industry: Consumer-Directed Broadcast Advertisements.”² This Guidance relaxed the responsibilities for the industry with respect to providing risk information in DTCA. The key new provision was that the FDA now required pharmaceutical manufacturers to provide only risk information related to the major side effects and contraindications of the advertised drugs in the audio or visual portion of the broadcast (referred to as the “major statement”) and make “adequate provision” for obtaining the full prescribing information in connection with the

advertisement.³ The latter could be accomplished by referral to a company-designated toll free phone number or web page, a print advertisement for the product or referral to the patient's physician or pharmacist for additional information.

With these changes, the appearance of DTCA in broadcast media increased substantially. By 2006, the industry was spending \$5.4 billion annually on DTCA. The *2007 Food and Drug Administration Amendments Act* gave the FDA the authority to require submission of any television drug advertisement for advisory review not later than 45 days before the ad is publicly disseminated. Although the FDA can make certain recommendations for the DTCA based on information included in the drug's package insert (including addressing efficacy of the drug in specific populations), it has no authority to require changes except for specific disclosure about serious risks, or the date of approval, if the ad would otherwise be deemed false or misleading. In 2012, the FDA issued draft guidance for industry on how it planned to implement the requirement for the pre-dissemination review of DTCA.³ This guidance establishes several categories of television ads subject to pre-dissemination review (e.g., initial ads for a new drug, any drug with a Risk Evaluation and Mitigation Strategy, controlled substances, and any drug with a black box warning). The FDA's Office of Prescription Drug Promotion (OPDP) is responsible for reviewing prescription drug advertising and promotional labeling to ensure the information contained in the promotional materials is not false or misleading. OPDP also encourages health care providers to report misleading ads through the Bad Ad program.

The regulatory structure around certain aspects of DTCA may change as the FDA moves to enact new regulations regarding risk communication. In 2015, the FDA sought public comments on new guidance for pharmaceutical marketers on communicating risks to consumers in print advertisements. The Agency's proposal is based on accumulated research showing that reprinting highly technical language in print advertisements does very little to communicate risks to consumers. Rather, the FDA is proposing that companies use a new "consumer brief summary" focused on the most important risk information in a way most likely to be understood by consumers. This would move the requirements for risk communication in print advertisements in the same direction as previously made for broadcast advertisements.

DTCA-Pro or Con?

The United States is one of only two countries in the world that allows DTCA in broadcast, print, and electronic media; the other is New Zealand. Last year the industry spent \$5.4 billion on such advertising, a 58% increase from 2012, and equivalent to the peak spending last achieved in 2006.⁴ During the same time period, the proportion of total DTCA spending devoted to television increased from 57% to 69%. Considerable debate has focused on whether DTCA is beneficial or harmful to patients or the patient/physician relationship, and whether physician prescribing behavior is significantly affected.

The following lists the major pro and con arguments that have been made regarding DTCA:

Arguments in Support of DTCA

- Educates patients and encourages patient responsibility for their health.
- Increases patient awareness of medical conditions and treatment options.
- Encourages patients to contact their physician, or otherwise engage the healthcare system.
- Results in cost savings; by seeking medical attention, patients have their conditions managed in a more prompt fashion, avoiding unneeded hospital stays or more costly interventions.
- Stimulates thoughtful dialogue and strengthens a patient's relationship with their health care provider.
- Encourages patient adherence, with drug ads serving as reminder aids.
- Reduces underdiagnoses and undertreatment of certain conditions or diseases.
- Removes the stigma associated with certain diseases.

Arguments Opposing DTCA

- Misinforms patients by omitting important information or using an inappropriate literacy level.
- Advertisements often do not exhibit fair balance and may overemphasize or create heightened expectations of drug benefits.
- Drives demand for a new drug before its safety profile in the general population is established, exacerbating harm.

- Leads to the “medicalization” of natural conditions, cosmetic issues, or trivial ailments.
- Promotes inappropriate prescribing and drives choice of more expensive branded products, increasing costs.
- Harms the patient-doctor relationship; wastes appointment time, especially when the advertised drug is inappropriate for the patient’s disease or condition.
- Is not sufficiently regulated by the FDA.

While it may seem relatively easy to validate these arguments, the available research suggests both beneficial and harmful effects of DTCA, with each of the arguments above supported by some evidence. Accordingly, the question of whether DTCA results in net benefit or harm remains unsettled even today. Several reviews are available on the subject.⁶⁻¹⁷

Another aspect of DTCA is how it can be structured to improve patient or public health benefits and/or reduce the potential for harm. Some suggested remedies include mandatory FDA preclearance, a moratorium or delay in the advertising for new products, better transparency involving online webpages or advertising, including quantitative information about risks and benefits in the advertisement, using communication strategies to improve patient comprehension about risks and benefits, and including cost information.⁸ The FDA continues to study ways in which patients react to DTCA. A recent study, updating a previous 2002 FDA phone survey, found that 46% and 52% of respondents believed that DTCA did not include enough information about benefits and risks, respectively, suggesting that the educational effects of DTCA can be substantially improved.¹⁸

There has been renewed Congressional interest in instituting a time-limited moratorium on DTCA for newly approved drugs based on the fact that new and important safety data not evident during the limited clinical trials conducted for FDA approval often emerge during the early marketing phase. The *Responsibility in Drug Advertising Act of 2016* (H.R. 4565) introduced by Rosa DeLauro seeks to establish a 3-year moratorium on advertising for new prescription drugs. Another approach is legislation introduced by Senator Franken. The *Protecting Americans from Drug Marketing Act* would eliminate the tax deduction that pharmaceutical companies can take on monies spent on prescription drug advertising. The AMA has expressed tentative support for this approach, which is consistent with a policy stance that seeks to scale back or eliminate DTCA.

SHOULD AMA POLICY H-105.988 BE RETAINED

DTCA comes in three forms: product-claim ads, reminder ads, and help-seeking ads. AMA policy H-105.988 addresses product-claim ads. Reminder ads (drug and dosage form) make no claims, so the “fair balance” requirement and other legal standards or risk information requirements (i.e., “brief summary” and “adequate provision”) are not required. Help-seeking ads are disease- or condition-specific and do not advertise a specific drug.

Current AMA Policy on what constitutes an acceptable DTCA has evolved over more than 20 years. With input from the FDA, the AMA developed an internal set of guidelines in 1993 for “acceptable” DTCA appearing in the organization’s consumer publications. These guidelines eventually became an integral part of Policy H-105.988 with adoption of BOT Report 38-A-99, “Direct-to Consumer Advertising of Prescription Drugs,” by the HOD.¹⁹ Policy H-105.988 was further amplified by adoption of BOT Report 9-A-06, “Direct-to-Consumer Advertising of Prescription Drugs.”⁶ In addition to modifying the existing AMA guidelines for an acceptable DTCA, BOT 9-A-06 also called for FDA pre-approval of all product-claim DTCA, as well as adequate funding of the FDA to effectively regulate DTCA; a moratorium on DTCA for newly approved prescription drugs until physicians are sufficiently educated about them; and a periodic assessment of DTCA by the Agency for Healthcare Research and Quality. AMA Ethical Opinion E-9.6.7, “Direct-to-Consumer Advertisements of Prescription Drugs,” provides additional guidance for physicians on how to respond in a responsible fashion to specific patient requests and inquiries prompted by DTCA.

The Pharmaceutical Research and Manufacturers of America (PhRMA) updated its voluntary principles for the conduct of DTCA in 2008 (see Appendix). In most respects, these voluntary standards are compatible with existing AMA guidelines for an acceptable DTCA. While companies pledge to adhere to these standards, some criticism has been leveled at individual companies for consistently failing to comply with the guiding principles, especially as they relate to minimizing exposure of children to adult content.²⁰ Given that it is unlikely that DTCA will be eliminated, it makes sense to have a policy in place stressing acceptable attributes and related recommendations.

CONCLUSION

Research suggests that DTCA can be both beneficial and detrimental, with several position points on both sides. Research is ongoing on how DTCA influences patients and physicians and other prescribers, and several remedies have been suggested to improve the likelihood of patient benefit and to reduce potential harm from this practice. DTCA differs from other forms of advertising because a learned intermediary (i.e., the prescriber) is required for the consumer to gain access to the product. The seminal question for this report is whether the AMA should retain a policy that articulates features comprising what the organization considers to be acceptable for DTCA, in the face of policy supporting a ban on the practice. The Board of Trustees agrees that since DTCA is legally permitted, this framework should be retained and recommends modest amendments to the current policy, including support for eliminating tax deductions for DTCA spending.

RECOMMENDATION

The Board of Trustees recommends that the following statements be adopted in lieu of Second Resolve, Resolution 927-1-15 and Resolution 514-A-16, and the remainder of the report be filed.

1. That Policy H-105.988, “Direct-to-Consumer ~~(DTC)~~ Advertising (DTCA) of Prescription Drugs and Implantable Devices,” be amended by addition and deletion to read as follows:

It is the policy of our AMA:

1. to support a ban on direct-to-consumer advertising for prescription drugs and implantable medical devices.

2. That until such a ban is in place, 4. That our AMA considers acceptable only those our AMA opposes product-claimspecific DTCA advertisements that does not satisfy the following guidelines:

- (a) The advertisement should be indication-specific and enhance consumer education about ~~both~~ the drug or implantable medical device, and the disease, disorder, or condition for which the drug or device is used.
- (b) In addition to creating awareness about a drug or implantable medical device for the treatment or prevention of a disease, disorder, or condition, the advertisement should convey a clear, accurate and responsible health education message by providing objective information about the benefits and risks of the drug or implantable medical device for a given indication. Information about benefits should reflect the true efficacy of the drug or implantable medical device as determined by clinical trials that resulted in the drug’s or device’s approval for marketing.
- (c) The advertisement should clearly indicate that the product is a prescription drug or implantable medical device to distinguish such advertising from other advertising for non-prescription products.
- (d) The advertisement should not encourage self-diagnosis and self-treatment, but should refer patients to their physicians for more information. A statement, such as “Your physician may recommend other appropriate treatments,” is recommended.
- (e) The advertisement should exhibit fair balance between benefit and risk information when discussing the use of the drug or implantable medical device product for the disease, disorder, or condition. The amount of time or space devoted to benefit and risk information, as well as its cognitive accessibility, should be comparable.
- (f) The advertisement should present information about warnings, precautions, and potential adverse reactions associated with the drug or implantable medical device product in a manner (e.g., at a reading grade level) such that it will be understood by a majority of consumers, without distraction of content, and will help facilitate communication between physician and patient.
- (g) The advertisement should not make comparative claims for the product versus other prescription drug or implantable medical device products; however, the advertisement should include information about the availability of alternative non-drug or non-operative management options such as diet and lifestyle changes, where appropriate, for the disease, disorder, or condition.
- (h) In general, product-claimspecific DTCA advertisements should not use an actor to portray a health care professional who promotes the drug or implantable medical device product, because this portrayal may be misleading and deceptive. If actors portray health care professionals in DTCA advertisements, a disclaimer should be prominently displayed.
- (i) The use of actual health care professionals, either practicing or retired, in DTCA to endorse a specific drug or implantable medical device product is discouraged but if utilized, the advertisement must include a clearly visible disclaimer that the health care professional is compensated for the endorsement.

- (j) The advertisement should be targeted for placement in print, broadcast, or other electronic media so as to avoid audiences that are not age appropriate for the messages involved.
- (k) In addition to the above, the advertisement must comply with all other applicable Food and Drug Administration (FDA) regulations, policies and guidelines.

2. That our AMA opposes product specific DTC advertisements, regardless of medium, that do not follow the above AMA guidelines.

3. That the FDA review and pre-approve all DTCA ~~advertisements~~ for prescription drugs or implantable medical device products before pharmaceutical and medical device manufacturers (sponsors) run the ads, both to ensure compliance with federal regulations and consistency with FDA-approved labeling for the drug or implantable medical device product.

4. That the Congress provide sufficient funding to the FDA, either through direct appropriations or through prescription drug or implantable medical device user fees, to ensure effective regulation of DTCA.

5. That DTCA ~~advertisements~~ for newly approved prescription drug or implantable medical device products not be run until sufficient post-marketing experience has been obtained to determine product risks in the general population and until physicians have been appropriately educated about the drug or implantable medical device. The time interval for this moratorium on DTCA for newly approved drugs or implantable medical devices should be determined by the FDA, in negotiations with the drug or medical device product's sponsor, at the time of drug or implantable medical device approval. The length of the moratorium may vary from drug to drug and device to device depending on various factors, such as: the innovative nature of the drug or implantable medical device; the severity of the disease that the drug or implantable medical device is intended to treat; the availability of alternative therapies; and the intensity and timeliness of the education about the drug or implantable medical device for physicians who are most likely to prescribe it.

6. That our AMA opposes any manufacturer (drug or device sponsor) incentive programs for physician prescribing and pharmacist dispensing that are run concurrently with DTCA ~~advertisements~~.

7. That our AMA encourages the FDA, other appropriate federal agencies, and the pharmaceutical and medical device industries to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as overall health outcomes and cost benefit analyses; research results should be available to the public.

8. That our AMA supports the concept that when companies engage in DTCA, they assume an increased responsibility for the informational content and an increased duty to warn consumers, and they may lose an element of protection normally accorded under the learned intermediary doctrine.

9. That our AMA encourages physicians to be familiar with the above AMA guidelines for product-claims specific DTCA and with the Council on Ethical and Judicial Affairs (CEJA) Ethical Opinion E-5.0159.6.7 and to adhere to the ethical guidance provided in that Opinion.

10. That the Congress should request the Agency for Healthcare Research and Quality (AHRQ) or other appropriate entity to perform periodic evidence-based reviews of DTCA in the United States to determine the impact of DTCA on health outcomes and the public health. If DTCA is found to have a negative impact on health outcomes and is detrimental to the public health, the Congress should consider enacting legislation to increase DTCA regulation or, if necessary, to prohibit DTCA in some or all media. In such legislation, every effort should be made to not violate protections on commercial speech, as provided by the First Amendment to the U.S. Constitution.

11. That our AMA supports eliminating the costs for DTCA of prescription drugs as a deductible business expense for tax purposes.

12. That our AMA continues to monitor DTCA, including new research findings, and work with the FDA and the pharmaceutical and medical device industries to make policy changes regarding DTCA, as necessary.

13. That our AMA supports “help-seeking” or “disease awareness” advertisements (i.e., advertisements that discuss a disease, disorder, or condition and advise consumers to see their physicians, but do not mention a drug or implantable medical device or other medical product and are not regulated by the FDA).
2. That Policy H-105.986, “Ban Direct-to-Consumer Advertisements of Prescription Drugs and Implantable Devices,” be rescinded as it is now incorporated into amended Policy H-105.988.

REFERENCES

1. Board of Trustees Report 25, “AMA Policy on Direct-to-Consumer Advertising.” American Medical Association House of Delegates. Annual Meeting. June 2016, Chicago, IL.
2. Guidance for Industry: Consumer-directed broadcast advertisements. Food and Drug Administration. August 1999. Available at: <http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3627b2bl.pdf>. Accessed August 1, 2016.
3. 21 CFR. 1(e)(5); see also 21 U.S.C. 321(n).
4. Guidance for Industry Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program. Food and Drug Administration. March 2012.
5. Pharmaguy. Pharma Marketing Blog.TM <http://pharmamktng.blogspot.com/2016/03/annual-spending-on-direct-to-consumer.html>.
6. 2012 DTC Study-Prevention Magazine.
7. Board of Trustees Report 9, “Direct-to-Consumer Advertising of Prescription Drugs.” American Medical Association House of Delegates. Annual Meeting, June 2006, Chicago, IL.
8. Ventola CL. Direct-to-consumer pharmaceutical advertising. Therapeutic or toxic? *P&T*. 2001;36:669-84.
9. Direct-to-Consumer Advertising’s Ability to Communicate to Subsets of the General Population: Report to Congress. Food and Drug Administration. September 2009.
10. Aiken KJ. Patient and physician attitudes and behaviors associated with DTC promotion of prescription drugs – Summary of FDA survey research result (Final report). Food and Drug Administration. November 19, 2004.
11. Auton F. The case for advertising pharmaceutical direct to consumers. *Future Med. Chem* 2009;1:587-92
12. Mintzes B, Mangin D. Direct-to-consumer advertising of prescription medicines: a counter argument. *Future Med Chem*. 2009;1:1555-60.
13. Gilbody S, Wilson P, Watt. Benefits and harms of direct-to-consumer advertising: a systematic review. *Qual Safety Health Care*. 2005;14:246-50.
14. Fain KM, Alexander GC. Mind the gap: understanding the effects of pharmaceutical direct-to-consumer advertising. *Med Care*. 2014;52(4):291-3.
15. Polen HH, Khanfqrar NM, Clauson KA. Impact of direct-to-consumer advertising on patient health-related behaviors and issues. *Health Marketing Quarterly*. 2009;26:42-55.
16. Mintzes B. Advertising of prescription-only medicines to the public: Does evidence of benefit counterbalance harm? *Annu Rev Public Health*. 2012;33:259-77.
17. Polen HH, Khanfqrar NM, Clauson KA. Impact of direct-to-consumer advertising on patient health-related behaviors and issues. *Health Marketing Quarterly*. 2009;26:42-55.
18. Sullivan HW, Campbell M. Do prescription drug ads tell consumers enough about benefits and side effects? Results from the health information national trends survey, fourth administration. *J Health Commun*. 2015;20:1391-6.
19. Board of Trustees Report 38, “Direct-to Consumer Advertising of Prescription Drugs.” American Medical Association House of Delegates Annual Meeting. June 1999, Chicago, IL
20. Arnold DG, Oakley JL. The politics and strategy of industry self-regulation: The pharmaceutical industry’s principles for ethical direct-to-consumer advertising as a deceptive blocking strategy. *J Health Politics, Policy and Law*. 2013;38:505-44.

APPENDIX - PhRMA Guiding Principles on Direct-to-Consumer Advertisements of Prescription Drugs

1. These Principles are premised on the recognition that DTC advertising of prescription medicines can benefit the public health by increasing awareness about diseases, educating patients about treatment options, motivating patients to contact their physicians and engage in a dialogue about health concerns, increasing the likelihood that patients will receive appropriate care for conditions that are frequently under-diagnosed and under-treated, and encouraging compliance with prescription drug treatment regimens.
2. In accordance with FDA regulations, all DTC information should be accurate and not misleading, should make claims only when supported by substantial evidence, should reflect balance between risks and benefits, and should be consistent with FDA approved labeling. Accordingly, companies should continue to base promotional claims on FDA approved labeling and not promote medicines for off-label uses, including in DTC advertisements.
3. DTC television and print advertising which is designed to market a prescription drug should also be designed to responsibly educate the consumer about that medicine and, where appropriate, the condition for which it may be prescribed. During the development of new DTC television advertising campaigns, companies should seek and consider feedback from appropriate audiences, such as health care professionals and patients, to gauge the educational impact for patients and consumers.

4. DTC television and print advertising of prescription drugs should clearly indicate that the medicine is a prescription drug to distinguish such advertising from other advertising for non-prescription products.
5. DTC television and print advertising should foster responsible communications between patients and health care professionals to help patients achieve better health and a more complete appreciation of both the health benefits and the known risks associated with the medicine being advertised.
6. In order to foster responsible communication between patients and health care professionals, companies should spend an appropriate amount of time to educate health professionals about a new medicine or a new therapeutic indication and to alert them to the upcoming advertising campaign before commencing the first DTC advertising campaign. In determining what constitutes an appropriate time, companies should take into account the relative importance of informing patients of the availability of a new medicine, the complexity of the risk-benefit profile of that new medicine and health care professionals' knowledge of the condition being treated. Companies are encouraged to consider individually setting specific periods of time, with or without exceptions, to educate health care professionals before launching a branded DTC television or print advertising campaign. Companies should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources.
7. Working with the FDA, companies should continue to responsibly alter or discontinue a DTC advertising campaign should new and reliable information indicate a serious previously unknown safety risk.
8. Companies should submit all new DTC television advertisements to the FDA before releasing these advertisements for broadcast.
9. DTC print advertisements for prescription medicines should include FDA's toll-free MedWatch telephone number and website for reporting potential adverse events. DTC television advertisements for prescription medicines should direct patients to a print advertisement containing FDA's toll-free MedWatch telephone number and website, and/or should provide the company's toll-free telephone number.
10. Companies that choose to feature actors in the roles of health care professionals in a DTC television or print advertisement that identifies a particular product should acknowledge in the advertisement that actors are being used. Likewise, if actual health care professionals appear in such advertisements, the advertisement should include an acknowledgement if the health care professional is compensated for the appearance.
11. Where a DTC television or print advertisement features a celebrity endorser, the endorsements should accurately reflect the opinions, findings, beliefs or experience of the endorser. Companies should maintain verification of the basis of any actual or implied endorsements made by the celebrity endorser in the DTC advertisement, including whether the endorser is or has been a user of the product if applicable.
12. DTC television and print advertising should include information about the availability of other options such as diet and lifestyle changes where appropriate for the advertised condition.
13. DTC television advertising that identifies a product by name should clearly state the health conditions for which the medicine is approved and the major risks associated with the medicine being advertised.
14. DTC television and print advertising should be designed to achieve a balanced presentation of both the benefits and the risks associated with the advertised prescription medicine. Specifically, risks and safety information, including the substance of relevant boxed warnings, should be presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content. In addition, DTC television advertisements should support responsible patient education by directing patients to health care professionals as well as to print advertisements and/or websites where additional benefit and risk information is available.
15. All DTC advertising should respect the seriousness of the health conditions and the medicine being advertised.
16. In terms of content and placement, DTC television and print advertisements should be targeted to avoid audiences that are not age appropriate for the messages involved. In particular, DTC television and print advertisements containing content that may be inappropriate for children should be placed in programs or publications that are reasonably expected to draw an audience of approximately 90 percent adults (18 years or older).
17. Companies are encouraged to promote health and disease awareness as part of their DTC advertising.
18. Companies should include information in all DTC advertising, where appropriate, about help for the uninsured and underinsured.

10. AMA INITIATIVES ON PHARMACEUTICAL COSTS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Physician concerns about the impact of the current and projected growth in pharmaceutical spending and pricing on patient access, affordability and adherence to prescription drugs resulted in the adoption of new American Medical Association (AMA) policy and directives at the 2015 Interim Meeting. Notably, Council on Medical Service Report 2-I-15, "Pharmaceutical Costs," established policy that encourages drug price and cost transparency among pharmaceutical companies, pharmacy benefit managers and health insurance companies; supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of generic

drug rises faster than inflation; encourages Federal Trade Commission actions to limit anticompetitive behavior by pharmaceutical companies to reduce competition from generic manufacturers through manipulation of patent protections and abuse of regulatory exclusivity incentives; and supports legislation to shorten the exclusivity period for biologics (Policy H-110.987). In addition, the report was amended to include the following two directives:

- That our AMA will convene a task force of appropriate AMA Councils, state medical societies and national medical specialty societies to develop principles to guide advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drug regimens.
- That our AMA generate an advocacy campaign to engage physicians and patients in local and national advocacy initiatives that bring attention to the rising price of prescription drugs and help to put forward solutions to make prescription drugs more affordable for all patients, and report back to the House of Delegates regarding the progress of the drug pricing advocacy campaign at the 2016 Interim Meeting.

The following report, which is presented for the information of the House of Delegates (HOD), summarizes the work of the Task Force on Pharmaceutical Costs and describes the first phase of the AMA's grassroots campaign on drug pricing.

TASK FORCE ON PHARMACEUTICAL COSTS

The AMA Board of Trustees appointed a 13-member task force in December 2015, consisting of representatives of three AMA councils (Council on Legislation, Council on Medical Service, and Council on Science and Public Health), four state medical associations (Medical Association of the State of Alabama, California Medical Association, Massachusetts Medical Society, and Minnesota Medical Association) and five national medical specialty societies (American Academy of Dermatology, American Academy of Pediatrics, American College of Cardiology, American College of Physicians, and American Society of Clinical Oncology). Current AMA Board of Trustees Chair-Elect Gerald E. Harmon, MD, was appointed chair of the task force.

Per the directive of the HOD, the charge of the task force was focused: to review current AMA policy and develop principles to help guide AMA advocacy and grassroots efforts aimed at addressing pharmaceutical costs and improving patient access and adherence to medically necessary prescription drugs. In particular, the task force was asked to offer recommendations on which combination of existing AMA policies should be pursued to advance a cohesive vision in order to successfully influence public policy.

The task force was asked to complete its work within six months—prior to the 2016 Annual Meeting. In January 2016, the task force held a face-to-face meeting in Washington, DC. At the meeting, the task force reviewed AMA policy on pharmaceutical costs and pricing; reviewed a draft document on possible metrics for evaluating AMA policy for inclusion in an AMA grassroots campaign; received a briefing on the 2016 political landscape and the impact of the presidential and congressional elections on this issue; heard from task force members on specific campaigns/advocacy efforts that their respective organizations have undertaken; and held an initial discussion on potential issues and issue combinations to feature in an AMA grassroots campaign.

The task force held follow-up conference calls in March, April and May of 2016, during which it reviewed and discussed documents that described advocacy campaign opportunities on the issue of transparency (for pharmaceutical companies, health plans and pharmacy benefit managers [PBMs]); explained Medicare drug price negotiations and compared how drug prices are currently determined by Medicare Part D and the Veterans Administration; summarized current federal legislation to allow such negotiation; and presented cost savings estimates from Congressional Budget Office, the Centers for Medicare & Medicaid Services' Office of the Actuary, and others.

In summary, the task force reached consensus on the following:

- Agreement on the use of a set of metrics for evaluating current AMA policy for inclusion in an AMA grassroots campaign (see appendix).

- Agreement that neither drug importation nor a ban on direct-to-consumer advertising should be pursued as part of the grassroots campaign at this time.
- Agreement that increasing transparency among pharmaceutical companies, health plans and PBMs should be the focus of Phase I of the grassroots campaign (remainder of 2016).
- Agreement that the specifics of Phase II of the grassroots campaign (2017) should be determined after the 2016 presidential and congressional elections and after any additional policy is established by the House of Delegates following completion of the planned I-16 report by the Council on Medical Service (e.g., value-based drug pricing and/or Medicare drug price negotiation). However, strong consideration should be given to including Medicare drug price negotiation in Phase II of the campaign.

AMA GRASSROOTS CAMPAIGN AND FURTHER POLICY DEVELOPMENT

To raise initial awareness regarding the need for pharmaceutical companies, health plans and PBMs to inject greater transparency in their process for determining drug prices, the AMA launched and promoted an online petition during the summer of 2016, calling on Congress to demand these companies introduce a basic level of transparency to the general public. The petition is currently featured on cause-oriented websites frequented by online activists on both sides of the political spectrum (e.g., standunited.org), and is also being specifically promoted to the AMA's Patient Action Network, along with other information including articles and other policy pieces that discuss the issue, through the network's website, email newsletters, and social media channels.

A specific campaign microsite, focused on drug pricing transparency, was scheduled to be launched in the fall of 2016 in order to build on the initial interest generated by the online petition and related promotional activities. The site will have a serious and generally hard-hitting tone in order to reinforce the importance of the issue and the need for people to get involved and take action. Although the primary audience is the general public and anyone concerned about the rising cost of drugs, specific content and resources for physicians to impact the debate will be made available as well. As the online hub for the campaign, the website will act primarily as a platform for activists to make their voices heard with members of Congress and potentially state legislators through email and social media communications. Additional key components of the site will include: lead/feature video summarizing the campaign's central arguments through flash animation or a still photo/headline carousel; a "get the facts" section housing one-pagers and links to more in-depth policy analysis and interactive infographics that showcase the campaign's arguments on cost, pricing, and the relationship between health insurers and PBMs; a news section with links to stories about what is happening on the issue at the state and national level; a "share-your-story" section that will prompt both patient and physician visitors to the site to share their experiences in grappling with the high-cost of prescription drugs; and an "action center" that in addition to the basic advocacy tools enabling users to email, tweet and post Facebook messages to their lawmakers, will house the campaign's main petition, as well as a tool that will help them in submitting letters-to-the-editor on this issue in publications in their local communities.

Following the November elections, additional public opinion research and message testing will be conducted. The extensive polling conducted in California related to its ballot initiative on drug pricing will provide substantial insight to further refine AMA messaging on this subject.

Finally, before the House of Delegates at its meeting, the Council on Medical Service presents a new report on "Incorporating Value in Pharmaceutical Pricing" (CMS Report 5-I-16). This report proposes a series of principles to guide the use of value-based drug pricing which the Council believes will serve as a more impactful and politically viable approach on this issue than further delineating AMA policy on Medicare drug price negotiation.

The Board of Trustees will continue to keep the HOD apprised of ongoing AMA advocacy and grassroots efforts to help put forward solutions to make prescription drugs more affordable for all patients.

APPENDIX - Metrics for Evaluating AMA Policy for Inclusion in AMA Grassroots Campaign on Pharmaceutical Costs

- Impact on patient access, safety and medication adherence
Would the policy directly or indirectly impact patient access to necessary therapies and high-quality care, cost-sharing and medication adherence? Would the policy lead to a pharmaceutical marketplace that works better for patients? How would

the policy impact innovation and the development of better treatment options for patients? Would the policy pose potential risks to patient safety?

- Impact on physicians and physician practices
How would the implementation of the policy impact physicians and physician practices?
- Likelihood of successful implementation
What is the likelihood that legislation or regulations to implement the policy will be successful on the state and federal levels? Would an advocacy campaign on the issue lend itself to the AMA partnering with patient organizations to achieve success?
- Issue/Message cohesion
If the task force considers multiple policies to feature in the advocacy campaign, are the policies complementary? Will they work together in media messaging and in a larger advocacy strategy?
- Unique perspective of the AMA on the issue
Is it appropriate for the AMA to take the lead on the issue? Does it make sense for physicians and patients to advocate on the issue? Can the AMA bring an effective, unique perspective to the table?
- Alignment with strategic focus areas
Does the policy support the ability of the AMA to improve health outcomes, create thriving physician practices, or create the medical school of the future?
- Alignment with other AMA advocacy priorities
How does the policy align with other AMA advocacy priorities?
- Ability of grassroots advocates to understand the policy/combination of policies
Will members of the AMA Physicians' Grassroots Network and the Patients' Action Network be able to understand the policy proposals we are asking them to help advance?
- Ability to differentiate from political campaign messaging
Will the AMA be able to effectively differentiate from the campaign messaging of presidential, federal and statewide candidates in its advocacy campaign on the issue? Could it be possibly interpreted that the AMA is endorsing proposals of a particular candidate?
- Balanced impact on stakeholders involved in pharmaceutical pricing
Would the policy impact and engage the range of stakeholders involved in pharmaceutical pricing, including but not limited to pharmaceutical companies, health plans and pharmacy benefit managers? Would an advocacy campaign on the policy align the AMA with one stakeholder while targeting another?

11. 2017 STRATEGIC PLAN

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Our AMA is making progress on its multi-year strategy to achieve significant positive impact for physicians, medical students and patients. The strategy, launched in 2013, identifies three areas of focus: Improving Health Outcomes, Accelerating Change in Medical Education, and Shaping Care Delivery and Payment for Professional Satisfaction and Practice Sustainability. These focus areas provide for tangible and meaningful implementation of our AMA's mission to promote the art and science of medicine and the betterment of public health.

Through this report, the Board of Trustees affirms AMA's multi-year strategic focus. This report summarizes what is on the horizon for each of the focus areas in 2017 and highlights other work to modernize the means through which physicians can engage in advancement of the mission.

CARE DELIVERY AND PAYMENT: PROFESSIONAL SATISFACTION AND PRACTICE SUSTAINABILITY

For nearly two decades, work toward repeal of the sustainable growth rate (SGR) formula was a core component of AMA's strategy. Since enactment of the Medicare and CHIP Reauthorization Act of 2015 (MACRA), our work has refocused – with even greater intensity – to ensure that MACRA's implementation supports a health care system that

delivers better care and more visible value while also supporting a sustainable practice environment. The goal is to create a pathway for physicians to choose from a broad array of alternative payment and health care delivery models, including viable fee-for-service options.

Successful navigation and implementation of evolving public and private payment systems requires heightened physician awareness, informed assessment of options, and, potentially, new ways of capturing, analyzing and reporting practice information. To support physicians through this changing landscape and improve care delivery and professional satisfaction, AMA will work in 2017 to:

- Advocate for legislative and regulatory changes that enhance prospects for physicians to succeed.
- Generate awareness and encourage physicians to prepare for impending payment model changes.
- Provide multi-modal, multi-channel physician education about what new payment model options mean for physicians and patients.
- Update the MACRA physician payment model evaluation tool, which was introduced in 2016, and supplement it with additional resources that not only help physicians make informed decisions, but also help them take steps to implement the decisions effectively.
- Guide physicians toward the best outcome in value-based care systems and establish the AMA as a valued source of support on issues spanning a wide range of care delivery and payment models.
- Expand the resources delivered through the STEPS Forward™: Practice Improvement Strategies program to help physicians in a variety of practice settings learn new techniques to improve practice workflow, patient care and professional satisfaction.
- Increase the awareness and importance of professional satisfaction and support the Quadruple Aim through new research, partnerships, and resources to assist physicians throughout the various settings and stages of their careers.
- Discover and promote the physician perspective across health technology sectors, directing development for improved usability, productive access to data, and respect for the patient-physician relationship.

With a view toward the longer-term horizon, in 2017 AMA will also expand current work toward modernizing medical information coding systems that will give physicians access to data needed to reliably report performance, assess financial risk and inform negotiations for new risk-sharing payment models.

IMPROVING HEALTH OUTCOMES (IHO)

Initiatives focused on health outcomes underscore AMA's foundational commitment to improving the health of the nation. Concentrating on risk factors for cardiovascular disease and type 2 diabetes, our AMA is working with physicians and care teams to bring new approaches for anticipating, preventing, and managing widely prevalent chronic conditions that often carry acute consequences for patients.

To achieve the scale required for this ambitious set of programs, AMA has developed multi-year strategic relationships with the Centers for Disease Control and Prevention (CDC) and the American Heart Association (AHA), whose national reach and influence reinforce and complement AMA resources. Our shared goals with the CDC and the AHA include significantly increasing the number of physician practices, health care systems and federally qualified health centers that:

- Screen patients for prediabetes and refer eligible patients to CDC-recognized diabetes prevention programs (DPPs) as the preferred option for preventing type 2 diabetes, and
- Improve care for patients with hypertension to achieve and sustain 70 percent or higher blood pressure control rates within the communities they serve.

AMA will expand collaboration with partner organizations to offer evidence-based products, tools and services to support physicians, care teams, health system leaders and medical students in achieving the health outcomes we seek. Materials are being developed and distributed for use in practice settings ranging from small private practices to large integrated systems. Examples include resources available through the AMA-AHA Target BP website (<http://targetbp.org/targetbp/participant-resources-and-tools/>) as well as plans for a new AHA-AMA Target BP "Recognition Program" as a vehicle for engaging healthcare delivery systems in improving blood pressure control nationally. We continue to define and promote the "business case" for public and private payer coverage of proven

interventions such as diabetes prevention programs (for which Medicare announced coverage in 2016) and self-measured blood pressure monitoring devices.

Involving patients is an important element of change as we will continue to seek venues to bring messages to broad public audiences, such as was accomplished through the national prediabetes awareness campaign launched in 2016.

ACCELERATING CHANGE IN MEDICAL EDUCATION (ACE)

The AMA is collaborating to accelerate change in medical education by creating a system that trains physicians to meet the needs of today's patients and to anticipate future changes. The initiative has funded major innovations at 32 medical schools and brought these schools together into a Consortium that shares best practices and lessons learned. The Consortium is disseminating the proven transformation strategies emerging from these leading medical schools across the medical education environment.

Highlights of major plans for 2017 include:

- Building on prototyping/models for the medical school of the future (faculty development; developmental models for health system science and health data analytics; competency-based assessment, etc.)
- Collaborating with other focus areas on student and trainee wellness; resilience/burnout; and new models for linking students, physicians and communities in shared goals of chronic disease management and health equity
- Developing work themes around transition to residency and transition to practice, including exploration of new ideas with the National Residency Match Program

In parallel with implementation of ACE-sponsored education innovations, AMA along with participating schools and partners will work in 2017 to develop a sustainable plan for the ACE Consortium into the future, ready for implementation in 2018.

ENGAGING PHYSICIANS IN ADVANCEMENT OF THE MISSION

Continuing physician professional development is a cornerstone of the strategy for activating the focus area objectives, which require changes in physician (and team) knowledge, skills and practice. The focus area objectives and other national imperatives--such as reducing opioid-related harm and increasing access to treatment for patients with opioid use disorders--require AMA to provide physicians and their team members pragmatic educational offerings, tools, and leadership training designed to address real-world practice and care delivery issues.

AMA's strategy in this domain calls for development of an improved Education Center portal and platform over the next two years. New capabilities and an improved user experience will be introduced in 2017. The Introduction to the Practice of Medicine program, currently deployed in approximately 150 residency settings across the country, will also be modernized and incorporated into the Education Center in 2017. As the multi-year effort progresses, our physician stakeholders will have access to educational tools and resources from diverse sources through a highly functional platform tailored to individual needs, accessible from desktops and mobile devices, with streamlined support for transcripts, reporting to boards, employers and payers to serve credentialing, licensing and certification requirements.

Evidence of AMA mission impact continues to grow, creating an opportunity for AMA to refresh its brand identity among physicians and other stakeholders. We will achieve this by linking relevant offerings and activities throughout the career lifecycle of students, residents, and practicing physicians. The goal is to strengthen the AMA brand through deeper stakeholder engagement. Traditional and interactive/social/digital media will be deployed to create new connections, awareness, and opportunities to interact with the AMA. More sophisticated monitoring of interactions also will yield insight into physician preferences so that we can continuously improve services to physicians, residents and fellows, and medical students so as to retain and grow our membership base.

The momentum that supports this multi-year strategy is a reflection of collaboration and shared commitment across the AMA and the Federation of medicine, academic institutions, public and private health sector organizations, technology innovators, physicians, and physicians in training. Together we will chart a course for health care delivery that will improve the health of the nation.

**12. SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES:
FIVE-YEAR REVIEW**

Reference committee hearing: see report of [Reference Committee on Amendments to Constitution and Bylaws](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
REMAINDER OF REPORT FILED**
See Policy D-600.984

The Board of Trustees (BOT) has completed its review of the specialty organizations seated in the House of Delegates (HOD) scheduled to submit information and materials for the 2016 American Medical Association (AMA) Interim Meeting in compliance with the five-year review process established by the House of Delegates in Policy G-600.020 and AMA Bylaw 8.5.

Organizations are required to demonstrate continuing compliance with the guidelines established for representation in the HOD. Compliance with the five responsibilities of professional interest medical associations and national medical specialty organizations is also required as set out in AMA Bylaw 8.2.

The following organizations were reviewed for the 2016 Interim Meeting:

American Academy of Insurance Medicine
 American Academy of Sleep Medicine
 American Society for Gastrointestinal Endoscopy
 American Society for Radiation Oncology
 American Society for Surgery of the Hand
 American Society of Cytopathology
 American Society of Plastic Surgeons
 American Urological Association
 AMSUS-The Society of Federal Health Professionals
 North American Spine Society
 Society for Vascular Surgery
 Society of American Gastrointestinal and Endoscopic Surgeons

The American Association of Clinical Endocrinologists was also reviewed at this time as a follow up to the 2016 AMA Annual Meeting review.

Each organization was required to submit materials demonstrating compliance with the guidelines and requirements along with appropriate membership information. A summary of each group's membership data is attached to this report (Exhibit A). A summary of the guidelines for specialty society representation in the AMA HOD (Exhibit B), the five responsibilities of national medical specialty organizations and professional medical interest associations represented in the HOD (Exhibit C), and the AMA Bylaws pertaining to the five-year review process (Exhibit D) are also attached.

The materials submitted indicate that: the American Academy of Insurance Medicine, American Association of Clinical Endocrinologists, American Society for Gastrointestinal Endoscopy, American Society for Radiation Oncology, American Society for Surgery of the Hand, American Urological Association, AMSUS-The Society of Federal Health Professionals, North American Spine Society, Society for Vascular Surgery and Society of American Gastrointestinal and Endoscopic Surgeons meet all guidelines and are in compliance with the five-year review requirements of specialty organizations represented in the HOD.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted and the remainder of this report be filed:

1. That the American Academy of Insurance Medicine, American Association of Clinical Endocrinologists, American Society for Gastrointestinal Endoscopy, American Society for Radiation Oncology, American Society for Surgery of the Hand, American Urological Association, AMSUS-The Society of Federal Health Professionals, North American Spine Society, Society for Vascular Surgery, and Society of American

Gastrointestinal and Endoscopic Surgeons retain representation in the American Medical Association House of Delegates.

- Having failed to meet the requirements for continued representation in the AMA House of Delegates as set forth in AMA Bylaw B-8.50, the American Academy of Sleep Medicine, American Society of Cytopathology, and American Society of Plastic Surgeons be placed on probation and be given one year to work with AMA membership staff to increase their AMA membership.

APPENDIX

Exhibit A - Summary Membership Information

Organization	AMA Membership of Organization's Total Eligible Membership
American Academy of Insurance Medicine	61 of 208 (30%)
American Academy of Sleep Medicine	956 of 5,303 (18%)
American Association of Clinical Endocrinologists	917 of 4,655 (20%)
American Society for Gastrointestinal Endoscopy	1,273 of 8,082 (16%)
American Society for Radiation Oncology	776 of 3,970 (20%)
American Society for Surgery of the Hand	439 of 2,015 (22%)
American Society of Cytopathology	205 of 1,246 (16%)
American Society of Plastic Surgeons	952 of 5,757 (16%)
American Urological Association	1,112 of 7,057 (16%)
AMSSUS-The Society of Federal Health Professionals	660 of 2,219 (30%)
North American Spine Society	1,131 of 4,642 (24%)
Society for Vascular Surgery	560 of 2,585 (22%)
Society of American Gastrointestinal and Endoscopic Surgeons	921 of 4,112 (22%)

Exhibit B - Summary of Guidelines for Admission to the House of Delegates for Specialty Societies (Policy G-600.020) and Professional Interest Medical Associations (G-600.022)

Policy G-600.020

- The organization must not be in conflict with the Constitution and Bylaws of the American Medical Association with regard to discrimination in membership.
- The organization must:
 - represent a field of medicine that has recognized scientific validity;
 - not have board certification as its primary focus; and
 - not require membership in the specialty organization as a requisite for board certification.
- The organization must meet one of the following criteria:
 - a specialty organization must demonstrate that it has 1,000 or more AMA members; or
 - a specialty organization must demonstrate that it has a minimum of 100 AMA members and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA; or
 - a specialty organization must demonstrate that it was represented in the House of Delegates at the 1990 Annual Meeting and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA.
- The organization must be established and stable; therefore it must have been in existence for at least five years prior to submitting its application.
- Physicians should comprise the majority of the voting membership of the organization.
- The organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges, and are eligible to hold office.
- The organization must be active within its field of medicine and hold at least one meeting of its members per year.
- The organization must be national in scope. It must not restrict its membership geographically and must have members from a majority of the states.
- The organization must submit a resolution or other official statement to show that the request is approved by the governing body of the organization.
- If international, the organization must have a US branch or chapter, and this chapter must be reviewed in terms of all of the above guidelines.

Exhibit C

8.2 Responsibilities of National Medical Specialty Societies and Professional Interest Medical Associations. Each national medical specialty society and professional interest medical association represented in the House of Delegates shall have the following responsibilities:

- 8.2.1 To cooperate with the AMA in increasing its AMA membership.
- 8.2.2 To keep its delegate(s) to the House of Delegates fully informed on the policy positions of the society or association so that the delegates can properly represent the society or association in the House of Delegates.
- 8.2.3 To require its delegate(s) to report to the society on the actions taken by the House of Delegates at each meeting.
- 8.2.4 To disseminate to its membership information as to the actions taken by the House of Delegates at each meeting.
- 8.2.5 To provide information and data to the AMA when requested.

Exhibit D – AMA Bylaws on Specialty Society Periodic Review

8 - Representation of National Medical Specialty Societies and Professional Interest Medical Associations in the House of Delegates

8.5 Periodic Review Process. Each specialty society and professional interest medical association represented in the House of Delegates must reconfirm its qualifications for representation by demonstrating every 5 years that it continues to meet the current guidelines required for granting representation in the House of Delegates, and that it has complied with the responsibilities imposed under Bylaw 8.2. The SSS may determine and recommend that societies currently classified as specialty societies be reclassified as professional interest medical associations. Each specialty society and professional interest medical association represented in the House of Delegates must submit the information and data required by the SSS to conduct the review process. This information and data shall include a description of how the specialty society or the professional interest medical association has discharged the responsibilities required under Bylaw 8.2.

- 8.5.1 If a specialty society or a professional interest medical association fails or refuses to provide the information and data requested by the SSS for the review process, so that the SSS is unable to conduct the review process, the SSS shall so report to the House of Delegates through the Board of Trustees. In response to such report, the House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates by majority vote of delegates present and voting, or may take such other action as it deems appropriate.
- 8.5.2 If the SSS report of the review process finds the specialty society or the professional interest medical association to be in noncompliance with the current guidelines for representation in the House of Delegates or the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will have a grace period of one year to bring itself into compliance.
- 8.5.3 Another review of the specialty society's or the professional interest medical association's compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2 will then be conducted, and the SSS will submit a report to the House of Delegates through the Board of Trustees at the end of the one-year grace period.
 - 8.5.3.1 If the specialty society or the professional interest medical association is then found to be in compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will continue to be represented in the House of Delegates and the current review process is completed.
 - 8.5.3.2 If the specialty society or the professional interest medical association is then found to be in noncompliance with the current guidelines for representation in the House of Delegates, or the responsibilities under Bylaw 8.2, the House may take one of the following actions:
 - 8.5.3.2.1 The House of Delegates may continue the representation of the specialty society or the professional interest medical association in the House of Delegates, in which case the result will be the same as in Bylaw 8.5.3.1.
 - 8.5.3.2.2 The House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates. The specialty society or the professional interest medical association shall remain a member of the SSS, pursuant to the provisions of the Standing Rules of the SSS. The specialty society or the professional interest medical association may apply for reinstatement in the House of Delegates, through the SSS, when it believes it can comply with all of the current guidelines for representation in the House of Delegates.
- 8.6 Discontinuance of Representation. A specialty society or a professional interest medical association that has been granted representation in the House of Delegates will automatically have its representation terminated if it is not represented by a properly certified and seated delegate at 3 of 5 consecutive meetings of the House of Delegates. The specialty society or the professional interest medical association may continue as a member of the SSS pursuant to the provisions of the Standing Rules of the SSS, and may apply for representation in the House of Delegates after 3 additional years as a member of the SSS, under all of the provisions for a new application.