

REPORTS OF THE BOARD OF TRUSTEES

The following reports, 1–15, were presented by Jack Resneck, Jr., MD, Chair:

1. DATA USED TO APPORTION DELEGATES (RESOLUTION 604-A-18)

Reference committee hearing: see report of Reference Committee F.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 604-A-18
REMAINDER OF REPORT FILED
See Policy G-600.016**

At the 2018 Annual Meeting, Georgia introduced Resolution 604-A-18, “AMA Delegation Entitlements,” which reads as follows:

RESOLVED, That our American Medical Association continue to provide a count of AMA members for AMA delegation entitlements to the House of Delegates as of December 31 and also provide a second count of AMA members within the first two weeks of the new year and that the higher of the two counts will be used for state and national specialty society delegation entitlements during the current year; and be it further

RESOLVED, That the Council on Constitution and Bylaws prepare appropriate language to add a second period of time to determine AMA delegation entitlements to be considered by the AMA House at its earliest opportunity.

The resolution was referred.

The reference committee reported that testimony was largely supportive. Some suggested the opportunity to increase representation in our AMA House of Delegates is used by many delegations in membership recruitment, and delegations believe that seeing the results of their membership recruitment efforts reflected in their delegate counts sooner would further support those efforts.

Following discussion the reference committee was unable to develop a means to implement the method proposed in the resolution and recommended referral to allow a review that focuses on the impact on our entire House of Delegates.

AMA MEMBERSHIP AND DELEGATE APPORTIONMENT BACKGROUND & HISTORY

Article III of the Constitution, “Members,” declares “The American Medical Association is composed of individual members who are represented in the House of Delegates through state associations and other constituent associations, national medical specialty societies and other entities, as specified in the Bylaws.” Individual members are recruited through the efforts of both our AMA and societies in the Federation as well as by current members who solicit their colleagues. The number of individual AMA members in a given society determines the number of delegates under the aforementioned representation in the House of Delegates. (This is true for nearly all societies in the House of Delegates. Under the bylaws, professional interest medical associations and a handful of national societies have a single delegate.)

The modern House of Delegates traces to the work of the Committee on Reorganization, which was established in 1900 and eventuated in the adoption of a new constitution and bylaws in 1901, redefining and modernizing the House of Delegates (Campion, 1984). Current membership became the basis for apportioning delegates, as the Committee’s work established a House of Delegates based on proportional representation in which constituent associations were represented on the basis of one delegate for 500 members. The following year, in June 1902, the House adopted a resolution stating “That state associations or societies in counting members for a basis of delegate representation in this House shall count only members in good standing, who pay regular dues to the state association, either directly or indirectly through county societies.”

While the ratio of members per delegate has been adjusted over the last 100 plus years to accommodate growth in the physician population and membership, delegate apportionment has always been based upon the number of current members. The current ratio of one delegate per 1000 AMA members dates from 1946. The 1948 constitution prescribed that the “number of delegates from the constituent associations shall be proportional to the number of active members in the respective associations,” and that year saw the start of the annual apportionment process.

Two significant changes were effected in the early 1950s. At the December 1950 meeting, the members to be counted were explicitly defined to be AMA members: “The apportionment of delegates from each constituent association shall be one delegate for each thousand (1,000) or fraction thereof, *dues paying active members of the American Medical Association* (emphasis added).” Whereas before this time counts focused on members of the constituent associations, now the relevant population was specified to be AMA members.* At the 1952 Annual Meeting, December 31 was set as the cutoff date for counting members to maximize the time allowed for societies to add members, with the effective date for apportionment January 1 (Proceedings of the House of Delegates, 1952).

Irrespective of how or when members join our AMA, under our current bylaws delegates are apportioned to constituent societies and national medical specialty societies at the rate of one delegate per 1000, or fraction thereof, AMA members as of December 31.† That is, one must be a member on December 31 to be counted for apportionment purposes. The apportionment is effective January 1 of the following year and is effective for one year. (See bylaws 2.1.1 and 2.2.1 and subsections.) Thus, for example, if a society has 1000 AMA members on December 31, it will be apportioned one delegate for the following year. A society with 1001 members will be apportioned two delegates. (Although they are endorsed by and seated with constituent and national medical specialty societies seated in the House of Delegates, separate bylaws provisions address the regional medical student and sectional resident delegates who are apportioned differently.)

Because of differences in data availability and because delegate apportionment for constituent societies determines the overall delegate apportionment for national medical specialty societies, characterizations below are couched in terms of constituent societies. Figures for those societies are also more easily captured in real time.

APPORTIONMENT UNDER RESOLUTION 604

As written, Resolution 604-A-18 calls for two enumerations of AMA membership, with the first being the usual year-end calculation and the second being a count of members in approximately mid-January. The larger of the two figures would be used for delegate apportionment. Unspecified is who would be counted in the mid-January enumeration. While the count should clearly include those whose now current year’s dues have been paid, it should properly exclude individuals who have not paid their appropriate dues by mid-January, as knowing who will (or will not) renew their membership is not possible. A substantial number of members unfortunately do not renew annually, and many members pay their current year dues after mid-January. Given these factors it seems likely that a mid-January count of current year dues paying members would almost certainly be lower than the year end count.

Calculations by AMA’s Membership Group suggest that the magnitude of the difference of the two counts would depend on the date of the second count. The largest number of AMA members is recruited through AMA’s own direct channel, and in any given year the vast majority of current year members have typically joined by February. Consequently, one might advocate for a count in early March or later, but even such a later count would exclude members who join later in the year, particularly the large number of medical students and residents who typically join in summer or fall. Pushing the count to a later date would also shorten the time for societies to adjust their delegation size when necessary.

In light of the ambiguity regarding who would be counted, prior to June’s House of Delegates meeting Georgia, the sponsor of Resolution 604-A-18, proposed that the first resolve would be implemented by counting for apportionment purposes current nonmembers who join the AMA for the succeeding year during the current year. That discussion as well as comments during the reference committee hearing suggested a revision of the first resolve to call for “the number of new AMA members who have already paid their dues for a membership that officially begins on January 1 of the following year will be included in the annual year-end count of AMA members, for the purposes of AMA Delegation entitlements for state and national specialty societies for that following year.” For example, a nonmember in 2018 who during calendar year 2018 joins (and pays dues) for the 2019 membership year would be counted as a member in apportioning delegates for the 2019 calendar year. Hereinafter these are referred to as “pending members,” as their active membership is still pending on December 31.

Whether any particular society would benefit from such a change would depend on whether the inclusion of pending members would carry it over a one thousand threshold. For those societies that gain a delegate, the increased representation would, other things being equal, be a one-time increase. That is because each year some current members choose not to renew their memberships. While they factor into the annual delegate apportionment process as current members, they drop out of the calculations at the end of the subsequent year, and unless the pending members consistently outnumber the non-renewing members, the gain would likely be a one-time event.

Data from year-end 2017, which were used for delegate allocation in 2018, indicate that five states would have gained a delegate this year if pending members had been included. The states that would gain in the future, however, depend on whether the addition of pending members pushes them across the threshold for an additional delegate. For example, only two of the four states currently needing fewer than 100 pending members to gain a delegate position would benefit, while among the 10 states that had the largest number of pending members (range 261–691) at the end of 2017, only the first and third largest would have picked up a delegate. The other three states that would have added a delegate using this method at the end of 2017 did not have the largest number of pending members, but the figure would push them over the additional delegate threshold. In other words, it would be the combination of pending members and actual members that determines which states would benefit from the change, adding an element of chance to the apportionment process.

DISCUSSION

Other than changes due the inclusion of more societies in the House of Delegates (and discounting freezes), the rules for apportioning delegates to constituent societies have remained essentially unchanged since 1952. For over a century, the apportionment rules have been based on current membership, and for seventy years it has been recognized that apportionment should be conducted annually to address membership fluctuations.

Another issue related to the counting of members warrants further discussion. Counting pending members, individuals who “join” our AMA at the end of a current year but whose memberships are not effective until the following year, means that one membership for AMA purposes effectively counts for two years membership for delegate allocation purposes. In addition, this could result in counting members for apportionment purposes that subsequently request a refund and are therefore never actual dues paying members in either year. Gaming of such a system would be possible, with for example panels of one-year members joining in alternate years or signing up for membership and then requesting a refund, which is generally provided upon request in the first half of a calendar year.

Membership accounting can only allocate the membership to the year for which dues are paid, so membership figures used for apportionment figures that include pending members would be inconsistent with figures reported in our AMA’s annual report. Both the apportionment figures and the official membership numbers are publicly available on the AMA website, which would require the divergent apportionment figures to include an explanatory note. It might also be noted that adjustments are not made during the year for losses such as deaths, resignations or CEJA actions that remove an individual from the membership rolls.

While no effort to recruit members to our AMA should be discounted, among current members the most often cited reason for belonging to our AMA is advocacy on behalf of the profession. This has been true for many years, and although the value of enhanced representation in the House of Delegates is often promoted to prospective members, little evidence supports the idea that physicians join our AMA because of the House of Delegates per se. Rather, the advocacy that stems from House actions is the more valued commodity. Indeed, the average physician—member or not—knows little about the House of Delegates and AMA policymaking processes. The prospect of enhanced representation may be a serviceable argument in the member recruitment quiver, but more successful appeals address current AMA activities dealing with critical matters of public health, medical education, practice sustainability and advocacy. Our AMA’s current Members Move Medicine™ campaign is based on this well-established foundation. The current apportionment system occurring at the end of the year recognizes the recruitment that occurs throughout the year, including the significant recruitment of medical students and residents that typically occurs well into the year.

Finally, some costs would be associated with the change. Our AMA would incur the expense of rebuilding the counting procedures and maintaining the distinct records necessary for membership accounting and apportionment processes. The associated complexity and expense would be greater if the selected methodology demanded counting pending and current members rather than a simple change in date of apportionment. Societies in the House of Delegates could

incur the intangible cost of some uncertainty in the number of delegates, which would depend on the counting scheme actually adopted, along with the real expense of supporting additional delegates. None of these costs are easily quantified.

RECOMMENDATION

The decision to count pending members for delegate apportionment purposes is clearly within the purview of the House. It would require revisions of the bylaws before it can be implemented with issues of how to handle those who join and those who no longer are AMA members during a calendar year after a fixed point in time of deciding HOD apportionment has occurred.[‡] The apparent concern about disenfranchising a new AMA member whose membership is effective after apportionment is readily addressed through the online member forums. With access to online member forums before HOD meetings, that AMA member can have active voice and influence in AMA policymaking.

The House of Delegates has for over a century counted only current members (ie, dues paid and received by AMA) in determining delegate apportionment. The idea that pending members should be added to the current membership seems unwarranted. It effectively double counts individuals, counts members who may or may not rejoin, artificially increases the size of the House of Delegates by including nonmembers in determining representation among Federation societies, and creates opportunities for abuse. Insofar as these pending members will be counted for apportionment purposes for the next cycle when they are actually members, arguments about fairness and representation seem overstated. Finally, under current bylaws any constituent society that may lose a delegate based upon the previous year final count is given a full year to recruit and retain members to retain their delegate count.

The following recommendations adopted in lieu of Resolution 604-A-18 and the remainder of the report filed:

1. Our American Medical Association (AMA) shall issue an annual, midyear report on or around June 30 to inform each national medical specialty and state medical society of its current AMA membership count status report.
2. That “pending members” be added to the number of active AMA members in the December 31 count for the purposes of AMA delegate allocations to national medical specialty and state medical societies for the following year.
3. That our AMA Physician Engagement department develop a mechanism to prevent a second counting of those previous “pending members” at the end of the following year until their membership has been renewed.

REFERENCES

Campion FD. *The AMA and US Health Policy since 1940*. Chicago: Chicago Review Press. 1984. See especially Chapter 7.

Caring for the Country: A History and Celebration of the first 150 years of the American Medical Association. American Medical Association, Chicago 1997

Proceedings of the House of Delegates, One Hundred and First Annual Session. Chicago: American Medical Association. 1952.

Notes:

* To be clear, under the 1901 constitutional revision, AMA membership was granted to all members of local medical societies affiliated with state medical societies who applied for membership, supplied certification and paid the annual fee. In 1899, the annual dues were \$10 (*Caring for the Country*, 1997, pages 40-41).

† Member counts for constituent (ie, geographic) societies are determined annually. The overall number delegates apportioned to constituent societies determines the total number of delegates apportioned to national medical specialty societies, with the number of delegates apportioned to any particular specialty society *generally* tied to that society’s most recent five-year review.

‡ Some bylaws issues are not clear cut. Bylaw 2.1.1.1.1, for example, allows a constituent society to retain a delegate in the event of a loss of AMA members. Whether so called “pending members” should be allowed to offset losses in “actual members” certainly merits discussion.

2. REDEFINING AMA'S POSITION ON ACA AND HEALTHCARE REFORM

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. BOT Report 6-I-13, "Redefining AMA's Position on ACA and Healthcare Reform," 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.

EFFORTS TO REPEAL THE ACA

Following the failure of Congress to repeal the Affordable Care Act, the Administration has continued to take steps to undermine the law or provide coverage options outside of the ACA exchanges which could have the impact of weakening the individual market. Previously, the Administration had decided to discontinue payment of cost-sharing reduction benefits to support required premium support for low income individuals enrolled in the ACA exchanges. Other recent actions have included:

- On June 7, 2018, the Department of Justice filed a brief declining to defend the ACA in a case (Texas v. United States) brought by 20 state attorneys general. A week later, our AMA and four physician specialty associations filed an Amicus Brief urging the court to reject the effort to undermine the ACA. In announcing the filing, the AMA noted that "if the lawsuit were successful, federal policy could roll back to 2009, which would be remarkably disruptive to our nation's health system and every single American." It would void protections for those with pre-existing conditions, and provisions that allow children to remain on their parents' plan until age 26. Insurers would no longer be held to the 85 percent medical loss ratio, meaning they could generate higher profits at the expense of coverage and payments for services, and 100 percent coverage for certain preventive services would cease. Furthermore, annual and life-time dollar limits could be reinstated, leading to more bankruptcies due to health care costs.
- Following on an earlier Executive Order and proposed rulemaking, the Department of Labor on June 19 issued a final rule that would allow more small employers and individuals to form Association Health Plans (AHPs). The Congressional Budget Office has estimated that most individuals in AHPs will be healthier and have higher incomes than individuals in the ACA exchanges, potentially driving up premiums in the exchanges. In comments on the proposed rule, our AMA noted support for increasing health plan choices for individuals and small businesses seeking coverage in the individual and small group markets, but expressed concern that the plans outlined in the proposed rule fell short of maintaining crucial state and federal patient and provider protections and could result in substandard health coverage. Our AMA also expressed concern over the preemption of state insurance laws and the potential for insolvent and fraudulent AHPs. On July 26, attorneys general of 14 states challenged the rule in the U.S. District Court for the District of Columbia alleging that changing the definition of employer is inconsistent with the ACA and is a violation of the Administrative Procedures Act.
- The Centers for Medicare & Medicaid Services (CMS) announced on July 7, 2018, a delay of ACA risk adjustments for 2017. As noted in a July 16 letter opposing the decision, the risk adjustment program protects insurers from unanticipated costs in the event their enrollees are less healthy by transferring funds from plans with healthier enrollees. It is the only ACA premium stabilization program that is permanent. The letter was signed by our AMA and 27 other organizations representing physicians, hospitals, and patients. Members of both parties in Congress also expressed concern with the decision. Late on July 24, CMS announced that the program would be reinstated following changes to the methodology that had played a part in the decision to suspend the program.
- On July 10, CMS announced a significant cut to funding for consumer enrollment assistance and outreach through the navigator program. Funding for the 34 states with ACA federal market places was cut to \$10 million, 80 percent less than just two years previous. Again, the patient and provider community came together to protest this action. On July 26, 190 organizations, including the AMA, wrote HHS Secretary Alex Azar and CMS administrator Seema Verma protesting the decision and urging the restoration of outreach funding.

- On August 1, the Administration gave the go ahead for short-term limited-duration plans of 364 days, with renewals allowed for up to 36 months. The plans would not be required to comply with ACA protections such as coverage for pre-existing conditions or provide for comprehensive benefits. In earlier comments urging withdrawal of the proposal, our AMA had expressed support for the goal of increasing health plan choices but warned that the proposal would undercut crucial state and federal patient protections, disrupt and destabilize the individual market and result in substandard, inadequate health insurance coverage.

REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR AND PAY-FOR-PERFORMANCE

On July 12, CMS released a proposed rule for calendar year 2019 addressing both the Medicare Physician Fee Schedule and the Quality Payment Program. In addition to the implementation of Medicare Access and CHIP Reauthorization Act (MACRA) modifications enacted as part of the Bipartisan Budget Act of 2018 (BBA18), discussed in a previous edition of this report, there are a number of additional positive elements in the 2019 Proposed Rule. These include:

- Reduced documentation burden for Evaluation & Management (E&M) office visit codes, though at this time, the degree of actual burden reduction is uncertain.
- New payments for physician services that are not part of a face-to-face visit (virtual check-ins with patients, remote consults with patients using videos/photographs, online consults with other physicians).
- Continuation of low volume threshold policy to exempt small practices from the Merit-based Incentive Payment System (MIPS).
- A reduction in problematic measures in the Promoting Interoperability provisions (formerly Meaningful Use and Advancing Care Information).

There are, however, areas of concern where the AMA will be recommending changes, including:

- E&M coding and related policies (add-on codes, multiple same day service reduction).
- AMA will urge reductions in quality measure requirements to reflect reductions in available quality measures.
- Simplifying the MIPS scoring framework to make it more clinically relevant and understandable for physicians.
- Keeping the cost category weight at 10 percent rather than increasing it to 15 percent.

The AMA is working closely with national, state and other physician groups to address widespread concerns with the proposed E&M coding changes. As part of our standard process to respond to major policy proposals our AMA is working with national specialty, state and other physician groups to develop recommendations that have broad support across the profession. A joint working group of CPT and RUC experts has been formed to develop recommendations for adjusting E&M coding policies. Given the complexity in this space, a coding change application may not be finalized until early November that may be voted on by the CPT Editorial Panel in early February. While the E&M coding issues have become a major focus, there are many important issues as part of the QPP or MACRA implementation that will have a significant impact on physician practices.

On July 24, 2018, AMA Immediate Past President David O. Barbe, MD, MHA, testified before the Health Subcommittee of the U.S. House of Representatives Committee on Energy and Commerce on the topic of “MACRA and MIPS: An Update on the Merit-based Incentive Payment System.” Dr. Barbe reminded the committee members that, despite challenges in implementing the MACRA reforms, they continue to be a significant improvement over the previous SGR update system and other legacy programs that were in place prior to MACRA. While the AMA has expressed support for recent improvements to MACRA, including those implemented as part of BBA18, we recognize the need for continued improvements to move further in the direction of choice, flexibility, simplicity and feasibility. These include further simplification and harmonization of the four separate components of MIPS. The AMA will continue to work with Congress and the Administration to refine the current system.

REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

The Bipartisan Budget Act of 2018 also repealed the IPAB which was to have been established under provisions of the ACA. Prior to its repeal, no appointments had ever been made to IPAB and the requirement for recommendations for Medicare cuts by the board was never triggered.

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

On July 11, 2018, the House Committee on Ways and Means reported 10 separate pieces of legislation to promote the use of consumer directed health care plans, including health savings accounts. After review, our AMA expressed support for eight of the proposals which were consistent with policies adopted by the House of Delegates.

On July 25, the full U.S. House of Representatives considered two bills which had been modified to substantially include the subject matter of nine of the bills previously considered by the Committee on Ways and Means.

H.R. 6199, the “Restoring Access to Medication and Modernizing Health Savings Accounts Act of 2018,” passed the House by a vote of 277-142. The underlying bill accomplished a long-supported AMA policy of restoring the ability of consumers to use HSAs, MSAs and HRAs to purchase over the counter drugs and expanded that policy to include feminine hygiene products as qualified expenses. Additionally, the bill adopted by the House allows those accounts to be used for the purchase of gym memberships and equipment, within certain limits; allows high-deductible plans to cover as much as \$250 of non-preventive care before the deductible is met; and allows individuals to keep eligibility for an HSA while maintaining a direct primary care service arrangement and, within limits, use HSA funds for those arrangements. The adopted bill also excludes some items and services from being considered as other coverage if provided at an employer-owned or retail clinic; allows transfer of funds from an FSA or HRA to an HSA under certain circumstances; and allows individuals to maintain eligibility for an HSA if their spouse had coverage under an FSA as long as the FSA is limited to expenses incurred by the spouse.

H.R. 6311, Increasing Access to Lower Premium Plans and Expanding Health Savings Accounts Act of 2018, passed the House by a vote of 242-176. The bill would delay for another two years the Health Insurance Tax imposed by the ACA. It would also allow anyone to purchase a catastrophic plan, as opposed to the current limitation to those under age 30 or with specific hardship conditions. The bill increases allowed HSA contributions to match the maximum in allowed out-of-pocket costs and would allow bronze and catastrophic plans offered through ACA exchanges to be used with an HSA. H.R. 6311 also allows beneficiaries enrolled only in Medicare Part A to contribute to an HSA and allows FSA balances to be carried over to subsequent years, though any contribution limits for the next year would be lowered by the amount over \$500 that was carried over.

At this writing, the potential for Senate consideration is not clear.

STEPS TO LOWER HEALTH CARE COSTS

Our AMA continues to engage with Congress and the Administration on a wide range of efforts designed to lower health care costs. Ongoing efforts to address the cost of prescription drugs remain among the highest profile of these efforts. On July 16, the AMA filed comments on the Administration’s “Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.” In the comments, AMA noted that “patients are increasingly taking greater clinical risks when treatments are cost prohibitive.” AMA comments, which are available on the AMA website, addressed a wide range of cost drivers, including issues related to competition, transparency, the Part B drug benefit program, value-based pricing, and the 340B discount program.

During June and July, the Senate Committee on Health, Education, Labor and Pensions held a series of hearings on reducing health care costs focusing on rural health cost drivers, administrative costs, the role of quality and value in reducing excess spending. The AMA remains engaged in conversation with the committee as well as in other Congressional efforts to address the impact of administrative and regulatory costs and improve transparency of health care costs.

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

Guidance released by the Department of Health and Human Services in 2014 included a positive interpretation of health plan requirements under section 2706(a) of the ACA, specifically clarifying that the section does not require “that a group health plan or health insurance issuer contract with any provider willing to abide by the terms and conditions for participation.” Nevertheless, the AMA will continue to seek legislative opportunities to repeal this provision.

CONCLUSION

Our AMA will remain engaged in efforts to improve the health care system through policies outlined in D-165.938 and other directives of the House of Delegates.

3. 2018 AMA ADVOCACY EFFORTS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

BACKGROUND

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 2018 American Medical Association (AMA) advocacy activities.

Once again in 2018, the AMA was a strong and effective advocate for our nation’s patients and physicians. Key wins included Anthem’s reversal of its Modifier 25 policy, Quality Payment Program (QPP) improvements, repeal of the Independent Payment Advisory Board (IPAB), and extension of the Children’s Health Insurance Program for 10 years. The AMA also conducted impactful research such as the Economic Impact Study report. AMPAC continued its strong performance and positioned the AMA to be influential in the 2018 elections (see separate report in Not for Official Business Bag). Finally, AMA grassroots networks and microsites were extremely effective with over 2 million grassroots engagements to advance our advocacy agenda through social media.

DISCUSSION OF 2018 ADVOCACY EFFORTS

Health system reform

In the Bipartisan Budget Act of 2018, Congress repealed the Independent Payment Advisory Board (IPAB) which was an AMA priority and came after several years of strong Federation advocacy. In the same bill, Congress extended the Children’s Health Insurance Program (CHIP) for 10 years. Further, the AMA convinced Congress to strike the House-passed language that would have extended the expiring “misvalued codes” provision for an additional year in 2019. Such a provision would have had both short term and longer term negative effects for physicians.

On June 7, 2018, the Department of Justice filed a brief declining to defend the Affordable Care Act (ACA) in a case (*Texas v. United States*) brought by 20 state attorneys general. A week later, the AMA and four physician specialty associations filed an amicus brief urging the court to reject the effort to undermine the patient care gains under the ACA. In announcing the filing, the AMA noted that “if the lawsuit were successful, federal policy could roll back to 2009, which would be remarkably disruptive to our nation’s health system and every single American.” It would void protections for those with pre-existing conditions, and provisions that allow children to remain on their parents’ plan until age 26. Insurers would no longer be held to the 85 percent medical loss ratio, meaning they could generate higher profits at the expense of coverage and payments for services, and 100 percent coverage for certain preventive services would cease. Furthermore, annual and life-time dollar limits could be reinstated, leading to more bankruptcies due to health care costs.

Also in 2018, the Administration and the Congress attempted to continue chipping away at the infrastructure of the ACA. The major “repeal and replace” efforts from 2017 were not repeated, but there were several efforts to modify the ACA’s impact. The AMA commented extensively in the regulatory process on the Administration’s actions—cutting back funds for navigators, shortening the enrollment period, eliminating the cost sharing reduction subsidies, expanding association health plans and short-duration limited coverage plans, and reducing risk adjustment payments. The AMA is concerned that these actions will lead to higher cost/lower quality health plan choices for many patients. The AMA is also opposing Medicaid work requirements that are being considered by both federal and state policymakers.

QPP implementation

The AMA continues to support physicians as they transition to the Quality Payment Program (QPP). The AMA is also working to improve the QPP at both the regulatory and legislative levels. The Bipartisan Budget Act of 2018 included a number of QPP refinements requested by the AMA:

- Medicare Part B drug costs will be excluded from the Merit-based Incentive Payment System (MIPS) payment adjustments and from the low-volume threshold determination;
- The Centers for Medicare & Medicaid Services (CMS) may reweight the MIPS cost performance category to not less than 10 percent for the third, fourth and fifth program years (rather than requiring a weight of 30 percent in the third year);
- CMS has more flexibility in setting the MIPS performance threshold for years three through five to ensure a gradual and incremental transition to the threshold being set at the mean or median performance level in the sixth year; and
- The Physician Focused Payment Model Technical Advisory Committee may provide initial feedback regarding the extent to which alternative payment model proposals meet criteria and an explanation of the basis for the feedback.

On July 12, CMS released a proposed rule covering Medicare physician fee schedule and QPP changes for 2019. Positive elements of the proposal included:

- Reduced documentation burden for evaluation and management (E/M) office visit services;
- New payments for services that are not part of a face-to-face visit (e.g., virtual check-ins with patients, remote patient consults using videos/photographs, online consults with other physicians);
- Continuation of the low volume threshold policy to exempt practices from MIPS; and
- A reduction in problematic measures in the Promoting Interoperability component of MIPS (formerly Meaningful Use and Advancing Care Information).

However, there were also several areas of concern for which the AMA will be recommending changes in its comments to CMS, which are due on September 10. These include:

- A proposed collapse of E/M payments for physician office visit codes;
- Reduced payments for office visits and procedures performed on the same day; and
- The need for a simplified MIPS scoring framework and reduced quality measure requirements.

The AMA has been working with Federation groups to further identify positive and problematic aspects of the proposed regulations, as well as potential constructive solutions.

Regulatory relief

The AMA is focused on regulatory relief and administrative simplification issues beyond what is included in the QPP. For example, in 2017 the AMA convinced CMS to retroactively align legacy pay-for-reporting programs with the current MIPS program for the 2016 reporting period, reducing penalties for physicians by \$22 million in 2018. This year, major regulatory wins include:

- The Veterans Administration agreed to exempt only employed physicians from multistate licensure requirements when delivering telehealth services;
- CMS created a new beneficiary look-up tool and launched an education campaign to assist physicians as beneficiaries' social security numbers are removed from their Medicare cards;
- CMS delayed implementation of appropriate-use criteria;
- Office of the National Coordinator promoted AMA STEPS Forward™ modules with the Federal Health IT Playbook;
- Medicare administrative contractors now must use targeted modeling for audits that emphasizes education to prevent billing errors before they are referred to recovery audit contractors (RACs);
- CMS auditors must use predictive analytics to focus audits on claims that are at high risk for improper payments; and
- RAC auditors now must reimburse physicians for medical records as part of the audit process.

The AMA also sponsored an online discussion board with practice managers and two focus groups with physicians in Chattanooga, TN, and Iselin, NJ, to further explore physicians' regulatory burdens in order to refine and prioritize its advocacy agenda. Topics covered during the discussions included electronic health record requirements, prior authorization, carrier audits, documentation burdens, prescription drug monitoring programs, and patient translators, among others.

The AMA also commented both to Congress and the Administration on the impact that current Stark self-referral and the anti-kickback statutes are having on physician development and adoption of alternative payment models.

Further, the AMA, through the Professional Satisfaction and Practice Sustainability focus area, has created a Debunking Regulatory Myths website to clarify common regulatory compliance questions for physicians as part of the broader effort to reduce administrative burdens.

Prior authorization (PA)

Prior Authorization (PA) has grown into a major concern among physicians due to patient care delays and practice burdens. The AMA conducted a survey of 1,000 practicing physicians at the end of 2017 which was released this year. Among surveyed physicians, 64 percent reported waiting at least one day for PA decisions from health plans, while 30 percent reported waiting at least three business days. Not surprisingly, 92 percent of physicians said that PA can delay access to necessary care. These delays may have serious implications for patients, as 78 percent of physicians reported that PA can lead to treatment abandonment, and 92 percent indicated that PA can have a negative impact on patient clinical outcomes. Moreover, PA hassles have been growing over time, with 86 percent of physicians reporting that PA burdens have increased over the past five years. Physicians and practice managers also placed PA at the top of their list of administrative frustrations in focus groups and online research conducted by the AMA.

To address these issues, the AMA has undertaken a major campaign to urge health plans to "right-size" PA programs. In January 2017, the AMA established a coalition of 16 other organizations and released a set of 21 Prior Authorization and Utilization Management Reform Principles. Over 100 additional provider and patient groups have signed on to the principles as formal supporters. The principles spurred conversations with health plans about the need for significant reform in PA programs. One result of these discussions was the January 2018 release of the Consensus Statement on Improving the Prior Authorization Process by the AMA, American Hospital Association, America's Health Insurance Plans, American Pharmacists Association, Blue Cross Blue Shield Association, and Medical Group Management Association. This document reflects an agreement between provider and health plan organizations to pursue PA reform in several key areas.

State legislative efforts are also critical in the AMA's campaign to improve PA processes, and the AMA is working with state and specialty societies to enact PA and utilization management legislation. The AMA offers model legislation that continues to serve as the basis for many of the state bills and provides resources and support for these efforts. This year alone, more than 20 states are addressing utilization management reform in their legislatures with significant enactments in Indiana, New Mexico, and West Virginia. Physicians struggle with PA in the Medicare Advantage (MA) and Medicare Part D drug plans, so the AMA is addressing PA issues at the federal level too. These efforts include a recent AMA letter to CMS disputing the findings of a Government Accountability Office report that recommended increased use of PA for Medicare-covered services.

The AMA has also launched a grassroots advocacy website dedicated to PA (www.FixPriorAuth.org). The website includes both patient- and physician-oriented online experiences that end with a "share your story" call to action. Compelling stories gathered thus far are featured in the site's story gallery, and additional physician and patient PA accounts will be added over time and used to guide and support the AMA's advocacy efforts. FixPriorAuth.org also contains a resource library of PA-related news stories and AMA PA advocacy and educational tools, including the three-part video series on electronic prior authorization that has been approved for 0.25 credits of *AMA PRA Category 1 Credit*[™].

Telemedicine

After concerted AMA advocacy coupled with the efforts of the Digital Medicine Payment Advisory Group (DMPAG), beginning January 1, 2018, Medicare expanded coverage of remote patient chronic care management. This represents a historic expansion of coverage that extends throughout the country without geographic limitations and includes

services delivered virtually in a patient's home. In addition, CMS has proposed to cover additional remote patient management services including a range of technical and professional components that accurately reflect the costs of delivering such services beginning January 1, 2019. Furthermore, the AMA's coalition building and strong support for the Medicare telehealth provisions of the Bipartisan Budget Act of 2018 which passed earlier this year paves the way for expanded Medicare coverage for telestroke and telehealth services for patients with end stage renal disease, chronically ill patients in Medicare Advantage, as well as coverage of telehealth for beneficiaries in certain accountable care organizations (two-sided risk models only).

The AMA has also worked at the state level to ensure coverage of telemedicine and modernization of medical practice acts. In the 2018 legislative session, 44 states introduced over 160 telehealth-related pieces of legislation. Many bills addressed different aspects of payment regarding both private payers and Medicaid, with some bills making changes to existing payment laws. Many states also proposed legislation directing licensure boards to establish standards for the practice of telehealth within their given profession. The AMA was pleased to see that many of these bills were either based on the AMA Telemedicine Act, or were amended to incorporate language from this model bill. In addition, the AMA supported several state efforts to join the Interstate Medical Licensure Compact, with now 24 states, DC, and Guam participating in the Compact's expedited licensure process.

Diabetes Prevention Program (DPP)

CMS approved coverage of the Medicare Diabetes Prevention Program (MDPP) effective April 2018. This was a very positive development in the effort to prevent diabetes on a national scale. To further advance these efforts, the AMA has been urging CMS to approve coverage of virtual or digital MDPP programs participation to improve access in rural and underserved areas. The AMA also has ongoing discussions with staff at the Center for Medicare & Medicaid Innovation (CMMI) about the MDPP and has been working to disseminate information about it to potential suppliers. For example, the AMA convened a webinar for health systems interested in the DPP with a CMMI presenter and developed a question-and-answer document for them following the webinar.

Mergers

The AMA was instrumental in last year's action to block the Anthem/Cigna and Aetna/Humana mergers. The Anthem/Cigna merger alone would have cost physicians \$500 million in payments annually. In 2018, the AMA had to evaluate several new potential mergers that were not just a health insurer merging with a health insurer but more complicated mergers such as CVS/Aetna which involves a health insurer merging with a pharmacy chain/pharmacy benefits manager (PBM).

In February, the AMA submitted a statement to the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law for a hearing on this merger. The statement expressed the AMA's concerns that the proposed merger has the potential to worsen competition (or reduce hopes for amelioration) in three poorly performing markets: PBM services; local health insurance markets; and many local retail pharmacy markets.

On June 19, the AMA moved to oppose the CVS/Aetna merger. This was announced in California at a Department of Insurance (DOI) hearing. AMA President Barbara L. McAneny, MD, presented testimony urging regulators to block the proposed CVS/Aetna merger because it is likely to substantially lessen competition in many health care markets, to the detriment of patients. A CVS/Aetna deal would allow the combined corporate entity to fortify dominant positions in health insurance, pharmaceutical benefit management, retail and specialty markets that already lack competition. The AMA's filing for the hearing also outlined further the merger's potential negative consequences for health care access, quality and affordability, including:

- An expected increase in premiums due to a substantial increase in market concentration in 30 of 34 Medicare Part D regional markets;
- An anticipated increase in drug spending and out-of-pocket costs for patients as Aetna and CVS fortify their dominant positions in the health insurance, pharmaceutical benefit management, retail and specialty pharmacy markets that already lack competition;
- Reduced competition in health insurance markets that will adversely affect patients with higher premiums and contribute to a decline in the quality of insurance; and
- A foreseeable failure to realize proposed efficiencies and benefits because the merger faces enormous implementation challenges, and those efficiencies have a questionable evidence base.

On August 1, 2018, the California DOI agreed with our arguments and those of the experts that testified, urging the U.S. Department of Justice (DOJ) to block the proposed merger. The AMA also submitted extensive comments to the DOJ on the proposed merger on August 8. At the time of this report, the outcome of the proposed merger had yet to be decided, so AMA advocacy continues.

Insurer coverage issues

In 2018, the AMA continued to collaborate with state and specialty medical societies to ensure that patients have appropriate coverage for unanticipated out-of-network care. The AMA continues to promote coverage policies that are based on reasonable physician charges, to financially protect patients and promote fair contracting between physicians and insurers. AMA model legislation serves as the basis for many of these proactive efforts. Similarly, problematic state bills have been regularly defeated as the AMA and medical societies communicate to legislators about their impact on patient access to care and physician practice stability. The AMA has worked closely with state medical associations and the American College of Emergency Physicians (ACEP) to combat Anthem/BCBS policies that deny coverage for emergency care when the final diagnosis is determined to be non-emergent. Legislative restrictions were adopted in Missouri.

Modifier 25

At the 2017 Interim Meeting, the House of Delegates established new policy to advocate against payment reductions for evaluation and management (E/M) codes appropriately reported with a Current Procedural Terminology (CPT) modifier 25. Considerable concerns regarding this issue have been raised by many state medical associations and national medical specialty societies, most recently in regard to health insurer Anthem's proposed policy to reduce payments by 50 percent for E/M services billed with CPT modifier 25 when reported with a minor surgical procedure code beginning in the first quarter of 2018. Several other insurers have followed suit with similar proposals.

Starting in November 2017, the AMA advocated directly to Anthem to halt this proposed move. The AMA sent a letter to Anthem expressing our concerns and hosted two meetings with AMA and Anthem senior leadership. During these discussions, the AMA voiced strong objections to this unwarranted reduction in physician payment and presented evidence showing that the recommendations of the AMA/Specialty Society Relative Value Scale Update Committee (RUC) do not include duplicative physician work or practice expense for procedures typically billed with an E/M service on the same date. Many state medical associations and national medical specialty societies also strongly advocated for Anthem to rescind this policy, which would impede the provision of unscheduled, medically necessary care. Following these combined efforts, Anthem withdrew its modifier 25 payment reduction. The AMA welcomed this news, as this policy would have had resulted in a \$100 million cut in physician payments nationwide.

The AMA has continued advocacy on this issue, to include provision of supporting documentation to assist medical societies in successfully fighting implementation of modifier 25 payment reductions by Blue Cross Blue Shield of Michigan and Health Net in California. This will be an ongoing campaign, and the AMA will engage national commercial insurers and governmental entities considering similar policies involving modifier 25 or other CPT modifiers. The Centers for Medicaid & Medicare Services proposed a new application of the Modifier 25 policy as part of the Evaluation and Management coding proposals. In comments on the proposed rule, the AMA stressed that these reductions were inappropriate and if advanced would necessitate an extensive review of related codes to assure that services were accurately valued.

Opioid epidemic

The opioid epidemic continues to have a devastating effect on our nation; however, there are signs of progress in physicians' actions to help end this public health epidemic. The AMA Opioid Task Force issued a report in June 2018 highlighting some of this progress:

- Between 2013 and 2017, the number of opioid prescriptions decreased by more than 55 million—or 22.2 percent;
- Use of prescription drug monitoring programs (PDMPs) is growing—more than 300 million queries were made in 2017;
- Naloxone prescriptions more than doubled in 2017, from approximately 3,500 to 8,000 dispensed per week;
- More than 549,000 physicians and other health care professionals completed continuing medical education (CME) trainings and other Federation education resources in 2017; and

- Finally, the number of physicians trained/certified to provide buprenorphine in-office continues to rise—more than 50,000 physicians are now certified—a 42 percent increase in the past 12 months.

Attention to the need for increased access to Medication Assisted Therapy (MAT) resources is a top priority in 2018—as is calling on health insurers to eliminate PA requirements and other barriers to MAT as well as enhancing access to comprehensive, multidisciplinary treatments for pain, including non-opioid alternatives. AMA model state legislation can help address these and other related areas.

At the federal level, Congress enacted the Consolidated Appropriations Act of 2018 which includes nearly \$4 billion for prevention, treatment, and law enforcement efforts targeted at addressing the opioid epidemic. The AMA has been calling for increased federal funding for several years.

In 2018, the AMA offered background, analysis, and technical support to at least 25 states as they addressed the opioid epidemic. This includes support for bills aligned with AMA policy, and efforts to amend or defeat bills with negative provisions. The AMA also continues to maintain and update the AMA opioid microsite, www.end-opioid-epidemic.org, with more than 400 education and training resources specific to state and specialty societies.

Pharmaceutical cost transparency

In 2018, the AMA is encouraging patients and physicians to share their stories about the impact of drug pricing and is urging state medical associations to advance AMA model legislation to increase transparency requirements on payers, pharmacy benefit managers and pharmaceutical manufacturers. The AMA also updated the Truthinrx.org website and continues to issue regular updates through the Patients Action Network (PAN) and the Physicians Grassroots Network (PGN) social media channels. The campaign is well-positioned to engage grassroots pressure in favor of positive reform-minded legislation once it materializes.

In May of 2018, the Trump Administration issued a Blueprint for addressing the problem, which is a high priority for the Secretary of HHS, Alex Azar. While the Blueprint lacks detail on key issues, it appears the focus will be on limited regulatory actions that the Administration can take without action by Congress.

The AMA commented on the Blueprint, and expressed strong support for a select number of provisions: (1) requiring pharmaceutical supply chain transparency; (2) accelerating and expanding regulatory action to increase pharmaceutical market competition and combat anti-competitive practices; (3) ensuring prescribers have accurate point-of-care coverage and patient cost-sharing information as part of their workflow, including in the electronic health record (EHR); and (4) ensuring federal programs and commercial practices billed as lowering prescription medication prices do so for patients directly. The AMA identified and expressed concern about Blueprint proposals that would increase patient costs and erect barriers, including onerous insurer paperwork requirements that impede timely patient access to affordable and medically necessary medications and treatments. Further, the AMA opposes policies that would financially penalize physicians and pharmacists for high cost prescription medication.

The AMA also sent a letter of support to the Hill for S. 2554, which would prohibit the use of gag clauses in a manner the AMA strongly supports and would provide the Federal Trade Commission with clear authority to combat pay for delay agreements entered into between biological/biosimilar companies.

The AMA has also been working to influence legislative efforts at the state level to address drug costs, often by questioning the business practices and value equation that pharmacy benefit managers (PBMs) add to the system. The AMA has been engaged in the development of model bills by both the National Association of Insurance Commissioners (NAIC) and the National Conference of Insurance Legislators (NCOIL) to better regulate PBM practices. Additionally, nearly 20 states have now enacted legislation to allow pharmacists to discuss drug costs and payment options with patients (gag clause legislation)—policies supported by the AMA and outlined in AMA model legislation.

Gun violence

After another series of tragic mass shootings, the AMA renewed the call for the U.S. Centers for Disease Control and Prevention (CDC) to investigate the root causes of gun violence. There is concern that the CDC is prohibited from conducting this research, but the Dickey Amendment only prohibits the CDC from using appropriated funds “to

advocate or promote gun control.” The AMA urged Congress to earmark appropriations specifically for gun violence research efforts. It also commented on proposed regulations issued by the Department of Justice on so-called “bump stocks.”

As the push for federal funding continues, the AMA recently partnered with the American Foundation for Firearm Injury Reduction in Medicine (AFFIRM), a physician-led, non-profit organization that aims to counter the lack of federal funding for gun violence research by sponsoring gun violence research with privately-raised funds. AMA Trustee, Albert Osbahr, III, MD, is on AFFIRM’s steering committee; other physician group partners include the American College of Surgeons, American College of Emergency Physicians, and the Massachusetts Medical Society. More information about the group can be found at www.affirmresearch.org.

In 2018, nine states (Kansas, Louisiana, Maryland, New York, Ohio, Oregon, Utah, Vermont and Washington) enacted laws restricting access to firearms for individuals convicted of domestic violence or subject to a restraining order due to domestic violence. Delaware, Florida, Illinois, Maryland, Massachusetts, New Jersey, Rhode Island and Vermont passed laws establishing gun violence restraining orders. Nine states (Connecticut, Delaware, Florida, Hawaii, Maryland, New Jersey, Rhode Island, Vermont, and Washington) banned bump stocks. Finally, Florida, Louisiana, New Jersey, Oregon, Tennessee and Vermont strengthened background check requirements.

The AMA adopted several policies on gun violence at its 2018 Annual Meeting and will continue to seek opportunities at the federal and state levels to advance new and existing AMA policy on this topic:

- Advocating for schools as gun-free zones;
- Calling for a ban on the sale of assault-type weapons, high-capacity magazines;
- Expanding domestic violence restraining orders to include dating partners;
- Removing firearms from high-risk individuals;
- Supporting an increase in legal age of purchasing ammunition and firearms from 18 to 21;
- Opposing federal legislation permitting “concealed carry reciprocity” across state lines; and
- Supporting gun buyback programs in order to reduce the number of circulating, unwanted firearms.

Scope of Practice

Policy adopted at the 2017 Interim Meeting called on the AMA to convene a meeting of relevant physician stakeholders to create a consistent national strategy to effectively oppose efforts to grant independent practice to non-physician practitioners. To implement this directive, the AMA hosted a summit at AMA headquarters in March 2018. The Scope of Practice Partnership (SOPP) provided funding to support the summit. Eighty-one physicians, executive staff, and government affairs staff from 32 state medical associations, 16 national medical specialty societies, and the American Osteopathic Association joined AMA leadership and staff at the summit. The strategy resulting from this meeting was discussed in detail at the A-18 SOPP meeting and will guide our ongoing advocacy efforts.

In 2018, there was a great deal of concern about the Advanced Practice Registered Nurse (APRN) Compact, a multistate licensure compact developed by the National Council of State Boards of Nursing (NCSBN). It establishes a process by which an APRN with certain credentials can receive a multistate license that allows the APRN to practice in any APRN Compact member state. APRNs practicing under this multistate license can practice and prescribe independently, despite any state law to the contrary. Idaho, North Dakota, and Wyoming have joined the APRN Compact, which will go into effect if 10 states join. Due to AMA and Federation efforts, bills were defeated in Iowa, Minnesota, Nebraska, and no further APRN Compact bills were enacted in 2018.

Immigration

Based on policy adopted at A-18, the AMA wrote to the Administration to withdraw its “zero tolerance” immigration policy and to stop separating children from their families. The fear is that Administration’s policy will do great harm to children and their parents or caregivers. The AMA sent the letter to the secretaries of the Homeland Security and Health and Human Services departments, as well as the U.S. Attorney General. The letter pointed out that childhood trauma and adverse childhood experiences created by inhumane treatment often create negative health impacts that can last an individual’s entire lifespan. The president subsequently issued an executive order reversing the Administration’s position on separating children. The AMA is closely monitoring the reunification of parents and children.

The AMA also voiced concerns in a letter to the Director of the U.S. Citizenship and Immigration Services about delays in H-1B visa processing due to increased inspection of prevailing wage data for incoming non-U.S. international medical graduates (IMGs) who have accepted positions in U.S. Graduate Medical Education (GME) programs.

Cybersecurity

The AMA has been raising awareness of cybersecurity threats to physician practices. Last year, an AMA/Accenture survey of 1300 physicians found that phishing and viruses are the most common types of cyberattacks encountered by small practices. Viruses often appear as a result of software that is not regularly updated or “patched.” To assist physicians, the HHS Office for Civil Rights (OCR) issued a monthly newsletter devoted to cybersecurity issues. In addition to encouraging the federal government to issue additional guidance like this to physicians, the AMA continues to urge stakeholders—including health information technology vendors—to pay special attention to the needs of small and mid-sized practices, which often lack the resources that larger practices and health systems enjoy.

Protecting the patient-physician relationship

In response to the Administration’s plan to withhold federal family planning funding from Planned Parenthood and other entities, the AMA issued a statement and submitted comments strongly objecting to the policy change, asserting that it interferes with patient-physician relationships and negatively affects quality of care. The HHS announcement specifically noted that the regulation update “would prohibit referral for abortion as a method of family planning.” The proposal would also endanger access to care that the Title X program has helped to facilitate. Title X has helped to expand access to basic reproductive health care like birth control, cancer screenings, STI testing and treatment, and exams. The program serves roughly 4 million people every year, many of whom would otherwise be unable to access care. The AMA’s stance on this issue is in keeping with its longstanding position on maintaining patient choice and physician freedom to practice in the setting they choose, and reflects a broader commitment to protecting free communication between patients and physicians.

Physician conscience rights

In 2018, HHS issued a Notice of Proposed Rulemaking on “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.” In response, the AMA sent a letter to Secretary Azar to express opposition to the measure, citing concern for vulnerable patient populations and asserting that conscience rights for physicians are not unlimited. The proposed rule would dramatically expand the discretion that religious or moral objectors have to refuse care without meaningful safeguards to ensure that the rights of those receiving care are protected. The rule is part of a broader Administration effort to protect religious rights and follows the announcement in late January of the creation of a new office within the Office of Civil Rights (OCR), the Conscience and Religious Freedom Division. The AMA is alarmed because if implemented, the rule would function as a shield for people asserting objections on religious or moral grounds and could permit them to withhold care from already vulnerable groups and create confusion in health care institutions. While the AMA is committed to conscience protections for physicians and other health professional personnel, the exercise of those rights must be balanced against the fundamental obligations of the medical profession and physicians’ paramount responsibility and commitment to serving the needs of their patients.

Equality issues

Five states (Delaware, Hawaii, Maryland, New Hampshire, and Washington) enacted laws opposing “conversion therapy.” AMA policy strongly opposes conversion therapy, and the AMA stands ready to work with state medical associations interested in pursuing a ban on this harmful practice.

In addition, the AMA advocated before the U.S. Department of Veterans Affairs and the Department of Defense on coverage for transgender-related health care services.

Tobacco

The AMA along with more than a dozen other physician groups sent a letter to ranking members of the Senate and House appropriations committees urging them to oppose any provisions that weaken or delay the U.S. Food and Drug Administration’s (FDA) ability to regulate any and all tobacco products. Responding to provisions passed by the

House in recent years that exempt thousands of tobacco products—including many candy- and fruit-flavored products now favored by teens—from the scientific review process mandated by the Family Smoking and Prevention Tobacco Control Act is cause for concern as 11.3 percent of high school students in 2016 reported using e-cigarettes during the last 30 days. Under these House provisions, many tobacco products that the FDA had only just begun to regulate, such as e-cigarettes and cigars, would be exempted from a product review if they were on the market prior to Aug. 8, 2016. The oft-cited reason for these provisions is the ability of e-cigarettes to help smokers quit traditional cigarettes; however, the efficacy of this is not yet proven by the research.

At the state level, Maine and Oregon raised the tobacco purchase age to 21. Five states now have this requirement. California, Hawaii, and New Jersey enacted laws in previous sessions.

Economic Impact Study

At the beginning of 2018, the AMA released its updated Economic Impact Study. The report gives policymakers concrete evidence demonstrating how their local communities tangibly benefit when they support legislation that helps physician practices thrive. The 2018 study found that nationally:

- Physicians support nearly 12.6 million jobs. On average, each physician supports more than 17 jobs;
- Physicians create a total of \$2.3 trillion in economic output, comprising about 13 percent of the total U.S. economy. On average, each physician supports \$3.2 million in economic output;
- Physicians contribute more than \$1 trillion in wages and benefits for all supported jobs. On average, physicians support \$1.4 million in total wages and benefits per physician; and
- Physicians support \$92.9 billion in state and local tax revenues—approximately \$126 thousand per physician on average.

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 Congress. A report summarizing AMPAC activities will be distributed at the Interim Meeting in National Harbor.

CONCLUSION

Once again, the AMA has delivered some significant advocacy victories in a challenging political environment. The outcome of the 2018 elections is unknown at the time this report was prepared, but the AMA is poised to work with both sides of the aisle in 2019 to advance the interests of patients and physicians on the most critical health care issues. The AMA thanks its Federation partners for their collaboration and support and looks forward to tackling medicine's biggest issues when newly elected state and federal officials take office in January.

4. INCREASED USE OF BODY-WORN CAMERAS BY LAW ENFORCEMENT OFFICERS (RESOLUTION 208-I-17)

Reference committee hearing: see report of Reference Committee B.

HOUSE ACTION: REFERRED

INTRODUCTION

At the 2017 Interim Meeting, the House of Delegates referred Resolution 208-I-17, "Increased Use of Body-Worn Cameras by Law Enforcement Officers," introduced by the Medical Student Section, which asked:

That our American Medical Association advocate for legislative, administrative, or regulatory measures to expand funding for (1) the purchase of body-worn cameras and (2) training and technical assistance required to implement body-worn camera programs.

The reference committee heard testimony largely in support of referral. Testimony emphasized the use of body-worn cameras by law enforcement officers was a matter of public health and directly related to existing American Medical Association (AMA) policy concerning the health of minorities. Others expressed concern that the issues being raised were outside of the expertise and scope of our AMA. The reference committee recommended referral in order to address all concerns raised by Resolution 218. This Board report provides background, discussion of body-worn cameras by law enforcement officers, and a recommendation.

BACKGROUND

Following a number of high-profile incidents involving deadly force used against minorities, law enforcement agencies have increasingly adopted body-worn cameras for their officers. Often affixed to the torso, body-worn cameras are small, wearable audio, video or photographic recording systems that record events in which law enforcement officers are involved. The recordings can be used to demonstrate transparency to the community, to document events and to deter inappropriate, illegal or unethical behavior by both the wearer of the camera and the public.

To date, 34 states and the District of Columbia have enacted laws governing the use of body-worn cameras by law enforcement, though not all law enforcement departments utilize cameras in the same manner.¹ For example, some permit officers to turn off the devices under certain circumstances; others do not. In addition, a 2016 survey of large police departments nationwide found that 95 percent intended to implement or had already implemented a body camera program. According to the survey, 18 percent had fully operational programs.²

The cost to law enforcement entities to implement and maintain a body camera program can be costly and is an ongoing expense. Implementing a program requires an initial capital outlay to purchase the technology and ancillary equipment; law enforcement agencies must account for continuing operational costs, such as training on use, data storage, software and staff and operational costs required for reviewing the recordings, redacting as necessary, and providing recordings to courts and the public as appropriate. In Washington, DC, for example, the city spent over \$1 million outfitting 2,800 officers and expects operating costs to top \$2 million per year.³

In 2015, the U.S. Department of Justice (DOJ) Bureau of Justice Assistance (BJA) awarded \$22.5 million in grant assistance to state and local law enforcement departments as part of the Body-Worn Camera Pilot Implementation Program. The Consolidated Appropriations Act, 2018 appropriated \$22.5 million for a competitive matching grant program for purchases of body-worn cameras for state, local and tribal law enforcement. The BJA expects to make up to 28 awards for a three-year period, to begin on October 1, 2018. State and local funding is also available for body-worn cameras.

DISCUSSION

Predicated on whether the AMA ought to support funding of body camera programs is the question of whether the AMA ought to support the expanded use of body cameras and whether the devices achieve their intended outcomes.

Policing Activity

The underlying theory in support of body-worn cameras is that both officers and members of the community will change their behaviors for the better if their actions are being recorded. Indeed, a large body of research suggests that people act differently when they believe they are being watched. In the context of law enforcement, body-worn cameras are expected to increase self-awareness and thus deter unprofessional, inappropriate and illegal behavior by officers and civilians alike. As law enforcement officers are more likely to use force against minority community members, many hope body-worn cameras will improve policing behavior toward minorities, using force only when warranted and de-escalation tactics have failed.^{4,5} In cases where law enforcement officers do use force, body-worn cameras offer contemporaneous evidence of the officers' actions so that improper behavior can be disciplined. Evidence about the impact of cameras on policing activity generally, though not universally, supports this theory.

An early study conducted in the Rialto, California police department found use-of-force incidents declined 58.3 percent over a three-year period after a body camera program was implemented.⁶ Importantly, researchers later found that use of force rates were higher in the same Rialto, California police force despite the presence of a camera when officers were allowed discretion to turn off cameras.⁷ Another randomized controlled trial conducted between 2014

and 2015 in the Las Vegas Metropolitan Police Department found that officers wearing body cameras were 12.5 percent less likely to be involved in a use of force incident.⁸ Similar results were found in Orlando, Florida.⁹ In contrast, the largest randomized controlled study to date, conducted in 2015 with the Metropolitan Police Department of the District of Columbia, found no statistically significant difference in the rates of police use of force.¹⁰

Research has found mixed results about other forms of police activity. In the study conducted in Las Vegas, body camera use was not associated with a change in the number of police-community interactions, but body cameras were associated with a 6.8 percent increase in the number of citations issued and a 5.2 percent increase in the number of events that resulted in an arrest. A 2015 study conducted in Mesa, Arizona found officers wearing a camera were less likely to perform stop-and-frisks and make arrests, but were more likely to give citations and initiate encounters.¹¹ In Phoenix, Arizona use of body-worn cameras were associated with a 17 percent increase in arrests.¹² However, other studies have found body-worn cameras are associated with slightly lower incidents of arrest.¹³

Community Relations

Changing policing behaviors is not the only way body-worn cameras could provide benefits. Many communities and law enforcement agencies see body cameras as a valuable way to improve policing transparency and community relations. Indeed, in 2015 when DOJ grants were announced, then-US Attorney General Loretta Lynch stated that body-worn cameras hold “tremendous promise for enhancing transparency, promoting accountability, and advancing public safety for law enforcement officers and the communities they serve.”¹⁴ Body cameras are lauded as a way for the public to better understand what transpires between law enforcement officers and civilians. Officers may also view body cameras positively, as recordings demonstrate to the community the difficult and dangerous job required of them.

Few studies have taken a comprehensive look at community attitudes toward police after the introduction of body-worn cameras.¹⁵ One such study conducted by the Urban Institute found that body-worn cameras do improve community members’ satisfaction with police encounters.¹³ Another study found that individuals viewed officers as having greater legitimacy, professionalism and satisfaction, but did not find significant differences between citizens’ perceptions of officers depending on whether the officer was wearing a camera.¹⁶

The evidence is clearer, however, that body-worn cameras are associated with decreased rates of complaints filed against law enforcement officers. For example, one early study found complaints against officers dropped 88 percent following implementation of a body cameras program.⁶ In Rialto, California, citizen complaints declined by 60 percent. In the Las Vegas Metropolitan Police, officers wearing body cameras were 14 percent less likely to be the subject of a citizen complaint.⁸ In Phoenix, complaints against officers who wore the cameras declined by 23 percent, compared to a 10.6 percent increase among comparison officers.¹² In contrast, research in the District of Columbia found no statistically significant difference in the rates of civilian complaints.

The available evidence does not identify the underlying behavioral changes responsible for the decline in complaint rates, however. It may be that body-worn cameras have the intended effect of changing officer behavior for the better, thus reducing circumstances that warrant citizen complaints. It may be that cameras have a “civilizing” effect on members of the public as well. Some evidence also suggests that frivolous complaints are less likely to be filed when recordings are available.¹⁵

It is important to note, however, that use of body cameras will not automatically foster greater trust between law enforcement and members of the community and should not be viewed, as one evaluation noted, as a “plug-and-play” solution.¹⁰ Notably, the Urban Institute found body-worn cameras improved community satisfaction to a lesser extent than did procedurally just practices, defined in that study as behaving fairly and acting with empathy.¹³

Privacy Considerations

Though the use of body cameras promises greater transparency of law enforcement behavior and actions, they also present new problems, namely intrusion into the privacy of victims, witnesses and bystanders. For instance, law enforcement officers frequently enter individuals’ homes and in-home recordings would become part of the public record. Similarly, interactions and conversations with victims and witnesses could make those individuals uncomfortable or put those individuals in danger. Heavily policed communities – often minority communities – will be more heavily recorded.

These privacy concerns could be addressed with policies to limit recording during such encounters and by limiting the circumstances under which recordings are made available to the public. The American Civil Liberties Union (ACLU) recommends use of body cameras with significant privacy protections. Officer privacy may also be a concern. Some law enforcement unions have opposed body-worn cameras, arguing that adoption of the technology must be negotiated as part of the collective bargaining agreement.

This report acknowledges the significant privacy concerns raised by the ubiquitous use of body-worn cameras, but notes that questions about when cameras need to be turned on and off, how long to keep footage, when recordings will be made publicly available and other policy details are beyond the expertise of the AMA.

Nexus with the AMA's Mission

The AMA does not have policy specifically addressing the use of body-worn cameras among law enforcement. During the debate over Resolution 208 during the 2017 Interim Meeting, the reference committee heard testimony questioning whether this topic is within the scope of the AMA's expertise. This concern is reasonable, as AMA has not historically delved into issues of policing and significant resources would be required to bring the AMA into the public policy debates surrounding community policing efforts. Further, while there are dozens of organizations (the Police Executive Research Forum, Leadership Conference on Civil and Human Rights, ACLU, etc.) that are actively engaged on this issue, it does not appear that any other major medical associations have emerged as significant stakeholders.

Nevertheless, there is a connection between health and police activity, particularly in terms of minority fatality rates. Research has demonstrated that minority communities are disproportionately subject to police force. Specifically, according to an analysis of FBI statistics, African-Americans account for 31 percent of police-involved shootings, but comprise 13 percent of the U.S. population.⁴ African-American males are particularly at risk. According to another analysis, African-American males are three times more likely to be killed by police than non-Hispanic white males.⁵

Research has also shown a correlation between policing and other health outcomes. In particular, a recent study found that police killings of unarmed African-Americans were associated with 1.7 days of poor mental health annually among African-Americans. The findings were seen regardless of whether the individual affected had a personal relationship with the victim or whether the incident was experienced vicariously. In addition, the numbers of police stops, coupled with the level of invasiveness during police encounters, is associated with increased levels of stress and anxiety.^{17,18} African-American men report more anxiety and post-traumatic stress disorder and more morbidity from these psychiatric conditions than Caucasian men.⁵ In addition, research of data from the New York Police Department revealed that residents in neighborhoods with higher rates of stop-and-frisks were more likely to be in poor health, measured in terms of high blood pressure, diabetes, asthma and self-rated health.¹⁸ Research on the correlation between health and policing, however, remains sparse and warrants further research.

RELEVANT AMA POLICIES

Existing AMA policy does not address the use or funding of body-worn cameras. However, AMA policy does state that physical or verbal violence between law enforcement officers and the public, particularly within ethnic and racial minority communities, is a social determinant of health and supports research into the public health effects of violent interactions. (H-515.955) In addition, Policy H-350.971 "AMA Initiatives Regarding Minorities" instructs the AMA to establish a mechanism to facilitate the development and implementation of a comprehensive, long-range, coordinated strategy to address issues and concerns affecting minorities, including minority health.

New policy adopted during the 2018 Annual Meeting encourages states to require the reporting of legal intervention deaths and law enforcement officer homicides to public health agencies. New policy also encourage appropriate stakeholders, including law enforcement and public health communities, to define "serious injuries" for the purpose of systematically collecting data on law enforcement-related non-fatal injuries among civilians and officers.

Additionally, Policy H-145.977 "Use of Conducted Electrical Devices by Law Enforcement Agencies" cautions against excessive use of conducted electrical devices (often called Tasers) and recommends that law enforcement departments and agencies should have in place specific guidelines, rigorous training and an accountability system for the use of conducted electrical devices. AMA policy recommends research into the health impacts of conducted electrical device use and development of a standardized protocol developed with the input of the medical community for the evaluation, management and post-exposure monitoring of subjects exposed to conducted electrical devices.

RECOMMENDATION

The Board recommends that the following be adopted in lieu of Resolution 208-I-17, and that the remainder of the report be filed.

That our American Medical Association work with interested state and national medical specialty societies to support state legislation and/or regulation that would encourage the use of body-worn camera programs for law enforcement officers and fund the purchase of body-worn cameras, training for officers and technical assistance for law enforcement agencies.

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5. EXCLUSIVE STATE CONTROL OF METHADONE CLINICS (RESOLUTION 211-I-17)

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 211-A-17
REMAINDER OF REPORT FILED
See Policy H-95.921**

INTRODUCTION

At the 2017 Interim Meeting, the House of Delegates referred Resolution 211-I-17, “Exclusive State Control of Methadone Clinics,” introduced by the Indiana Delegation, which asked:

That our American Medical Association support complete state control of all aspects of methadone clinic approval and operations; and, if deemed necessary, this control could be granted on a state by state basis.

Reference committee testimony generally was mixed and noted that there is likely both a state and federal role as it relates to methadone clinic approval and operations. Delegates encouraged further study, including discussion about methadone clinic reporting to state prescription drug monitoring programs (PDMP). This report reviews existing information, provides background and presents recommendations.

DISCUSSION

Your Board strongly agrees with the authors of Resolution 211-I-17 that methadone clinics provide a valuable service to patients with an opioid use disorder. Methadone maintenance therapy (MMT) for the treatment of opioid use disorder has been used for more than 40 years to help patients, having been approved in 1972 by the U.S. Food and Drug Administration (FDA) for treatment of heroin addiction. The health and safety of methadone has been studied extensively and ample evidence exists supporting its use to aid in mortality and crime reduction.¹

There are more than 1,600 certified opioid treatment programs (OTPs) offering methadone in the U.S.² According to the Substance Abuse and Mental Health Services Administration (SAMHSA), the number of persons receiving methadone increased by 34 percent from 2006 (258,752) to 2016 (345,443).³ With respect to opioid-related mortality, deaths attributed to methadone increased rapidly from 1999 (784 deaths) to their peak in 2007 (5,518) and have steadily declined since with 3,373 methadone-related deaths in 2016, according to the Centers for Disease Control and Prevention.⁴ It is beyond the scope of this report to detail whether the methadone use in these deaths was for the treatment of pain, for opioid use disorder, related to illicit use or was a complicating polypharmacy factor.

The FDA, U.S. Drug Enforcement Administration (DEA), U.S. Department of Health and Human Services (HHS) and states each have a role to play in the oversight and administration of MMT.

FDA Regulatory Authority

Within the broad scope of FDA’s regulatory authority is the review and approval of drugs, both brand name and generic. A general overview of the FDA process can be found online: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm#FDA>. With respect to methadone, the FDA approved a New Drug Application for methadone in 1947. There were intervening actions, but for the purposes of this report, the FDA issued regulations for methadone Investigational New Drugs in 1971; proposed new regulations in April 1972; and issued final regulations in December 1972.⁵

DEA Regulatory Authority

DEA authority with respect to methadone focuses on the medication’s classification as a Schedule II controlled substance.⁶ Included within DEA’s responsibilities is the “enforcement of the provisions of the Controlled Substances Act as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances.” As a controlled substance, methadone falls within this scope.

HHS Regulatory Authority

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), a division within HHS, has broad regulatory authority concerning MMT and opioid treatment programs (OTP). This includes the authority to certify OTPs, which is defined as “a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 USC 823(g)(1).”⁷

Regulations concerning OTPs, where patients receive MMT (and other medications and treatments), provide guidance for numerous issues. These issues include accreditation of opioid treatment programs, certification and treatment standards for OTPs, procedures for review of suspension or proposed revocation of OTP certification, and of adverse action regarding withdrawal of approval of an accreditation body, and more.⁸

Specifically related to methadone, 42 CFR Part 8 provides that “methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.” It also provides that:

For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opioid abstinence symptoms.

There also are requirements for frequency of patients receiving toxicology tests, treatment of pregnant patients, requirements for take-home doses of methadone, and more.⁹

State Authority

There are numerous areas where state regulatory authority and linkages with federal oversight exist regarding OTPs. One prominent area concerns who shall serve as the medical director of the OTP. Federal regulations require that the medical director must be “a physician licensed to practice medicine in the jurisdiction in which the [OTP] is located.” State licensure is squarely within the exclusive control of state licensing boards. Federal regulations also require that there are adequate staffing requirements, employment qualifications and other personnel-related issues. These are within the control of the state. And while it is complicated and beyond the scope of this report, states also have a certain amount of leeway in determining zoning requirements for where an OTP would be located. Notably, your Board strongly supports OTPs being treated no differently than any other medical clinic that may seek to provide care in a community.¹⁰

SAMHSA also has recognized the clear need for OTPs to work with leaders in the community to ensure comprehensive support services. That is, to support/encourage collaborative, multiagency surveillance efforts to obtain timely and comprehensive data to target interventions and inform prevention and response efforts. This includes working with the community to help determine where an OTP is most needed; how an OTP can be integrated into the community with the least impact on neighborhoods and traffic, for example; how to help educate the community on the benefits of treatment for opioid use disorder so as to reduce stigma; and other areas.¹¹

Another area of state control—which raises potential conflicts with federal law—concerns whether OTPs should be required to report methadone dispensing information to the state PDMP. This issue is extremely controversial. In fact, while this issue was raised by the resolution that gave rise to this report, it also was raised in Resolution 507 from the 2018 Annual Meeting. Resolution 507-A-18 was referred for further study of a more extensive range of privacy and clinical issues relating to PDMPs and OTPs. Given that your Board is currently deliberating on Resolution 507-A-18, and the fact that SAMHSA has not specifically resolved the many issues associated with reporting OTP information to state PDMPs,¹² your Board believes it would be prudent to delay further comment here so as not to cause confusion with pending research and discussions. Your Board does note, however, that our AMA continues to urge physicians to use PDMPs to help inform their clinical decision making. There is nothing to prevent physicians and other health care professionals in an OTP from checking the state PDMP to ensure a patient is not receiving prescriptions for controlled substances from other providers. Whether an OTP should report to a PDMP, however, is a matter of federal—not state—jurisdiction.

Additional areas where states can help complement the medical care provided at OTPs include promotion of take-home naloxone (governed by state law); education that helps remove the stigma associated with MMT and medication assisted treatment (MAT); working toward policies that remove health insurance and pharmacy benefit management

company barriers to receiving MMT and MAT (e.g., prior authorization, network adequacy for mental health care); prompt and accurate overdose reporting for surveillance efforts related to prevention, treatment, and response; identification of linkages within the community to peer counseling and other support services, to name a few.

Furthermore, to complement and assist OTPs with the federal requirement to help an OTP identify and prevent patients from enrolling in multiple OTPs concurrently, states can develop communications and other tools to help OTPs (and other health care providers) identify all OTPs doing business in a state and in surrounding areas. Federal rules already require an OTP to take reasonable measures to do this. It seems reasonable that this would be an area where the state, working with health insurance companies and other payers, as well as with the medical community, would be well-advised to develop such a mapping/informational tool. This would not only allow OTPs to more easily communicate with each other, but it would help patients identify where OTPs exist in the state.

In Indiana, for example, the federal OTP locator maintained by SAMHSA identifies 16 OTPs operating in the state,¹³ but it does not allow for multiple states to be displayed simultaneously. The SAMHSA locator also does not allow for multiple OTPs within the state to be displayed simultaneously. While the AMA appreciates the technical and other challenges that may be present in maintaining and keeping a current list of OTPs, creating a more robust OTP locator tool may be an area where state-based expertise and multistate partnerships can tailor solutions so that patients and physicians would be able to more easily locate and communicate with OTPs.

AMA POLICY

Relevant AMA policy provides for strong support of access to methadone. This includes MMT used in combination with behavioral and social supports, as well as support for physicians and organized medicine to provide education and training regarding treatment of substance use disorders (Policy H-95.957, “Methadone Maintenance in Private Practice;” Policy D-120.985, “Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone”). AMA policy also calls for continued funding of OTPs operating in states (Policy D-95.999, “Reduction of Medical and Public Health Consequences of Drug Abuse: Update”); and for the AMA to “advocate for legislation that eliminates barriers to, increases funding for, and requires access to all appropriate FDA-approved medications or therapies used by licensed drug treatment clinics or facilities” (Policy D-95.968, “Support the Elimination of Barriers to Medication-Assisted Treatment for Substance Use Disorder”). AMA policy also clearly supports MAT in correctional settings and in the community in conjunction with counseling (Policy H-430.987, “Opiate Replacement Therapy Programs in Correctional Facilities”).

AMA policy also calls for continued funding of OTPs operating in states (Policy D-95.999, “Reduction of Medical and Public Health Consequences of Drug Abuse: Update”); and for the AMA to “advocate for legislation that eliminates barriers to, increases funding for, and requires access to all appropriate FDA-approved medications or therapies used by licensed drug treatment clinics or facilities” (Policy D-95.968, “Support the Elimination of Barriers to Medication-Assisted Treatment for Substance Use Disorder”).

AMA policy also provides, in part, that “local communities or regions should exercise the responsibility for assessing their needs with respect to the type, size, scope, and location of health care facilities. State governments should ensure that needs of the underserved are being met satisfactorily without wasteful duplication” (Policy H-205.992, “Supply and Distribution of Health Care Facilities”).

RECOMMENDATIONS

The Board recommends that the following recommendation be adopted in lieu of Resolution 211-I-17, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) support the right of federally certified Opioid Treatment Programs (OTPs) to be located where there is a demonstrated medical need; and
2. That our AMA encourage state governments to collaborate with health insurance companies and other payers, state medical societies, national medical specialty societies, OTPs and other health care organizations to develop and disseminate resources that identify where OTP providers operate in a state and take part in surveillance efforts to obtain timely and comprehensive data to inform treatment opportunities; and

3. That our AMA advocate for the federal agencies responsible for approving opioid treatment programs to consider the views of state and local stakeholders when making decisions about OTP locations and policies.

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6. UPDATE ON TruthInRx GRASSROOTS CAMPAIGN

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2017 Interim Meeting, the House of Delegates adopted Policy D-110.988[2] “Prescription Drug Price and Cost Transparency,” which asked for a report back to the House of Delegates at the 2018 Interim Meeting on the progress and impact of the TruthinRx grassroots campaign. This report, which is presented for the information of the House, summarizes the creation of the TruthinRx grassroots campaign, its evolution, and its progress and impact. The report also summarizes relevant American Medical Association (AMA) policy and advocacy, which is reflected in the TruthinRx grassroots campaign.

BACKGROUND

In 2015, Policy H-110.987, “Pharmaceutical Costs,” directed the AMA to 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. Accordingly, the AMA convened a Task Force on Pharmaceutical Costs, which met four times in the first six months of 2016 to develop principles to guide advocacy and grassroots efforts aimed at

addressing pharmaceutical costs. The Task Force agreed that increasing transparency among pharmaceutical companies, health plans, and pharmacy benefit managers (PBMs) should be the initial focus of the campaign, which led to the launch of a grassroots campaign in the third quarter of 2016, and the launch of the TruthinRx website, *TruthinRx.org*, on November 1, 2016.

EVOLUTION OF THE TruthInRx GRASSROOTS CAMPAIGN

The goal of the TruthinRx campaign has been to mobilize the AMA Physician Grassroots Network (PGN), the AMA Patient Action Network (PAN), the public, and thought leaders around the challenges posed by the lack of transparency surrounding prescription drug pricing and costs. *TruthinRx.org* engages physicians, patients/consumers, and health care policy influencers by:

(a) providing critical information about prescription drug price and cost challenges, as well as the lack of drug price and cost transparency, and (b) facilitating grassroots action in support of improving prescription drug price and cost transparency. Since its launch in November 2016, *TruthinRx.org* has evolved through two key stages. In its first stage, the *TruthinRx.org* landing page focused on informing visitors about how drug price negotiations happen behind closed doors and how pharmaceutical companies, PBMs, and health insurance companies participate in these negotiations. The page concludes that “when patients are left out, health care suffers.” This landing page directs visitors to four main website subsections:

- “Your Stories” – invites visitors to read and contribute their own stories about how the lack of transparency in drug pricing impacts our health care system.
- “Behind the Label” – illustrates how the lack of transparency in prescription drug pricing and costs – involving opaque price agreements between PBMs, health plans, and pharmaceutical manufacturers – contributes to adverse patient effects such as increased costs and unpredictable price swings for patients, and ultimately adversely affects patients and physicians.
- “Get Involved” – facilitates grassroots advocacy by providing visitors with a customizable message that can be personalized to US Senators and Representatives, calling on legislators to support increased transparency in prescription drug prices. Additionally, visitors have an opportunity to subscribe to future legislative updates and alerts from the AMA.
- “Get Informed” – provides visitors with a myriad of timely articles to help them understand the seemingly arbitrary costs of prescription medication. The articles are categorized according to the following thought-provoking questions:
 - “What influences the price of drugs?”
 - “How does drug pricing affect patients like you?”
 - “What’s being done to help?”

At the time that this report was written, the second stage of *TruthinRx.org* was scheduled to be launched in fall of 2018 to further mobilize voters around the issue of prescription drug price transparency. *TruthinRx.org* will include an interactive data visualization that highlights various reasons why drug prices fluctuate. The data visualization will explore the roles of four key themes behind drug price fluctuation: (1) generics – despite the assumption that generic drugs will be affordable, over time, the prices of generic drugs can rise significantly; (2) competition – despite the expectation that competition in the marketplace would lead to lower prices, competitors’ prices can seemingly increase simultaneously; (3) acquisition – the price of drugs produced by a given company can rise significantly after the company is acquired; and (4) supply chain dynamics – PBMs cast themselves as saving money, but with the lack of supply chain transparency, it is unclear how these middlemen negotiate drug prices. The data visualization will lead to a call to action for improved transparency. This interactive subsection of *TruthinRx.org* can be used both on mobile and desktop devices, and is designed so that it can be shared on social media.

PROGRESS AND IMPACT OF THE TruthInRx GRASSROOTS CAMPAIGN

The TruthinRx grassroots campaign has significantly impacted public awareness of, and grassroots action in response to, the opaque process that pharmaceutical companies, PBMs, and health plans engage in when pricing prescription drugs. Between the website’s launch in November 2016 and August 2018, the TruthinRx campaign has achieved the following milestones:

- The TruthinRx campaign generated 827,759 messages sent to Congress demanding price transparency.

- As part of the TruthinRx grassroots campaign, the PAN launched a petition calling for increased prescription drug price and cost transparency, and this petition has been signed by 275,590 individuals.
- *TruthinRx.org* has been visited 117,474 times, by 95,873 unique internet users.
- The AMA has published 656 posts on Twitter and Facebook focused on the TruthinRx campaign. Combined, these posts were displayed 10,859,853 times (“impressions”). This led to 514,118 people interacting with the posts (“engagements”).
- Evidencing the TruthinRx campaign’s continued impact on public discussion, since July 2017, the hashtag “#TruthinRx” has been mentioned on Twitter and/or Facebook 1,617 times.

AMA POLICY AND ACTIVITY

It is important to recognize that the TruthinRx grassroots campaign is one key component of a much broader, ongoing AMA focus on prescription drug affordability. Recent AMA policy and activity aimed at improving prescription drug price and cost transparency include:

- The AMA developed and disseminated model state legislation entitled, “An Act to Increase Drug Cost Transparency and Protect Patients from Surprise Drug Cost Increases during the Plan Year.”
- The AMA submitted comments in July 2018 in response to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. Patient and other stakeholder experiences with affordability and lack of access that were obtained through the TruthinRx campaign were incorporated as vignettes in this comment letter. The AMA has received positive feedback on these vignettes.
- In April 2018, Jack Resneck, Jr., MD, testified at the US House of Representatives Democratic Steering and Policy Committee Briefing on Prescription Medication Pricing and Access Challenges and Solutions. Dr. Resneck’s testimony focused on how the lack of prescription drug pricing transparency impacts his patients.
- In December 2017, Gerald e. Harmon, MD, testified before the Health Subcommittee of the US House of Representatives Committee on Energy and Commerce on the topic of “Examining the Pharmaceutical Supply Chain.” Dr. Harmon’s testimony focused on what the escalating cost and complexity of obtaining medically necessary prescriptions or physician-administered drug treatments mean for patient adherence, timely access, and health outcomes.
- Policy H-110.987, which encourages prescription drug price and cost transparency among pharmaceutical companies, PBMs, and health insurance companies and establishes extensive AMA policy aimed at improving access to affordable prescription drugs, including: promoting legislation that authorizes the Attorney General and/or the Federal Trade Commission (FTC) to take legal action to address price gouging by pharmaceutical manufacturers and increase access to affordable drugs for patients, and encouraging FTC actions to limit anticompetitive behavior by pharmaceutical companies attempting to reduce competition from generic manufacturers.
- Policy H-110.987, also directs the AMA to provide assistance upon request to state medical associations in support of state legislative and regulatory efforts addressing drug price and cost transparency.
- Policy H-125.979, which supports legislation or regulation that secures private health insurance formulary transparency.
- Policy H-110.991, which advocates for greater prescription drug price transparency at the pharmacy point-of-sale.
- Policy H-110.991, also supports physician education regarding drug price and cost transparency and challenges patients may encounter at the pharmacy point-of-sale.

Moreover, the AMA is continuing to develop evolving policy in support of improved prescription drug affordability. Ongoing AMA initiatives include:

- At this Interim Meeting, the Council on Medical Service is presenting Report 1-I-18 that addresses prescription drug importation for personal use.
- At the 2019 Annual Meeting, the Council on Medical Service will present a report that addresses the impact of PBMs on patients.
- At the 2019 Annual Meeting, the Board of Trustees will present a report that addresses three related referred resolutions that address reforming the Orphan Drug Act, legislation related to an optional national prescription drug formulary, and modifications to the Hatch-Waxman Act and Biologics Price Competition and Innovation Act (i.e., Biosimilars Act).

CONCLUSION

In the approximately two years since the TruthinRx grassroots campaign was launched, the initiative has demonstrated significant success in engaging physicians, patients/consumers, and health care policy influencers in discussion of and advocacy to improve prescription drug price and cost transparency. As described above, the TruthinRx campaign is a key component of a broader, ongoing AMA focus on prescription drug affordability, and *TruthinRx.org* will continue to evolve as relevant AMA policy evolves. The objective metrics outlined above indicate that the TruthinRx grassroots campaign is succeeding in stimulating public discourse, and *TruthinRx.org* will continue to be updated to capture public attention and mobilize action.

7. ADVOCACY FOR SEAMLESS INTERFACE BETWEEN PHYSICIANS ELECTRONIC HEALTH RECORDS (EHRs), PHARMACIES AND PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs) (RESOLUTION 212-A-17; BOT REPORT 12-A-18)

Reference committee hearing: see report of Reference Committee B.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 212-A-17 AND BOT REPORT 12-A-18 REMAINDER OF REPORT FILED

See Policy H-95.920

INTRODUCTION

At the 2017 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 212-A-17, submitted by the American College of Legal Medicine (ACLM). The resolution asked that our AMA:

Join the American College of Legal Medicine to advocate federally-mandated interfaces between provider/dispenser electronic health record systems in the clinical, hospital and pharmacy environments and state prescription drug databases and/or prescription drug management plans;

Advocate that the cost of generating these interfaces be borne by the commercial EHR and dispensing program providers;

Advocate that the interface should include automatic query of any opioid prescription, from a provider against the state prescription drug database/prescription drug management plan (PDMP) to determine whether such a patient has received such a medication, or another Schedule II drug from any provider in the preceding ninety (90) days;

Advocate that the prescriber and the patient's EHR-listed dispensing pharmacy should then be notified of the existence of the referenced patient in the relevant PDMP database, the substance of the previous prescription(s) (including the medication name, number dispensed and prescriber's directions for use) in real time and prior to the patient receiving such medication;

Advocate that the electronic record management program at the pharmacy filling the relevant prescription, contemporaneously as it enters the filling of the prescription by the pharmacist, likewise be required to automatically query the state PDMP as a secondary mechanism to prevent inappropriate prescribing, forgery, duplication and/or too great a frequency of use of the involved controlled medication;

Work with ACLM and other concerned societies to urge Congress to timely enact and implement such a statutory scheme supported by a workable and concise regulatory framework, chiefly concentrating on the interfacing of all applicable electronic health record and pharmaceutical dispensing systems with every individual state's PDMP, thereafter designating a timeframe wherein all treating providers and dispensing pharmacists would be required to perform such queries, in concert with the routine ordering of and filling of a controlled substance to be used in the treatment of patients;

Advocate that oversight of the appropriate prescribing of and filling of prescriptions for controlled substances remain with the involved individual federal and state criminal law enforcement agencies, the involved state departments of health, or similar entities and the involved relevant state provider and/or pharmacy licensure authorities; and

Advocate that statistics be maintained and reviewed on a periodic basis by state PDMP personnel and relayed to state departments of health or agencies similarly situated so as to identify and possibly treat those patients identified through this screening mechanism as potential drug abusers and/or at risk of addiction.

Board of Trustees (BOT) Report 12-A-18 summarized work that the AMA has done in support of ensuring accurate, reliable Prescription Drug Monitoring Programs (PDMPs) that support clinical decision-making. It also addressed many of the complexities raised in the original resolution, including evolution of PDMPs, and their integration with electronic health records (EHRs) and electronic prescribing of controlled substances (EPCS).

After debate, the HOD referred BOT Report 12-A-18 back for consideration. While general support existed for the recommendations contained in the report, the HOD asked for additional information on the evolution of PDMPs. This report, therefore, updates and expands upon the information in BOT Report 12-A-18 and presents amended policy recommendations.

DISCUSSION

More than 300 million queries of state PDMPs were made in 2017, more than doubling the 136 million queries in 2016, and five times the 61 million queries submitted in 2014.¹ Physician adoption of EHRs also continues to grow. The Office of the National Coordinator for Health Information Technology maintains that nearly 90 percent of office-based physicians are using EHRs.²

A major goal of AMA advocacy and many others continues to be the integration of electronic systems that can support efforts to address the opioid epidemic. To effectively support physician and public health efforts to prevent opioid overdose deaths, the AMA has urged that electronic systems be interoperable and integrated into medical practice workflows. As noted in BOT Report 12-A-18, information exchanged with EHRs is not well incorporated into the physician's workflow. Obtaining important information, including PDMP data, often requires multiple "clicks," opening multiple windows, and the use of separate logins even before the physician locates what he or she is looking for—and that situation must be repeated for each patient and every prescription for a controlled substance. Effective PDMP and EHR integration means that the workflow must achieve "functional interoperability," or the ability for systems to exchange, incorporate and display data in a meaningful and contextual manner.

The Centers for Medicare & Medicaid Services highlighted this in a recent letter to state Medicaid directors, noting that when integration occurs, it "removes the requirement for providers to log in to a separate system, manage a separate log in, and disrupt their workflow to query the PDMP. Single sign-on interoperability between EHR and PDMP such that PDMP results are displayed when the EHR indicates a controlled substance is prescribed could be supported, as an example."³

Many consider the ideal practice to be a "one-click" solution with PDMP data and EPCS integrated into physicians' EHR systems. On one hand, many EHR vendors are pulled in too many directions to focus on this need. Federal regulations require vendors to develop EHRs that meet administrative requirements. To achieve the ideal for PDMP and EPCS integration, more must be done to reduce the regulatory pressure on health IT development, allowing vendors the flexibility to respond to physician and patient needs, rather than spending the bulk of their time complying with administrative demands.

Yet, there have been reports of progress of successful PDMP-EHR integration. For example, the University of North Carolina (UNC) Health Care at Chapel Hill, reported that efforts to integrate its Epic EHR with the state PDMP have been positive. A news report from July found that "[i]n the first two weeks, more than 540 UNC clinicians used the PDMP when treating some 2,950 patients, which officials said has saved physicians about 119 hours already."⁴ Oschner Health System in New Orleans, Louisiana, also has used Epic to integrate the EHR with the state PDMP.⁵ Deaconess Health, which operates several hospitals in Indiana, also has made strides to integrate EHRs with the state PDMP. And there are many different options in the commercial market, although your Board notes that a Google search of effective PDMP-EHR integration efforts results in dozens of options.⁶

In addition to growing physician use of PDMPs, interstate interoperability has expanded considerably. According to the National Association of Boards of Pharmacy, 44 states now can securely share PDMP information across state lines.⁷ The effects of expanded PDMP use on patient care are mostly unknown; physicians and other health care professionals are not the only ones interested in using the PDMP data.

As noted above, PDMP use among physicians and other health care professionals has significantly increased in recent years; however, opioid-related mortality continues to increase, driven principally by heroin, illicit fentanyl, and other synthetic derivatives. Moreover, as PDMP use increases and opioid prescribing rates decrease, it is not clear that PDMPs are making a significant impact on improving patients' pain care. One review concluded that "[e]vidence that PDMP implementation either increases or decreases nonfatal or fatal overdoses is largely insufficient, as is evidence regarding positive associations between specific administrative features and successful programs. Some evidence showed unintended consequences. Research is needed to identify a set of "best practices" and complementary initiatives to address these consequences."⁸

There may also be a need for additional clarity on how PDMP data may be used by non-health care professionals, including health insurance companies, pharmacy benefit management companies (PBMs), and law enforcement. For example, earlier this year, the U.S. Department of Justice and 48 attorneys general reached an agreement to share data. According to the news release, "Drug Enforcement Agency DEA will provide the Attorneys General with that data, and the states will provide their own information, often from prescription drug monitoring programs (PDMPs) to DEA. Under the agreement, both state and federal law enforcement will have more information at their disposal to find the tell-tale signs of crime." It is not clear what these "tell-tale signs" might be.

Progress has been considerably slower in achieving EPCS uptake,⁹ largely due to outdated regulations from the DEA. The combination of personal identification numbers (PINs), passwords, and biometrics required to meet DEA standards for "two-factor authentication" increase EPCS security but add to workflow disruptions and increase costs. DEA, EPCS requirements include onerous limits on use of biometric devices, which must comply with federal standards that set an unnecessarily high bar and prevent use of user-friendly consumer electronics already found in physicians' offices for two-factor authentication. The biometric fingerprint scanners found on these consumer devices, i.e., smart phone, tablets, and laptop computers, are used for secure access to other sensitive information, like banking and medical records, but typically do not comport with rigid rules for EPCS.

The AMA views EPCS as important to support high-quality patient care. Physicians commonly report that they are frustrated that they can e-prescribe non-controlled substance medications but must still use written prescriptions for controlled substances. More than 70 percent of physicians are e-prescribing non-controlled drugs but only 20 percent used EPCS. One reason for this is due to the fact that not all EHR vendors understand or can satisfy EPCS requirements—state EPCS mandates have increased uptake, but implementation has been delayed due to questions about system certification, cost to providers, and patient concerns, i.e., transferring prescriptions between pharmacies. Moreover, EHR vendor processes for EPCS do not always align well with normal e-prescribing workflows—often physicians must start new computer programs and windows each time they use EPCS. Cumbersome workflows and applications that do not take physician needs into account impede EPCS uptake. Finally, although EPCS reduces prescription fraud and diversion, it is less clear how it affects valid prescriptions for opioid analgesics. For example, does the prescriber using EPCS put in a dose and duration or are numbers suggested by the EPCS system and, if so, how are these amounts derived? These are among the questions the AMA has been asking from vendors and physicians.

To help resolve other barriers, the AMA and the President's Commission on Combating Drug Addiction and the Opioid Crisis have recommended the DEA modify EPCS regulations in order to reduce barriers to EPCS adoption. The AMA asked DEA to reexamine the scope of technology that is compliant with EPCS requirements and allow use of lower-cost, high-performing biometric devices in two-factor authentication. The AMA also believes that there must be further study to evaluate the variations in how EPCS systems handle initial dosing, i.e., are opioid doses or durations auto-populated in EPCS systems and, if so, are the amounts appropriate.

A final point is that the AMA has made clear to the DEA that its requirements for biometric devices limit user-friendly consumer electronics already found in physicians' offices, such as fingerprint readers on laptop computers and mobile phones, from being utilized for two-factor authentication in EPCS. This and other rules contribute to cumbersome workflows and applications which are an impediment to physician EPCS uptake. Encouraging EPCS uptake and

interoperability of PDMP databases and electronic health records would improve the integration of controlled substance use data into practice workflows and clinical decision-making.

The AMA also continues its efforts in support of making PDMPs better clinical tools. The use of PDMPs continues to increase in states regardless of mandates—tied mainly to quality of the PDMP as a decision-support tool in those states without mandates. Important policies that have improved PDMP workflow and data reliability include delegate access, data input by pharmacists within 24 hours, and states sharing PDMP information. PDMP usability continues to improve, but usage in rural and other areas may be affected by lack of access to broadband and other technologies. Consistent, long-term funding of state PDMPs is also a concern—most states depend on federal grants for ongoing maintenance and improvements. The AMA also continues to try and identify best practices in designing PDMPs to identify risk including: distinguishing between uncoordinated care, misuse, and “doctor shopping,” identifying opportunities for referrals to specialized care; providing reports to prescribers to better inform prescribing decisions; and conducting public health surveillance activities.¹⁰

One best practice is PDMP and EHR integration, but, as previously discussed, that goal remains largely elusive. It is not clear, for example, how many PDMPs are integrated into EHRs, which makes identification of best practices challenging given the variety of EHR systems in use. Each state PDMP may require a slightly different interface to connect to an EHR. With over 600 different EHRs on the market, the number of custom EHR/PDMP interfaces required can reach into the thousands. Custom software development is time-consuming and expensive—with costs being passed on to the physician. Without PDMP and EHR integration, physicians must use multiple usernames and passwords to shuttle between different systems, often having to re-enter login information if one system times out while they are using the other one. This results in increased time to enter information, decreased satisfaction with the technology, and potentially less use of the systems.

Furthermore, the AMA notes that one dominant PDMP developer is responsible for the PDMP platforms of more than 40 states. PDMP quality and uptake has improved and it is clear that the PDMP interface is moving toward greater integration through the use of more advanced tools offered by the developer.¹¹ This development, along with the growing interstate interoperability has led, anecdotally, to physicians receiving a greater number of alerts about potentially dangerous drug combinations, multiple prescriber events, and other clinical issues. Yet, these advanced tools are not without costs, and it is not clear how these tools may be affecting patient care. The PDMP interface can help identify a patient’s prescription history, but that is only one component of effectively screening a patient for a potential substance use disorder or helping understand whether a patient’s pain is being effectively managed.

Similarly, while there are some positive examples with PDMP-EHR integration, EHRs are generally not interoperable between different organizations, making coordination between primary care physicians, pain medicine physicians, addiction medicine physicians and other providers much more difficult. When PDMP and EHR integration does exist (e.g., Oregon’s EDIE), the patient, public health and cost utilization benefits are extremely positive.¹² This integration requires time and broad, institutional support. For example, the state of Washington’s integration project with the state Health Information Exchange (HIE) began in 2012. As of August 2017, more than 90 percent of emergency departments include PDMP data in the EHR using data through the HIE.¹³ The state’s major health systems still are working to accomplish this integration.

To help resolve some of these issues, the AMA advocates for consistent and sufficient appropriations to support a state’s ability to maintain and improve its PDMP, including broad state-based grants to improve statewide HIEs and the ability to integrate HIE data into the EHR of statewide emergency departments and other providers. The AMA also would support a U.S. Government Accountability Office study on best practices for small and large physician practices on using PDMPs to improve pain care as well as treatment for substance use disorders. This would include identifying how PDMPs can distinguish uncoordinated care from misuse or “doctor shopping” as well as help coordinate care for a patient with a substance use disorder or other condition requiring specialty care. In addition, a need exists to evaluate the variations in state-based PDMP technology and work with the health IT industry to discuss “common understanding” of how each PDMP works—providing transparency for EHR vendors to facilitate development of custom connections between their products and PDMP software. This could include funding for programs that pilot test low-cost technologies to better integrate EHRs and PDMPs as well as efforts to identify burdensome federal regulations that prevent EHRs from being designed and developed to support objective clinical decision-making.

The AMA also has been engaged in the SMART project to help EHR systems work better for physicians and patients. A key component of this effort is the development of a flexible information infrastructure that allows for free, open development of plug and play applications (apps) to increase interoperability among health care technologies, including EHRs, in a more cost-effective way. The infrastructure development specific to PDMPs is part of both ongoing research as well as work by states working to achieve more comprehensive data integration.¹⁴ In addition, the Office of the National Coordinator for Health Information Technology has compiled multiple sources and pilot examples for PDMP and EHR integration.¹⁵ The pilot examples, not surprisingly, found that PDMPs were most helpful when they were integrated into physicians' workflow as well as EHRs.

AMA POLICY

The AMA House of Delegates has provided strong guidance to the AMA that reflects the issues raised by the original resolution that is the subject of this report. Relevant policies include:

Policy H-120.957, "Prescription of Schedule II Medications by Fax and Electronic Data Transmission," which "encourages the Drug Enforcement Administration to support two factor authentication that is easier to implement than the current DEA and EPCS security requirements; and because sufficient concerns exist about privacy and confidentiality, authenticity, and other security measures, does not support the use of "hard copy" facsimile transmissions as the original written prescription for Schedule II controlled substances, except as currently allowed in Section 1306 of Title 21 of the Code of Federal Regulations."

In addition, Policy H-95.928, "Model State Legislation Promoting the Use of Electronic Tools to Mitigate Risk with Prescription Opioid Prescribing," provides that the AMA support multiple facets of PDMP development, including interoperability, assisting physicians and pharmacists in identifying "when their patients have received a prescription for controlled substances from multiple prescribers or multiple pharmacies within a short time frame."

Policy D-478.972, "EHR Interoperability," calls for the AMA to continue efforts in support of EHR interoperability standards, reducing excessive costs and generally reducing barriers to EHR adoption.

Finally, Policy D-478.994, "Health Information Technology," broadly notes AMA support for "legislation and other appropriate initiatives that provide incentives for physicians to acquire health information technology," which reasonably would include PDMP EPCS and EHR uptake.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 212-A-17, and the remainder of the report be filed:

1. That our American Medical Association (AMA) advocate for a federal study to evaluate the use of prescription drug monitoring programs (PDMPs) to improve pain care as well as treatment for substance use disorders. This would include identifying whether PDMPs can distinguish team-based care from uncoordinated care, misuse, or "doctor shopping," as well as help coordinate care for a patient with a substance use disorder or other condition requiring specialty care.
2. That our AMA urge electronic health records (HER) vendors and Health Information Exchanges (HIEs) to increase transparency of custom connections and costs for physicians to integrate their products in their practice.
3. That our AMA support state-based pilot studies of best practices to integrate EHRs, EPCS and PDMPs as well as efforts to identify burdensome state and federal regulations that prevent such integration from occurring.
4. That our AMA support initiatives to improve the functionality of state PDMPs, including (1) lessening the time delay between when a prescription is dispensed and when the prescription would be available to physicians through a PDMP, and (2) directing state-based PDMPs to support improved integrated HER interfaces.

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8. 340B DRUG DISCOUNT PROGRAM (RESOLUTION 225-A-18, RESOLVE 3)

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 225-A-18, RESOLVE 3
REMAINDER OF REPORT FILED
*See Policy H-110.985***

INTRODUCTION

At the 2018 Annual Meeting of the House of Delegates (HOD), the third resolve of Resolution 225-A-18 was referred for report back at the 2018 Interim Meeting. Resolution 225-A-18, sponsored by American Society of Clinical Oncology (ASCO), asked that our American Medical Association (AMA):

- (3) support discontinuing the use of the Disproportionate Share Hospital (DSH) adjustment as a determining measure for 340B program eligibility;

The reference committee heard mixed testimony on this resolve. Testimony was offered that additional research and analysis is needed to assess how to identify the DSH hospitals that should not benefit from 340B program rebates and those that should. The reference committee recommended adopting Resolves 1, 2, and 4, and referral of Resolve 3 for a report back at the 2018 Interim Meeting.

AMA POLICY

Our AMA has an extensive policy that supports increased pharmaceutical drug and biological affordability and policies to ensure patient access to medically necessary prescription medication. However, our AMA does not have specific policy concerning the 340B program other than the HOD adopted resolves of Resolution 225-A-18 (Policy H-110.985, “340B Drug Discount Program”). There is a policy related to rebates which provides that our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation. (Policy H-110.987, “Pharmaceutical Cost”). Thus, there is support for rebate programs to the extent such programs benefit underinsured patients and patients living on low-incomes. Consistent with the foregoing, AMA policy provides support for the subsidization of prescription drugs for Medicare patients based on means testing (Policy H-330.902, “Subsidizing Prescription Drugs for Elderly Patients”). However, AMA policy also includes support for economic assistance, including coupons (and other discounts), for patients, whether they are enrolled in government health insurance programs, enrolled in commercial insurance plans, or are uninsured (Policy H-125.977, “Non-Formulary Medication and the Medicare Part D Coverage Gap”).

BACKGROUND

The 340B program, which is administered by the U.S. Department of Health and Human Services’ (HHS) Health Resources and Services Administration (HRSA), requires pharmaceutical manufacturers to sell outpatient prescription medication at a discount to covered entities. Congress established the 340B program in order to produce savings for certain safety-net health care providers by allowing them to purchase outpatient drugs at these discounted prices.¹ The U.S. House of Representatives’ report, accompanying the original legislation, stated that these savings would “enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”² Pharmaceutical manufacturers are required to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient prescription medication purchased by “covered entities.”

The 340B program definition of “covered entity” includes six categories of hospitals: (1) disproportionate share hospitals (DSHs); (2) children’s hospitals; (3) cancer hospitals exempt from the Medicare prospective payment system; (4) sole community hospitals; (5) rural referral centers; and (6) critical access hospitals (CAHs).³ In addition, to qualify hospitals must be (1) owned or operated by state or local government, (2) a public or private non-profit corporation which is formally granted governmental powers by state or local government, or (3) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare.⁴ Also, hospitals must meet payer-mix criteria related to the Medicare DSH program with the exception of CAHs.⁵ There are also 11 categories of non-hospital covered entities that are eligible based on receiving federal funding that include: federally qualified health centers (FQHCs); FQHC “look-alikes;” state-operated AIDS drug assistance programs; Ryan White Comprehensive AIDS Resources Emergency Act clinics and programs; tuberculosis, black lung, family planning, and sexually transmitted disease clinics; hemophilia treatment centers; Title X public housing primary care clinics; homeless clinics; urban Indian clinics; and Native Hawaiian health centers.⁶ Covered entities may provide drugs purchased through the 340B program to all eligible patients, regardless of a patient’s payer status and whether the drug is intended for self-administration or administration by a clinician. Discounts have been estimated to range from 20-50 percent of the drug’s cost.⁷

DISCUSSION

Affordability and access to prescription medication is an area of increased focus by Congress and the Trump Administration. In the past year the 340B program has become the subject of significant scrutiny. A central question posed by a number of stakeholders: do the rapidly increasing number of DSH hospitals eligible for the 340B program discounts provide low-income patients the benefit of the prescription drug rebates that they receive? (Other aspects of the 340B program, addressed by the newly adopted AMA policy concerning the 340B program, have also been flagged including manufacturer and covered entity noncompliance with 340B program requirements and insufficient federal agency authority and resources to provide appropriate oversight.)

The Affordable Care Act increased the size and scope of the 340B program by expanding eligibility to more types of hospitals, such as critical access hospitals and sole community hospitals, and expanded Medicaid eligibility. As a result of the latter, the number of hospitals qualifying as DSH hospitals increased as DSH designation is calculated based on a formula that utilizes the number of Medicaid covered patients that a hospital serves. The number of

participating unique covered entities has grown from 3,200 in 2011 to 12,722 in October 2017.⁸ The number of hospitals has grown significantly, from 591 in 2005 to 2,479 as of October 2017.⁹

There have also been a number of unintended consequences of the 340B program. A 2015 Avalere study found that hospitals participating in the 340B program were more likely than non-340B hospitals to acquire independent physician practices.¹⁰ These acquisitions create financial windfalls for hospitals due to the 340B program yet do not necessarily improve affordability for patients. Patient costs and resultant co-pays/co-insurance and deductibles for care in a hospital outpatient department (HOPDs) can be higher than those in physician offices.¹¹ (In those instances, patient care in HOPDs is more costly for health insurers too.) Furthermore, some 340B eligible hospitals may have commercial contracts that pay substantially more than the Medicare rate for drugs,¹² so the profit margin can be multiples of the cost of the drug. Patients may face a 20 percent coinsurance on this higher amount. Yet, hospitals eligible for the 340B program obtain drugs at a substantial discount. The 340B program does not require that the hospital pass the savings to uninsured or underinsured low-income patients. To the extent that the hospital does not pass along the savings, the combined payment by insurer and patient provides profit for the 340B hospital; the additional volume generated when 340B hospitals acquire independent physician practices results in even greater profits. There are also reports that hospital systems have acquired 340B program eligible hospitals in order to purchase drugs for their suburban clinics utilizing the discounts even though such clinics do not serve uninsured or underinsured low-income patients.

There have been several congressional hearings on the 340B program convened by the U.S. Senate's Health, Education, Labor, and Pension (HELP) Committee as well as the U.S. House of Representatives' Energy and Commerce (E&C) Committee. Testimony offered by the U.S. Government Accountability Office (GAO),¹³ the HHS Office of the Inspector General (OIG),¹⁴ and other witnesses included concerns with the 340B program's: (1) inadequate "patient" definition; (2) eligibility criteria for covered entity; (3) oversight of covered entities and manufacturers; and (4) oversight of the use of contract pharmacies. The lack of program data to assess the extent to which 340B program covered entities are ensuring low-income patients benefit from the rebates and the savings has particularly troubled policymakers and other stakeholders.

In addition to the hearings, over 17 federal bills have been introduced concerning the 340B program in this Congress. A number of the bills would mandate reporting on care provided to low-income individuals and would impose new eligibility requirements for certain categories of covered entities. For example, in December 2017, Representative Larry Buschon (R-IN) introduced H.R. 4710, Protecting Access for Underserved and Safety-net Entities Act (340B PAUSE Act). The bill would impose a moratorium on registration for certain new 340B program hospitals and associated sites. H.R. 4710 would also mandate data collection by covered entities including the number and percentage of insured (by insurer) and uninsured individuals who are dispensed or administered 340B program discounted drugs. In January 2018, Senator Bill Cassidy (R-LA) introduced S. 2312, Helping Ensure Low-income Patients have Access to Care and Treatment Act (HELP Act). The bill would impose a registration moratorium on new non-rural 340B program covered entities and associated sites as well as new eligibility requirements for covered entities. It would also require reports on the level of charity care provided by covered entities. Similarly, in April 2018, Representative Earl Carter (R-GA) introduced H.R. 5598, 340B Optimization Act. The bill would amend the Public Health Service Act to require certain disproportionate share hospital covered entities under the 340B drug discount program submit to HHS reports on low-income utilization rates of outpatient hospital services furnished by such entities.

In order to address the lack of data available directly from 340B program hospital covered entities or HRSA vis-à-vis the benefit to low-income patients, the House E&C Committee Chairman Greg Walden (R-OR) and health subcommittee Chairman Michael Burgess (R-TX) requested a report on the topic from the GAO. On June 18, 2018, the GAO issued the report, [Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program](#). The report found that:

[i]n 2016 ... the median amount of charity care provided by all 340B hospitals ... was similar to the median amount provided by all non-340B hospitals, and the median amount of uncompensated care provided by these 340B hospitals was higher than that provided by their non-340B counterparts. But again, the differences between the 340B and non-340B hospitals varied across the different hospital types. For example, while the median amount of uncompensated care provided by 340B general acute care hospitals (340B DSH) was higher than that of their non-340B counterparts, the median amount provided by 340B CAHs was lower than that of non-340B CAHs.

While the report provides additional needed analysis and data, more information is needed concerning the programs implementation and benefit to low income patients. To ensure the 340B program covered entity criteria aligns with the goal of ensuring low income patients are able to access affordable treatments, at least one national medical specialty society has recommended that Congress establish new metrics that such entities must meet that are objective, universal, verifiable and align program eligibility with the care provided by the covered entity to indigent and underserved individuals. Consistent with the foregoing, alternative eligibility measures could be calculated by analyzing the amount of charity care provided by hospitals in the outpatient setting. Ultimately, eligibility should be designed to qualify entities based on the amount of care delivered to underserved populations in outpatient settings. This would dovetail with new AMA policy to work with policymakers to establish 340B program eligibility for all physician practices demonstrating a commitment to serving low-income and underserved patients, new covered entity criteria should promote participation by institutions and practices of all sizes in all settings. To advance this goal, ASCO has convened an expert workgroup to develop recommendations for a revised eligibility formula in order to appropriately capture the level of outpatient charity care provided by hospitals, as well as standalone community practices. ASCO will provide policymakers and other stakeholders with the recommendations during the current congressional session.

CONCLUSION

The significant growth of the 340B program, particularly among DSH hospitals, should align with newly adopted HOD policy concerning 340B program and related AMA policies. Specifically, the program should promote access to affordable prescription drugs by low-income patients receiving care from 340B program covered entities. In addition, our AMA should engage with national medical specialty societies to leverage expertise and align recommendations to federal policymakers.

RECOMMENDATIONS

In light of these considerations, your Board of Trustees recommends that the following recommendations be adopted in lieu of the third resolve Resolution 225-A-18 and the remainder of this report be filed:

1. That our American Medical Association support a revised 340B drug discount program covered entity eligibility formula, which appropriately captures the level of outpatient charity care provided by hospitals, as well as standalone community practices.
2. Our AMA will confer with national medical specialty societies on providing policymakers with specific recommended covered entity criteria for the 340B drug discount program.

REFERENCES

1. Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b.
2. H.R. Rept. No. 102-384 (Part 2), at 12 (1992) (Conf. Rept.).
3. 42 U.S.C. § 256b(a)(4)(A)–(K)
4. Id.
5. Id.
6. Id.
7. Statement of Debra A. Draper Director, Health Care, GAO, July 18, 2017, U.S. House of Representatives, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce hearing on Drug Discount Program, Updated on Agency Efforts to Improve 340B Program Oversight, Available from <https://www.gao.gov/assets/690/685903.pdf>
8. Review of the 340B Drug Pricing Program, U.S. House of Representatives Energy and Commerce Committee. Available from: https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf
9. Id.
10. Hospital Acquisitions of Physician Practices and the 340B Program, June 2015, Available from <http://340breform.org/userfiles/Avalere%20Acquisition.pdf>; and, National Patient Advocate Foundation’s Response to Additional Questions for the Record Relating to the Hearing Entitled “Examining Reforms to Improve the Medicare Part B Drug Program for Seniors” July 2013, Available from <https://docs.house.gov/meetings/IF/IF14/20130628/101055/HHRG-113-IF14-Wstate-Davenport-EnnisN-20130628-U4.pdf>
11. An Avalere report on Cost of Cancer Care stated that its “risk-adjusted results suggest that treatment for patients receiving chemotherapy in a HOPD costs on average 24 percent more than treatment received in a physician’s office.” Available from <http://www.communityoncology.org/pdfs/avalere-cost-of-cancer-care-study.pdf>

12. Physician-administered Drugs: Comparison of Payer Payment Methodologies, U.S. Government Accountability Office, August 2016, Available at <https://www.gao.gov/assets/680/678784.pdf>
13. Statement of Debra A. Draper, Director, Health Care, GAO, May 15, 2018, U.S. Senate Committee on Health, Education, Labor, and Pensions hearing on Examining Oversight Reports on the 340B Drug Price Program.
14. Testimony of Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, OIG HHS, May 15, 2018, U.S. Senate Committee on Health, Education, Labor, and Pensions hearing on Examining Oversight Reports on the 340B Drug Price Program.

9. HOSPITAL CLOSURES AND PHYSICIAN CREDENTIALING (RESOLUTION 716-A-18)

Reference committee hearing: see report of Reference Committee J.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 716-A-18
REMAINDER OF REPORT FILED
*See Policy D-230.984***

At the 2018 Annual Meeting, the House of Delegates (HOD) referred Resolution 716-A-18, “Hospital Closures and Physician Credentialing.” Resolution 716 was sponsored by the Organized Medical Staff Section and asked the AMA to:

work with appropriate stakeholders—such as the AMA Organized Medical Staff Section and National Association Medical Staff Services (NAMSS)—to produce an AMA credentialing repository that would allow hospitals and other organizations that credential physicians to access verified credentialing information for physicians who were on staff at a hospital (or one of its departments) at the time of closure, and report back at the 2018 Interim Meeting.

Testimony largely supported the intent of Resolution 716. However, some members noted that not only would the cost of implementing Resolution 716 be significant, but there are also many unanswered questions about the demand for such a service and how it would work. Other members were concerned as to whether the AMA is the organization best positioned to take up this issue.

DISCUSSION

Resolution 716 suggests that a lack of institutional policies for preserving medical staff credentialing files when a hospital closes can lead to undue delays in future credentialing efforts due to inaccessibility of historical credentialing information. To minimize the potentially devastating impact this shortcoming may have on physicians and other displaced medical staff members, Resolution 716 asks that the AMA create a centralized repository to facilitate the verification of credentialing information as it relates to a physician’s hospital affiliation history.

Existing AMA policy supports the appropriate disposition of physician credentialing records following the closure of hospitals, ambulatory surgery facilities, nursing homes and other health care facilities. Policy H-230.956, “Hospital, Ambulatory Surgery Facility, Nursing Home, or Other Health Care Facility Closure: Physician Credentialing Records” states that, where in accordance with state law and regulations, “[t]he governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility shall be responsible for making arrangements for the disposition of physician credentialing records or CME information upon the closing of a facility...” and “...make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, CME information, and medical staff status.” Policy H-230.956 also states that the closing facility “...shall attempt to make arrangements with a comparable facility for the transfer and receipt of the physician credentialing records or CME information.”

Notwithstanding this comprehensive policy, a thorough review of existing law reveals few requirements for the retention of physician credentialing records when a hospital closes. While some states require hospitals to implement policies for the preservation of medical staff credentialing files (e.g., Illinois and New York), most states have no specific law or regulations providing for the timely transfer of medical staff credentialing files and proper notification

to physicians of the location of those files. As a starting point, the AMA should encourage emulation of appropriate existing laws and regulations by developing model state legislation that supports timely physician access to credentialing files following the closure of a hospital.

Even if closing hospitals were required by law to preserve credentialing files, it remains to be seen where and how this information would be most appropriately stored. Resolution 716 suggests the development of a comprehensive and centralized repository of credentialing files from closed hospitals. States, payors, and other stakeholders are already in the process of developing credentialing repositories for verification of physicians' current and past hospital affiliations. For example, Oregon passed legislation to establish a centralized credentialing database from which medical staff professionals, hospitals, health plans, and other organizations can get up-to-date information on every licensed physician in the state. Additionally, the National Association Medical Staff Services (NAMSS) has launched an online repository to provide medical staff offices a place to quickly find and upload physician affiliation history. Either of these efforts could be expanded to address the problems raised by closed facilities. Recognizing the value that the AMA could provide alongside expert leaders in the credentialing industry, the AMA should continue to monitor these efforts and explore the feasibility of developing a universal clearinghouse that centralizes the verification of physician practice and affiliation history.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 716-A-18 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-230.956, which states that the governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility should be responsible for making arrangements for the disposition of physician credentialing records upon the closing of a facility and should make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, and medical staff status.
2. That our AMA develop model state legislation and regulations that would require hospitals to: (a) implement a procedure for preserving medical staff credentialing files in the event of the closure of the hospital; and (b) provide written notification to its state health agency and medical staff before permanently closing its facility indicating whether arrangements have been made for the timely transfer of credentialing files and the exact location of those files.
3. That our AMA: (a) continue to monitor the development and implementation of physician credentialing repository databases that track hospital affiliations, including tracking hospital closures, as well as how and where these closed hospitals are storing physician credentialing information; and (b) explore the feasibility of developing a universal clearinghouse that centralizes the verification of credentialing information, and report back to the House of Delegates at the 2019 Interim Meeting.

APPENDIX - Relevant AMA Policy

H-230.956, "Hospital, Ambulatory Surgery Facility, Nursing Home, or Other Health Care Facility Closure: Physician Credentialing Records"

1. AMA policy regarding the appropriate disposition of physician credentialing records following the closure of hospitals, ambulatory surgery facilities, nursing homes and other health care facilities, where in accordance with state law and regulations is as follows:
 - A. **Governing Body to Make Arrangements:** The governing body of the hospital, ambulatory surgery facility, nursing home, or other health care facility shall be responsible for making arrangements for the disposition of physician credentialing records or CME information upon the closing of a facility.
 - B. **Transfer to New or Succeeding Custodian:** Such a facility shall attempt to make arrangements with a comparable facility for the transfer and receipt of the physician credentialing records or CME information. In the alternative, the facility shall seek to make arrangements with a reputable commercial storage firm. The new or succeeding custodian shall be obligated to treat these records as confidential.

- C. Documentation of Physician Credentials: The governing body shall make appropriate arrangements so that each physician will have the opportunity to make a timely request to obtain a copy of the verification of his/her credentials, clinical privileges, CME information, and medical staff status.
 - D. Maintenance and Retention: Physician credentialing information and CME information transferred from a closed facility to another hospital, other entity, or commercial storage firm shall be maintained in a secure manner intended to protect the confidentiality of the records.
 - E. Access and Fees: The new custodian of the records shall provide access at a reasonable cost and in a reasonable manner that maintains the confidential status of the records.
2. Our AMA advocates for the implementation of this policy with the American Hospital Association.

10. TRAINING PHYSICIANS AND PHYSICIANS-IN-TRAINING IN THE ART OF PUBLIC SPEAKING (RESOLUTION 606-A-18)

Reference committee hearing: see report of Reference Committee F.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 606-A-18
REMAINDER OF REPORT FILED
TITLE CHANGED
*See Policy H-445.984***

INTRODUCTION

At the 2018 Annual Meeting, the House of Delegates referred Resolution 606 as introduced by the delegation from New Jersey to the Board of Trustees, to investigate a proposal that the AMA should “establish a program for training physicians in the art and science of conducting public forums in order to ensure that the public is well informed on the health care system of our country.”

Within the reference committee, there was considerable supportive testimony about the need to improve physicians’ ability to speak publicly. Several who testified believed that the resources needed to undertake training in public speaking are already available throughout the Federation and could be utilized instead of creating new training materials. However, others believed that developing the ability of physicians to positively present themselves in the public arena is too important to leave to other organizations, and that training in public speaking could be offered as a valuable AMA member benefit.

In evaluating the goal and the desired outcome, it is important to survey the existing landscape of resources available to physicians to help inform AMA’s approach.

BACKGROUND

The leading organization that assists individuals with public speaking and leadership development is Toastmasters International. Individuals can improve their speaking and leadership skills by attending one of the 16,400 clubs worldwide. By regularly giving speeches and receiving feedback, individuals can learn to tell their stories and leverage their voices.

AMPAC, the bipartisan political action committee of the American Medical Association, provides high level training to physicians who are considering pursuit of elected office. For those who want to campaign for public office and advocate for issues important to patients and physicians, this is a premiere training program and valuable resource for physicians.

Other general communication resources available by the AMA include STEPS Forward modules on topics like “Conducting Effective Team Meetings” and “Implementing a Daily Team Huddle.”

Within the Federation, several physician groups provide opportunities for training on effective communications, including the American College of Physicians, American Academy of Family Physicians, and the American Medical Women's Association.

Perhaps the leader in providing this training to physicians is the American Association of Physician Leadership (AAPL). Training topics offered by this organization include: "Present like a Pro," "Delivering Effective Feedback," "Fundamentals of Physician Leadership: Communication," and "Improving Communication and Feedback in Healthcare Leadership." Courses are offered online or in-person. Many of the self-study courses offer the option to watch the video lectures or attend the sessions. A majority of the courses are accessible for up to three years after purchase. The organization also offers live education courses that allow physicians to network with their peers. There are also faculty-led courses that allow physicians to participate in discussions and case studies throughout a six-week class session.

RECOMMENDATION

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 606-A-18 and the remainder of the report be filed.

1. Physicians who want to learn more about public speaking can leverage existing resources both within and outside the AMA. AMA can make public speaking tips available through online tools and resources that would be publicized on our website. Physicians and physicians-in-training who want to publicly communicate about the AMA's ongoing work are invited to learn more through the AMA Ambassador program.

Meanwhile, STEPS Forward[®] provides helpful tips to physicians and physicians-in-training wanting to improve communication within their practice, and AMPAC is available for physicians and physicians-in-training who want to advocate and communicate about the needs of patients, physicians and physicians-in-training in the pursuit of public office. There are also resources provided to physicians and physicians-in-training at various Federation organizations and through the American Association of Physician Leadership (AAPL) to support those who are interested in training of this nature.

Because public speaking is a skill that is best learned through practice and coaching in a small group or one-on-one setting, we also encourage individuals to pursue training through their state or specialty medical society or through a local chapter of Toastmasters International.

The Board of Trustees recommends that the AMA's Enterprise Communications and Marketing department work to develop online tools and resources that would be published on the AMA website to help physicians and physicians-in-training learn more about public speaking.

2. That our AMA offer live education sessions at least annually for AMA members to develop their public speaking skills.

11. VIOLENCE PREVENTION (RESOLUTION 419-A-18, RESOLVES 1 AND 3)

Reference committee hearing: see report of Reference Committee B.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 419-A-18, RESOLVES 1 AND 3,
AND RESOLUTIONS 213 AND 233
REMAINDER OF REPORT FILED**

See Policies H-140.970, H-145.972, H-145.990, H-145.994 and H-145.996

INTRODUCTION

Resolution 419-A-18, "Violence Prevention," was introduced by the Washington Delegation. The first and third Resolves, which were referred by the House of Delegates, asked:

That our American Medical Association (1) advocate that a valid permit be required before the sale of all rapidly-firing semi-automatic firearms and (3) study options for improving the mental health reporting systems and patient privacy laws at both the state and federal levels and how those can be modified to allow greater information sharing between state and federal government, law enforcement, schools and mental health professionals to identify, track and share information about mentally ill persons with high risk of violence and either report to law enforcement and/or the National Instant Criminal Background Check System, with appropriate protections.

Accordingly, this report addresses both firearm licensing and mental health reporting requirements.

CURRENT AMA POLICY

As one of the main causes of intentional and unintentional injuries and deaths, the American Medical Association (AMA) recognizes that firearm-related violence is a serious public health crisis in the United States. The AMA has extensive policy on firearm safety and violence prevention. Relevant to this report is existing policy that supports requiring the licensing of firearm owners, including completion of a required safety course and registration of all firearms. The AMA also supports a waiting period and background check for all firearm purchasers.

AMA also supports (1) the establishment of laws allowing family members, intimate partners, household members, and law enforcement personnel to petition a court for the removal of a firearm when there is a high or imminent risk for violence; (2) requiring states to have protocols or processes in place for requiring the removal of firearms by prohibited persons; (3) requiring gun violence restraining orders to be entered into the National Instant Criminal Background Check System; and (4) efforts to ensure the public is aware of the existence of laws that allow for the removal of firearms from high-risk individuals.

BACKGROUND

Council on Science and Public Health Report 4-A-18, “The Physician’s Role in Firearm Safety,” reviewed the epidemiology of firearm morbidity and mortality, identified barriers to physician counseling, discussed the 11th U.S. Circuit Court of Appeals decision, which held that Florida’s Firearm Owners’ Privacy Act violated the First Amendment, explained that there are no state or federal laws that prohibit physicians from counseling patients on firearm safety, outlined the risk factors for firearm injuries, and identified policies that grant the authority to remove firearms from high-risk individuals who already possess them. Because these issues were recently addressed, they are not considered in this report. This report focuses on the issues of licensing of firearm purchasers and mental health reporting.

The National Instant Criminal Background Check System (NICS)

The Brady Handgun Violence Prevention Act of 1993 required the establishment of a computerized system to facilitate background checks on individuals seeking to acquire firearms from federally licensed firearms dealers. The NICS was activated in 1998 and is administered by the Federal Bureau of Investigation (FBI). In 2010, federal and state agencies conducted 10.4 million background checks and more than 150,000 purchases were denied when purchasers were identified as prohibited persons.¹ However, records in the NICS are provided voluntarily by state, local, tribal, and federal agencies. Inconsistencies in states’ reporting of disqualifying records to the NICS, as well as loopholes (i.e., unlicensed dealers) in the requirements for background checks prior to a firearm purchase, contribute to the lack of success in consistently identifying individuals who are disqualified from possessing firearms.

Prohibited Persons and Mental Health

The federal Gun Control Act (GCA) of 1968 makes it unlawful for certain categories of persons to ship, transport, receive, or possess firearms or ammunition. Those categories include, but are not limited to individuals convicted of a felony; unlawful users or those with addiction involving any controlled substance; individuals adjudicated as a “mental defective” or under an order of civil commitment; individuals subject to a court order restraining them from harassing, stalking, or threatening an intimate partner or child of the intimate partner; or persons who have been convicted of a misdemeanor crime of domestic violence. “Adjudicated as a mental defective” is further defined as:

A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease: (1) Is a danger to himself or to others; or (2) Lacks

the capacity to manage his own affairs. The term shall include – (1) a finding of insanity by a court in a criminal case, and (2) those persons found incompetent to stand trial or found not guilty by lack of mental responsibility (under the Uniform Code of Military Justice).²

Furthermore, “committed to a mental institution” is defined as:

A formal commitment of a person to a mental institution by a court, board, commission, or other lawful authority. The term includes a commitment to a mental institution involuntarily. The term includes commitment for mental defectiveness or mental illness. It also includes commitments for other reasons, such as for drug use. The term does not include a person in a mental institution for observation or a voluntary admission to a mental institution.³

It is important to note that a diagnosis of, or treatment for, mental illness does not alone qualify an individual for reporting to the NICS.^{4, 5} Existing federal criteria for firearm-disqualifying mental health records are not perfect. They have been criticized for being both over-inclusive and under-inclusive.⁶ It is the American Psychiatric Association’s position that:

Reasonable restrictions on gun access are appropriate, but such restrictions should not be based solely on a diagnosis of mental disorder. Diagnostic categories vary widely in the kinds of symptoms, impairments, and disabilities found in affected individuals. Even within a given diagnosis, there is considerable heterogeneity of symptoms and impairments.⁷

Furthermore, individuals with mental illness, when appropriately treated, do not pose an increased risk of violence compared with the general population.⁸ However, mental illness is strongly associated with suicide, which represents nearly 60 percent of firearm-related deaths in the United States.

DISCUSSION

State Licensing Requirements

Federal law does not require the licensing of firearm purchasers or owners. A number of states have enacted licensing requirements to help prevent prohibited individuals from purchasing firearms. Different types of firearm licensing laws exist in states. Permits-to-purchase (PTP) licensing systems require prospective firearm purchasers to have direct contact with law enforcement or judicial authorities that review the purchase application and verify the passage of a background check.⁹ While similar to PTP laws, license to own firearm laws differ in that the license must remain valid for as long as the person owns the firearm. Firearm safety certificates require completion of a required safety training course as a part of the firearm licensing process in addition to the passage of a background check. Firearm registration laws require individuals to record their ownership of a firearm with a designated law enforcement agency.

PTP laws, which have been enacted in 10 states and the District of Columbia, are the most common type of firearm licensing laws.¹⁰ In these jurisdictions, both licensed and unlicensed dealers can only sell firearms to individuals with a current PTP license, closing the loophole that exists under federal law. While the licensing requirements vary by state, they generally require an individual to fill out a license or permit application form, submit the form in-person to the licensing authority, and pay the required fees. A background check through the NICS is usually required. Some states also require fingerprints to be taken as a part of the application process. In some jurisdictions (Massachusetts, New York and New Jersey), law enforcement agencies have discretion in denying a permit. If approved, the permit or license is issued. State licensing laws usually apply to specific types of firearms (i.e., handguns or long guns and rifles).

States with PTP laws tend to have lower firearm-related death rates than states without these laws after controlling for demographic, economic and other differences across states.¹¹ Evidence suggests that state laws leading to tighter regulation of sale and possession of firearms, including PTP laws, reduce the availability of in-state guns involved in crimes and traced by law enforcement.¹² Furthermore, criminals who used firearms in places with PTP laws typically acquired them from states with weaker laws.¹³ PTP laws also are associated with reductions in firearm homicide and suicide rates. Connecticut’s PTP law was associated with a 40 percent reduction in firearm homicide rates during the first 10 years the law was in place while there was no evidence for a reduction in non-firearm homicides.¹⁴ Missouri’s firearm-related homicide rate increased abruptly after the state repealed its PTP handgun licensing law in 2007. The state saw a 25 percent higher rate in the first three years post repeal than during the prior nine years.¹⁵ A study

conducted in large urban counties found that PTP laws were associated with a 14 percent reduction in firearm homicides.¹⁶ PTP law enactment was associated with protective effects against firearm suicides in Connecticut, and PTP repeal in Missouri was associated with increased risk of firearm suicides.¹⁷

Mental Health Reporting

In 2007, the NICS Improvement Amendments Act (NIAA) authorized the Attorney General to provide grants to states to improve electronic access to records and incentivize states to turn over records of persons prohibited from possessing firearms.¹⁸ The NIAA created the NICS Act Record Improvement Program (NARIP), which provides funding to states to ensure that the appropriate mental health records are included in the NICS. In November of 2011, a report by Mayors Against Illegal Guns found that for complex legal and logistical reasons, records of serious mental health and substance use problems that disqualify people from firearm ownership have been difficult to capture in NICS.¹⁹ In 2012, the Government Accountability Office examined states' progress in reporting mental health records to the NICS. They found that from 2004 to 2011, the total number of mental health records that states made available to the NICS increased by 800 percent – from 126,000 to 1.2 million records.²⁰ However, the increase largely reflected the efforts of 12 states. A variety of technological, coordination, and legal (i.e., privacy) challenges limit states' ability to report mental health records.²¹

Technological challenges are relevant to mental health reporting because the records originate from multiple sources within a state (i.e., courts, private hospitals, state mental health agencies) and are not captured by a single agency.²² In terms of legal challenges, some states indicated that the lack of explicit state-level authority to share mental health records with NICS was an impediment.²³ Coordination challenges involved getting hospitals and departments of mental health to collaborate with law enforcement, who make the majority of records available to NICS.²⁴ Non-criminal justice entities may not be aware of NICS reporting requirements, or, if they are aware, may be unfamiliar with how to report.

Relationship to NARIP Funding. NARIP funding has been provided to states to address these barriers. In order to receive NARIP funding, states are required to have a “relief from disabilities statute” whereby firearm purchasing rights can be restored to a person who had them removed because of a mental health adjudication or involuntary commitment. Information on the level of funding by state from FY 2009-2017, as well as promising practices for improved record reporting to the NICS, are available on the Bureau of Justice Statistics website.²⁵ As of July 2015, there were 3.8 million state-submitted mental health records in the NICS.²⁶ Forty-three states have enacted laws that require (32) or authorize (11) the reporting of mental health records to NICS. The largest increase in reported mental health data from 2008 to 2015 occurred in states with a reporting requirement.²⁷ Twenty of the 26 states with the largest increase in mental health data also received NARIP funding.

HIPAA Considerations. In 2013 there was considerable focus on whether the Health Insurance Portability and Accountability Act (HIPAA) or state privacy laws were an obstacle to the submission of mental health records to NICS.²⁸ On January 4, 2016, the U.S. Department of Health and Human Services modified HIPAA to expressly permit certain covered entities to disclose to the NICS the identities of those individuals who, for mental health reasons, are prohibited by federal law from having a firearm.²⁹ The final rule noted that creating a limited express permission in the HIPAA Privacy Rule to use or disclose certain information relevant to the federal mental health prohibitor for NICS purposes was necessary to address barriers related to HIPAA, and to ensure that relevant information can be reported for this important public safety purpose. The rule specifically prohibits the disclosure of diagnostic or clinical information from medical records or other sources, and any mental health information beyond the indication that the individual is subject to the federal mental health prohibitor, and does not apply to most treating providers.³⁰

Education Records. The Family Educational Rights and Privacy Act (FERPA) is a Federal law that protects the privacy of student education records. Due to the nature of mental health records reported to the NICS, schools are not likely to be among the organizations reporting. However, FERPA does have an exception that allows educational agencies and institutions to disclose personally identifiable information from education records to appropriate parties in connection with an emergency if knowledge of the information is necessary to protect the health and safety of the student or other individuals.³¹ The information may be disclosed to any person whose knowledge of the information is necessary to protect the health or safety of the student or other individuals.

CONCLUSION

The AMA House of Delegates adopted policy at A-18 to require the licensing of all firearm owners. PTPs are a type of license, thus a separate policy requiring a permit prior to the sale of rapidly-firing semi-automatic firearms is not necessary. This requirement is encompassed in the existing licensing policy. However, amending the policy to clarify that permits are a type of license would be helpful to avoid future confusion.

In terms of mental health reporting, several national reports have identified the technological, coordination, and legal (i.e., privacy) challenges that limit states' ability to report mental health records to the NICS. In recent years, progress has been made to increase the reporting of these records through the enactment of state reporting requirements, federal grants to states to address collaboration through state level task forces focused on NICS improvement, training to help identify the records that should be reported, automated transfer of mental health data to the NICS, and clarification of federal privacy laws. In addition, legislation was enacted by Congress as part of the FY 2018 Omnibus Appropriations bill—the Fix NICS Act of 2017—that, among other provisions, requires states to develop a plan to ensure maximum coordination and automation of the reporting the NICS.³² The law also reauthorizes NARIP through FY 2022.³³ While existing AMA policy supports a waiting period and background checks for all firearm purchases, AMA policy does not currently address deficiencies in the current NICS system.

In addition to the NICS system, it is important to have policies in place that remove current access to firearms rather than just preventing the purchase of new firearms by individuals who are at high or imminent risk for harming themselves or others. The Council on Science and Public Health report and recommendations on “The Physician’s Role in Firearm Safety,” at A-18 led to the adoption of policy addressing the removal of firearms from high risk individuals, which includes support for gun violence restraining orders. Since overlapping policy on gun violence restraining was adopted and appended to Policy H-145.996, “Firearm Availability.” We recommend streamlining AMA policy in this area and removing the reference to “red flag” laws.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of the first and third resolves of Resolution 419-A-18 and the remainder of the report be filed.

1. That Policy H-145.996, “Firearm Availability,” be amended by addition and deletion to read as follows:

H-145.996, Firearm Availability

1. Our AMA: (a) Advocates a waiting period and background check for all firearm purchasers; (b) encourages legislation that enforces a waiting period and background check for all firearm purchasers; and (c) urges legislation to prohibit the manufacture, sale or import of lethal and non-lethal guns made of plastic, ceramics, or other non-metallic materials that cannot be detected by airport and weapon detection devices.

2. Our AMA ~~policy is to~~ supports requiring require the licensing/permitting of owners of firearms-owners and purchasers, including the completion of a required safety course, and registration of all firearms.

3. ~~Our AMA supports local law enforcement in the permitting process in such that local police chiefs are empowered to make permitting decisions regarding “concealed carry”, by supporting “gun violence restraining orders” for individuals arrested or convicted of domestic violence or stalking, and by supporting “red flag” laws for individuals who have demonstrated significant signs of potential violence. In supporting local law enforcement, we support as well the importance of “due process” so that decisions could be reversible by individuals petitioning in court for their rights to be restored. Our AMA supports “gun violence restraining orders” for individuals arrested or convicted of domestic violence or stalking, and supports extreme risk protection orders, commonly known as “red-flag” laws, for individuals who have demonstrated significant signs of potential violence. In supporting restraining orders and “red-flag” laws, we also support the importance of due process so that individuals can petition for their rights to be restored.~~

2. That Policy H-145.972, “Firearms and High-Risk Individuals,” be reaffirmed.

H-145.972, Firearms and High-Risk Individuals

Our AMA supports: (1) the establishment of laws allowing family members, intimate partners, household members, and law enforcement personnel to petition a court for the removal of a firearm when there is a high or imminent risk for violence; (2) prohibiting persons who are under domestic violence restraining orders, convicted

of misdemeanor domestic violence crimes or stalking, from possessing or purchasing firearms; (3) expanding domestic violence restraining orders to include dating partners; (4) requiring states to have protocols or processes in place for requiring the removal of firearms by prohibited persons; (5) requiring domestic violence restraining orders and gun violence restraining orders to be entered into the National Instant Criminal Background Check System; and (6) efforts to ensure the public is aware of the existence of laws that allow for the removal of firearms from high-risk individuals.

3. That our American Medical Association: (1) encourages the enactment of state laws requiring the reporting of all classes of prohibited individuals, as defined by state and federal law, to the National Instant Criminal Background Check System (NICS); (2) supports federal funding to provide grants to states to improve NICS reporting; and (3) encourages states to automate the reporting of relevant information to NICS to improve the quality and timeliness of the data.
4. That Policy H-145.990, "Prevention of Firearm Accidents in Children," be amended by addition and deletion to read as follows:

H-145.990, Prevention of Firearm Accidents in Children

Our AMA (1) supports increasing efforts to reduce pediatric firearm morbidity and mortality by encouraging its members to (a) inquire as to the presence of household firearms as a part of childproofing the home; (b) educate patients to the dangers of firearms to children; (c) encourage patients to educate their children and neighbors as to the dangers of firearms; and (d) routinely remind patients to obtain firearm safety locks, to store firearms under lock and key, and to store ammunition separately from firearms; (2) encourages state medical societies to work with other organizations to increase public education about firearm safety; ~~and~~ (3) encourages organized medical staffs and other physician organizations, including state and local medical societies, to recommend programs for teaching firearm safety to children; and (4) support enactment of Child Access Prevention laws that are consistent with AMA policy.

5. That Policy H-145.994, "Control of Non-Detectable Firearms," be amended by addition to read as follows:

H-145.994, Control of Non-Detectable Firearms

The AMA supports a ban on the (1) manufacture, importation, and sale of any firearm which cannot be detected by ordinary airport screening devices, including 3D printed firearms and (2) production and distribution of 3D firearm digital blueprints.

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33. Public Law No: 115-141.

12. INFORMATION REGARDING ANIMAL-DERIVED MEDICATIONS (RESOLUTION 515-A-18)

Reference committee hearing: see report of Reference Committee K.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 515-A-18
REMAINDER OF REPORT FILED
See Policy H-100.947**

INTRODUCTION

Resolution 515-A-18, "Information Regarding Animal Derived Medications," introduced by the Michigan Delegation and referred by the House of Delegates (HOD) asked:

That our American Medical Association (AMA): (1) Support efforts to improve cultural awareness pertaining to the use of animal-derived medications when considering different prescription options. (2) Encourage the U.S. Food and Drug Administration to make available to the public an easily accessible database that identifies medications containing ingredients derived from animals.

Some chemical products used as inactive excipients for prescription drugs, as well as some active prescription medications and also some surgical implants, dressings, and mesh, are derived from animal sources. The consumption

or use of such products may be objectionable to certain religions or based on consumer choice. The objective of this report is to summarize the issue and current evidence related to animal-derived components of medical products.

BACKGROUND

Some religious faiths forbid the consumption or use of certain animals and substances derived from them. Additionally, individuals who adhere to a vegetarian or vegan diet may prefer to avoid animal-derived medical products. Individuals who want to avoid animal-derived substances for religious or cultural reasons may inquire about the origin or source of the ingredients in their medical products for informed decision-making regarding treatment with the product. Frequently, however, the information regarding ingredients or composition in medications is difficult to obtain by physicians, pharmacists, and patients.¹

Many pharmaceutical products (both active and inactive ingredients used in capsules, tablets, injections, vaccines, creams) and surgical products (implants, wound dressings, surgical mesh) contain ingredients derived from animal sources. Animal-derived ingredients (ADIs) are used in many medical fields and cover an array of products usually at minimal concentrations.¹ However, a substantial percentage of patients and physicians are unaware that some medications and medical products contain animal products;² one survey indicated that 84% of patients and 70% of physicians were unaware that several medications contain ADIs. Additionally, 70% of physicians thought it was important to inform patients who might object if such medications are prescribed.³ Some authors have even suggested obtaining informed consent before using animal-derived products.¹

POLICY AND LAW

The U.S. Pharmacopeial Convention is a private, nongovernmental organization that publishes the United States Pharmacopeia (USP) and the National Formulary (NF) as official compendia, collectively called the USP-NF. The Federal Food, Drug and Cosmetic Act (FFDCA) expressly recognizes the USP quality standards for medicines.⁴ Although much of the USP-NF is legally enforceable, the USP chapters numbered above <999> are general information and generally do not contain any mandatory requirements, but can include recommendations that may help a firm meet the requirements of current good manufacturing processes (CGMPs) as defined by the U.S. Food and Drug Administration (FDA).⁵

FDA Guidance regarding CGMP includes recommendations and precautions when manufacturing ADIs to ensure that contamination by pathogenic agents does not occur. No guidance regarding labeling of ADIs could be located. Although the FDA does have a database that provides information on inactive ingredients present in FDA-approved drug products, its main purpose is to aid industry in drug development; once an inactive ingredient is part of the formulation for an approved drug product, it is no longer considered new and may require less extensive review when used again. The database includes no information regarding the source of the ingredient.⁶

USP-NF general chapter <7> “Labeling” details the requirements for the labeling of active ingredients in pharmaceutical products. No discussion of ingredient source is included. It is noted, however, that many monographs have unique labeling requirements that should be used consistently. USP-NF informational chapter <1091> “Labeling of Inactive Ingredients” states that all ingredients should be disclosed for all medications. The information can be found on the package or insert of a prescription drug and on the drug facts label on the outside of the box for over-the-counter drugs. No requirement exists for a manufacturer to declare how an ingredient is sourced. Additionally, the Code of Federal Regulations calls for all ingredients to be listed, but inactive ingredients are exempt from provisions on misbranding, including some that relate to false or misleading labeling.⁷

CULTURAL CONSIDERATIONS

Some religious groups avoid products from certain animals and many patients have strong religious convictions and beliefs. Vegetarians do not consume foods either directly obtained or using products from the slaughter of an animal. Vegans do not consume any foods originating from animals.

Several investigators have surveyed worldwide religious leaders for their opinions regarding the acceptability of certain medical products, both medications and surgical implants/dressings/mesh, for their religions.^{1,8-11} The surveys generally focused on the six largest religions worldwide and reported varied practices. Many Hindus and Sikhs do not approve of the use of bovine- or porcine-derived products and also follow vegetarian diets. Many who practice Islam

or Judaism do not accept the use of porcine-derived products. No principle in Buddhism prohibits the use of animal-derived medical products; however, many members of one of the two major branches follow a vegetarian diet. Most Christians, other than those who follow vegetarian or vegan diets, do not have restrictions. Although Jehovah's Witnesses refuse blood transfusions, all other medical related products and decisions are at the discretion of the patient and physician. Notably, leaders from all surveyed religions stated that the use of animal-derived medical products would be accepted in the absence of any other alternative or in emergency situations. In difficult situations, religious leaders can also be contacted for guidance.

OTHER CONSIDERATIONS

Various communication practices for patient-directed medication information including readability, container labeling (font, format, and organization), information content length, and supplementary medication instructions have been described, but do not address ingredient lists and source.¹²

Reports of medication non-adherence or discontinuation because of ADI avoidance exist.¹³ Some authors have suggested that when healthcare professionals listen to patients' cultural beliefs, actively involve them in medication prescribing decisions, and take their views and preferences into account, adherence is more likely.¹⁴

Nevertheless, ADI information is inconsistently reported, difficult to obtain, and sometimes incorrect.^{2,15} Also noteworthy is the fact that excipients and inactive ingredients likely differ between branded and generic forms of medications; therefore, knowledge of the ingredients in a particular branded medication will not guarantee knowledge of generic versions. Some drugs, especially those produced in gelatin capsules, may be available in alternative formulations that do not contain ADIs. Literature discussing clinical decision support systems for physicians and drug databases used by pharmacists has not addressed the issue of ADIs and the inclusion of relevant ADI information. If the source of ADIs, or the fact that an ingredient is an ADI, were required labeling for manufacturers, the potential would exist for this information to be included in the datasets used by clinical decision support systems and drug databases downstream.

PROBLEM MEDICAL PRODUCTS

Both active and inactive pharmaceutical ingredients as well as implants, dressings, and mesh used in surgery can contain ADIs. Some of the more common examples of these ADIs are included in discussion below.

Active Ingredients

The following are examples of products that contain an active ingredient derived from an animal source:

- Conjugated estrogens (Premarin) are derived from the urine of pregnant mares.¹⁶
- Low molecular weight heparin is porcine-derived.¹⁷
- Corticotropin is obtained from porcine pituitary gland.¹⁸
- Hyaluronidase is derived from crude extracts of ovine or bovine testicular tissue.¹⁹
- Pancreatin (also known as pancreatic enzymes, pancrelipase) is bovine derived.²⁰

The product information for these medications indicates that they are animal-derived. However, for some, the information is difficult to locate, often only becoming obvious because of a statement in the "allergy" or "contraindications" section (e.g., This medication is contraindicated in patients with sensitivity to proteins of porcine origin.).

Inactive Ingredients

In a recent review, the use of ADIs in the 100 most commonly prescribed medications in primary care in the United Kingdom found that 74 contained at least one of the three most common excipient ADIs used – gelatin, lactose, and magnesium stearate.¹⁵ Of these 74 products, 42 provided no indication of the presence of an ADI, and 2 products incorrectly stated that no animal content was contained in the product.¹⁵

Gelatin is a generic term for a mixture of purified protein fractions obtained by hydrolysis of animal collagen obtained from bovine or porcine bone, or from bovine, porcine, or fish skin. It is most frequently used in the capsules of medications. Due to the demand for gelatin-free medication, the production of vegetarian capsules made from

hypermellose has expanded, and the use of bioreactors utilizing “cellular agriculture” to create purified proteins that are assembled into collagen and then made into gelatin is becoming popular; but animal-derived gelatin is still used commonly.^{2,21}

Lactose is a natural disaccharide present in the milk of most mammals and is traditionally extracted from milk using bovine rennet. Some manufacturers now use a vegetarian process instead of bovine rennet to extract lactose from bovine milk, but this has caused confusion about suitability for those who avoid bovine products.¹⁵ Lactose is widely used as a filler and diluent in tablets and capsules and is also used as a diluent in dry-powder inhalations, in the preparation of sugar-coating solutions, and in some injections.^{2,15}

Stearic acid, utilized as magnesium stearate in products, is a fatty acid sourced from rendered bovine, porcine, or ovine fat or produced from vegetable matter. It is primarily used as a lubricant in capsule and tablet manufacture and improves the solubility of some medications. If the source of the magnesium stearate is not indicated on a drug label, whether or not it is an ADI is unknown and difficult to determine.²

Vaccines

Materials used in the production of some vaccines, e.g., excipients or nutritional supplements for cell cultures, are ADIs. These include gelatin, trypsin (usually bovine sourced), and bovine serum or albumin.²² Religious scholars distinguish between the use of ADIs in oral or non-oral medications and have issued rulings or waivers that allow use of non-oral medications containing ADIs, such as vaccines.² Despite this distinction, reports persist of concern with ADIs in vaccines.¹⁵

Surgical Sutures, Implants, Dressings, and Mesh

The use of synthetic and biological products is widespread in surgeries, and the use of a biologic product that is prohibited or is sacred in a surgical setting is a concern.^{8,10} Sutures used to close wounds or surgical incisions can contain animal-derived ingredients. A recent study confirmed the frequent use of ADIs, such as collagen membrane, collagen gel, fibrin glue, fibrinogen, aprotinin and some types of chitosan culture media and scaffold, in various arthroscopy products.¹⁰ Allograft and xenograft mesh products have also been cited as problematic for patients with issues related to the use of ADIs.¹¹ Authors encourage surgeons to know the source of the products they use as well as the basic requirements of their patient’s faith, possibly even gaining informed consent before the use of animal-derived surgical implants.^{8,11}

CURRENT AMA POLICY

No AMA policy addresses this issue.

CONCLUSION

Several medication ingredients, both active and inactive, and surgical products contain ingredients derived from animal sources. Patients may have strong religious convictions and cultural beliefs leading them to object to using medical products with animal-derived ingredients.

It has been documented that physicians may have a hard time determining the origin of ingredients because the information is inconsistently reported, difficult to obtain, and sometimes incorrect. Many times, reading the list of ingredients of a medical product will not clarify if the product contains any animal-derived ingredients or components. Additionally, the products can vary in regard to ADIs based on the manufacturer, and between brand name and generic versions.

Because no requirement exists for a manufacturer to declare how an ingredient is sourced on label information, this information is not present in clinical decision support systems for physicians and drug databases. Including additional information, such as the presence of ADIs and their source, in the ingredients lists on drug labels and in product information would be beneficial because this information could then be included in information systems used by clinicians and would be more accessible to patients.

RECOMMENDATION

The Board of Trustees recommends the following be adopted in lieu of Resolution 515-A-18, and the remainder of the report be filed:

Animal-Derived Ingredients

Our AMA:

1. Urges manufacturers to include all ingredients and components present in medical products on the product label, including both active and inactive ingredients, and denote any derived from an animal source.
2. Encourages cultural awareness regarding patient preferences associated with medical products containing active or inactive ingredients or components derived from animal sources.

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13. 2019 STRATEGIC PLAN

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Our AMA continues to execute its multi-year strategy to achieve significant positive impact for physicians, medical students, and patients. The strategy, launched in 2013, identified three areas of emphasis in our mission areas: Improving Health Outcomes, Accelerating Change in Medical Education, and Shaping Care Delivery and Payment for Professional Satisfaction and Practice Sustainability. These areas have evolved to more encompassing strategic arcs: 1) improving the health of the nation by confronting the chronic disease burden, 2) reimagining medical education, training, and lifelong learning, and 3) attacking the dysfunction in health care by removing the obstacles and burdens that interfere with patient care. They 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 is devoted to what is on the horizon for each of these areas in 2019 and highlights other work to modernize the means through which physicians can engage in advancement of the mission.

ATTACKING THE DYSFUNCTION IN HEALTH CARE

With the continued dramatic shifts in the health care landscape putting more pressure on physicians and their practices, our work continues to focus on addressing the organizational and system level dysfunction that hinders physicians' ability to provide high quality patient care. Through our ongoing work, we are committed to making the patient-physician relationship more valued than paperwork, technology an asset and not a burden, and physician burnout a thing of the past. The goal is to create a future pathway for physicians to choose from a broad array of payment and health care delivery models, including viable fee-for-service options, which can provide a sustainable and satisfying physician practice. We are focused on improving—and setting a positive future path for—the operational, financial and technological aspects of a physician's practice.

Successful navigation and implementation of evolving public and private payment systems requires heightened physician awareness, informed assessment of options, and, potentially, new strategic and operating methods to optimize success. To support physicians through this changing landscape and improve care delivery and professional satisfaction, AMA will work in 2019 to:

- Advocate for legislative and regulatory changes that enhance prospects for physicians to succeed.
- Generate awareness and encourage physicians to prepare for evolving payment model changes.
- Provide multi-modal, multi-channel physician education about what new payment model options mean for physicians and patients.
- 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 and other tools 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 additional research, partnerships, and resources to assist physicians throughout the various settings and stages of their careers.
- Build on the foundation of prior years' work in the area of physician burnout and professional satisfaction by expanding our empirical research in and understanding of the organizational, system, and environmental factors that contribute to burnout with the aim of developing efficacious methods to defeat the problem at its source.
- 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.

In addition based on new AMA policy (Policy H-480.940, "Augmented Intelligence in Health Care") passed at A-18 we will build on our research and development capacity to further our understanding of how best to incorporate the emerging field of artificial intelligence into medical practice to preserve and enhance the patient physician relationship.

IMPROVING THE HEALTH OF THE NATION

Initiatives focused on health outcomes, particularly in the area of prevention and management of chronic care, 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. We have fixed on two ambitious long-term goals:

- To have a nation where there is no incidence of preventable type 2 diabetes.
- To have a nation where all adults are meeting their blood pressure goals.

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's partnerships with the CDC and AHA are solid and we are complementing them with collaborations with medical societies, business groups, payers, technology companies, and medical schools (through the ACE consortium) 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 have been developed and distributed for use in practice settings ranging from small private practices to large integrated systems. The material and programs have been empirically demonstrated to be effective and our main focus is to create the environmental, distribution, and awareness elements conducive to wide spread scaling. In this regard, 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 began coverage in 2018) and self-measured blood pressure monitoring devices. Looking forward in 2019, we intend to blend the "best of" our prediabetes and hypertension work and add programming on cholesterol management to assist physicians and care teams more comprehensively with cardiovascular risk reduction for their patients.

REIMAGINE MEDICAL EDUCATION, TRAINING, AND LIFE LONG LEARNING

We are committed to a comprehensive approach to physician professional education and learning. In 2019, the AMA will have mature and substantial effort in undergraduate medical education, be expanding to graduate medical education and have a growing presence in physician lifelong learning. These programs are designed to respond to the on the ground needs of physicians in the evolving environment in which practice by utilizing modern adult education knowledge and digital technology.

Since 2013 the AMA has supported a Consortium of medical schools, now 32 in number, 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. Facilitated by the AMA through individual and collaborative work the consortium schools have created new and innovative programs and technologies that are increasingly adopted by medical schools throughout the nation. Of particular note are the consortium's health system science textbook that is being adopted by more and more medical schools and the successful application of the chronic care curriculum based on work done in our Improving Health Outcomes area. The latter is an example of the application of work emanating from one strategic area to another critical arena.

The initial grant period of the Consortium ends in 2018, but due to the success of this collaboration the schools have committed to continue to work together with AMA programmatic support to sustain and grow this community of innovation, but without further grant funds. This is an example of our efforts to cost effectively catalyze change through partnerships and collaborations. In 2019, based on the experience and learning from the work in undergraduate medical education, we will initiate a multi-year program to smooth the transition from medical school to residency

through a number of demonstration programs that include medical schools, residency programs, and associated health systems.

In 2018, we continued to build education delivery capabilities with the development and launch of the new AMA Ed Hub™ platform. The platform blends innovations in content, technology, and user experience to deliver increasingly more personalized and compelling virtual learning experiences to meet individual needs and preferences. AMA Ed Hub brings together the AMA's diverse educational offerings under one unified umbrella. Included are Learning™, STEPS Forward™, GME Competency Education Program (GCEP), e-learning modules that support the AMA's Health Systems Science textbook, interactive micro-learning modules based on the AMA's modernized Code of Medical Ethics, curricula related to pain management, firearm safety and other topics. As we look to 2019 and beyond, we will continue to build and enhance the platform as a set of digital solutions that optimizes discovery of educational content for individual users, facilitates delivery of an educational curriculum at an organization level, explores innovations in learning experiences more closely connected to physicians' daily practice, and expands automatic reporting capabilities to support licensure and certification. We also will be exploring collaborations with other organizations to advance both educational content and platform offerings.

ENGAGING PHYSICIANS AND ADVANCING THE MISSION

Our ambitions are high and we must utilize all available tools and assets to reach them. To this end we wish to highlight three areas of leverage.

First, beginning in 2016 we have been building an innovation ecosystem that connects AMA experience, knowledge, and mission priorities with technology and private sector groups. Our wholly owned Silicon Valley situated subsidiary Health 2047 is a centerpiece of this effort. Accessing world class technology, product development, and venture expertise it focuses on the commercial complements of the AMA's strategic arcs. It has already founded a data interoperability company and we anticipate several new ventures in 2019 that will address other important areas that advance our mission.

Second, the goal of health equity is infused in all our strategic work. Each of the mission areas have components directed toward the health equity goal. Based on guidance from the House and with the support of the Board of Trustees in 2019 AMA management will establish a functional hub that further facilitates and enhances concentration on this area. The unit's objective will be to ensure optimal coordination, collaboration, and program development across the AMA's mission areas in support of our commitment to national health equity.

Third, as evidence of AMA mission impact continues to grow, there is an opportunity for AMA to deepen its engagement and strengthen its brand identity among physicians, students, residents and other stakeholders. By leveraging more sophisticated approaches to identifying interests and needs of the physician population, we can continuously improve our services and offerings to retain and grow our membership base. We will create new connections, drive awareness and increase opportunities to interact with the AMA using traditional and interactive/social/digital media, building off our experience in 2018.

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.

14. PROTECTION OF PHYSICIAN FREEDOM OF SPEECH (RESOLUTION 5-I-17)

Reference committee hearing: see report of Reference Committee on Amendments to Constitution and Bylaws.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 5-I-17
REMAINDER OF REPORT FILED
See Policy H-435.940**

INTRODUCTION

Resolution 5-I-17, introduced by the American Academy of Pain Medicine (AAPM), consisted of the following proposals:

RESOLVED, That our American Medical Association strongly oppose litigation challenging the exercise of a physician's First Amendment right to express good faith opinions regarding medical issues; and be it further

RESOLVED, That our AMA's House of Delegates encourage the AMA Litigation Center to provide such support to a constituent or component medical society whose members have been sued for expressing good faith opinions regarding medical issues as the Litigation Center deems appropriate in any specific case.

The reference committee heard testimony that physicians had been sued for expressing their opinions on such politically sensitive issues as the treatment of chronic pain or the potential benefits of medical marijuana. Physicians testified that these lawsuits are expensive, produce anxiety, and impact physicians' willingness to speak publicly on controversial public issues. While testimony generally supported the resolution, concerns were raised regarding the term "good faith," which the reference committee found to be "a complex and sensitive issue." The resolution was referred to the Board of Trustees in order to investigate the optimal language needed to accomplish the goals of Resolution 5.

This report is submitted in response to that referral. Notably, though, the scope of the House referral and thus of this report is much narrower than the heading, "Protection of Physician Freedom of Speech," might suggest. Physician freedom of speech encompasses far more than the subject of Resolution 5. In conformity with the Board's interpretation of the request from the House, this report is focused on the specific proposals of Resolution 5 and particularly on the term "good faith."

FIRST RESOLVE

The Board believes that the term "good faith" should be omitted from AMA policy based on the first resolve of Resolution 5. Thus, AMA policy would appropriately read as follows:

RESOLVED, That our American Medical Association strongly oppose litigation challenging the exercise of a physician's First Amendment right to express opinions regarding medical issues.

The problem with the "good faith" limitation is that there is no simple test of whether a specific opinion has been made in good faith or in bad faith. For example, suppose a physician were to opine on a medical issue without disclosing that the physician's interests were financially conflicted regarding that issue. As another example, suppose a physician were to advocate for a specific treatment option, but the physician had previously recommended a different option and failed to acknowledge this discrepancy. As a third example, suppose a lawsuit were brought against a physician because of the physician's opinion on a medical issue, and the lawsuit, without setting forth a further basis for the statement, alleged that the opinion had been rendered in "bad faith." Each of these examples might suggest that the physician's opinion lacked good faith, but the ultimate determination of that issue would require a much fuller factual development than has been set forth.

AAPM introduced Resolution 5 to protect physicians' First Amendment right to express opinions. A tenet of First Amendment law is that expression of opinions should be encouraged, and the bad faith ones will be ultimately discredited in the "marketplace of ideas." The truth will prevail. *McCullen v. Coakley*, 134 S. Ct. 2518, 2529 (2014).

If the AMA is to stand behind the right of free expression, it should not be undercut by a policy requiring that it ascertain at some point whether a physician's opinion has been expressed in good faith.

If the first resolve of Resolution 5 is modified as suggested, it will be similar, but not quite identical, to existing Policy H-460.895, "Free Speech Applies to Scientific Knowledge," which states as follows: "Our AMA will advocate that scientific knowledge, data, and research will continue to be protected and freely disseminated in accordance with the U.S. First Amendment."

SECOND RESOLVE

The Board believes that the second resolve of Resolution 5 would be undesirable. During the June 2017 Open Meeting of the Litigation Center, AAPM publicly discussed the abusive litigation which led to Resolution 5. Thus, the Litigation Center is aware of the problem and is already committed to taking whatever appropriate steps may be available to assist AAPM and its members.

Unfortunately, the problems AAPM faces are not, at least presently, readily susceptible to assistance from the Litigation Center. Abusive litigation must be combatted under the procedures available through the legal system. The Litigation Center has communicated closely with AAPM to ascertain the point at which assistance might be helpful. The various lawsuits that have been brought against AAPM and its members have simply not reached that point – if the point will ever be reached.

As it happens, though, adoption of the first resolve, with the modification suggested above (*viz.*, deletion of the "good faith" requirement), will increase the likelihood that the Litigation Center will ultimately be able to support AAPM. In other words, the Litigation Center would find it difficult to support AAPM if it had to convince itself that the physicians in question had written or spoken in good faith. With the removal of the good faith impediment, the Litigation Center can premise its support on the general principle of protecting free speech, without a detailed analysis of the facts underlying a specific case.

The Board and the Litigation Center appreciate that AAPM has been respectful of the discretion accorded to the Litigation Center. Nevertheless, the second resolve suggests that the Litigation Center might benefit from additional encouragement from the House of Delegates. Such encouragement, in this situation, would be unnecessary and might undercut the ability of the Litigation Center to act according to its determination of how the interests of the AMA can be best served through advocacy in the courts.

RECOMMENDATION

The Board of Trustees recommends that the following be adopted in lieu of Resolution 5-I-17 and the remainder of this report be filed:

1. That our American Medical Association support a physician's First Amendment right to express opinions relating to medical issues; and
2. That AMA Policy H-460.895, "Free Speech Applies to Scientific Knowledge," be reaffirmed.

15. 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 2018 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,

“Summary of Guidelines for Admission to the House of Delegates for Specialty Societies,” and AMA Bylaw 8.5, “Periodic Review Process.”

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, “Responsibilities of National Medical Specialty Societies and Professional Interest Medical Associations.”

The following organizations were reviewed for the 2018 Interim Meeting:

- American Academy of Allergy, Asthma & Immunology
- American Academy of Ophthalmology, Inc.
- American Academy of Orthopaedic Surgeons
- American Academy of Otolaryngology-Head and Neck Surgery
- American Academy of Pain Medicine
- American Academy of Pediatrics
- American Academy of Physical Medicine & Rehabilitation
- American Association of Neurological Surgeons
- Society of Nuclear Medicine and Molecular Imaging

The Society of Nuclear Medicine and Molecular Imaging was reviewed at this time because they failed to meet the requirements of the review in 2017.

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: American Academy of Allergy, Asthma & Immunology, American Academy of Ophthalmology, Inc., American Academy of Orthopaedic Surgeons, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pain Medicine, American Academy of Pediatrics, American Academy of Physical Medicine & Rehabilitation, American Association of Neurological Surgeons and the Society of Nuclear Medicine and Molecular Imaging are in compliance with all requirements for representation in the HOD.

RECOMMENDATIONS

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

That the American Academy of Allergy, Asthma & Immunology, American Academy of Ophthalmology, Inc., American Academy of Orthopaedic Surgeons, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pain Medicine, American Academy of Pediatrics, American Academy of Physical Medicine & Rehabilitation, American Association of Neurological Surgeons, and the Society of Nuclear Medicine and Molecular Imaging retain representation in the American Medical Association House of Delegates.

APPENDIX

Exhibit A – Summary Membership Information

Organization	AMA Membership of Organization’s Total Eligible Membership
American Academy of Allergy, Asthma & Immunology	324 of 1,600 (20%)
American Academy of Ophthalmology, Inc.	3,021 of 17,125 (18%)
American Academy of Orthopaedic Surgeons	3,897 of 23,682 (16%)
American Academy of Otolaryngology-Head and Neck Surgery	2,081 of 8,436 (25%)
American Academy of Pain Medicine	371 of 1,208 (31%)
American Academy of Pediatrics	3,827 of 42,035 (9%)

American Academy of Physical Medicine & Rehabilitation	1,146 of 6510 (18%)
American Association of Neurological Surgeons	787 of 3,639 (22%)
Society of Nuclear Medicine and Molecular Imaging	293 of 1,361 (22%)

Exhibit B – Summary of Guidelines for Admission to the House of Delegates for Specialty Societies (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 – Bylaws provisions regarding responsibilities of societies

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.

REPORT OF THE SPEAKERS

The following report was presented by Susan R. Bailey, MD, Speaker; and Bruce A. Scott, Vice Speaker:

1. RECOMMENDATIONS FOR POLICY RECONCILIATION

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

RECOMMENDED ACTIONS ACCOMPLISHED

Policy G-600.111, "Consolidation and Reconciliation of AMA Policy," calls on your Speakers to "present one or more reconciliation reports for action by the House of Delegates relating to newly passed policies from recent meetings that caused one or more existing policies to be redundant and/or obsolete."

Your Speakers present this report to deal with policies, or portions of policies, that are no longer relevant or that were affected by actions taken at the recent Annual Meeting. Suggestions on other policy statements that your Speakers might address should be sent to hod@ama-assn.org for possible action. Where changes to language will be made, additions are shown with underscore and deletions are shown with strikethrough.

RECOMMENDED RECONCILIATIONS

Obsolete references to be deleted from policies

Policy G-600.031 characterizes the roles and responsibilities of delegates and alternate delegates. The policy dates from 1999 and was most recently reaffirmed at the 2012 Annual Meeting. Your Speakers regard it as an important policy, but it includes a reference to a program that no longer exists. That clause will be deleted and a minor editorial change made.

G-600.031 Roles and Responsibilities of AMA Delegates and Alternate Delegates

- (1) Members of the AMA House of Delegates serve as an important communications, policy, and membership link between the AMA and grassroots physicians. The delegate/alternate delegate is a key source of information on activities, programs, and policies of the AMA. The delegate/alternate delegate is also a direct contact for the individual member to communicate with and contribute to the formulation of AMA policy positions, the identification of situations that might be addressed through policy implementation efforts, and the implementation of AMA policies. Delegates and alternate delegates to the AMA are expected to foster a positive and useful two-way relationship between grassroots physicians and the AMA leadership. To fulfill these roles, AMA delegates and alternate delegates are expected to make themselves readily accessible to individual members by providing the AMA with their addresses, telephone numbers, and email addresses so that the AMA can make the information accessible to individual members through the AMA Web site and through other communication mechanisms.
- (2) The roles and responsibilities of delegates and alternate delegates are as follows: (a) regularly communicate AMA policy, information, activities, and programs to constituents so he/she will be recognized as the representative of the AMA; (b) relate constituent views and suggestions, particularly those related to implementation of AMA policy positions, to the appropriate AMA leadership, governing body, or executive staff; (c) advocate constituent views within the House of Delegates or other governance unit, including the executive staff; (d) attend and report highlights of House of Delegates meetings to constituents, for example, at hospital medical staff, county, state, and specialty society meetings; (e) serve as an advocate for patients to improve the health of the public and the health care system; (f) cultivate promising leaders for all levels of organized medicine and help them gain leadership positions; and (g) actively recruit new AMA members and help retain current members; ~~and (h) participate in the AMA Membership Outreach Program.~~

Directives to be rescinded in full

The following directives will be rescinded in full, as the requested studies have been completed and presented to the House of Delegates.

At the 2017 Annual Meeting, the House adopted Policy D-215.987, "Studying Healthcare Institutions that Provide Child Care Services," directing our AMA to work with relevant entities to study healthcare institutions to determine whether they provide childcare services and report on those findings at the 2018 Annual Meeting. Board of Trustees Report 32-A-18, "Studying Healthcare Institutions that Provide Child Care Services," was presented to the House as an informational report and was filed. Consequently, the policy will be rescinded.

D-215.987, "Studying Healthcare Institutions that Provide Child Care Services"

1. Our AMA will work with relevant entities to study healthcare institutions to determine whether they provide childcare services. Survey elements should include the size of the institutions in terms of the number of physicians, physicians-in-training, and medical students, how these services are organized, and the various funding mechanisms.
2. Our AMA will report back to the House of Delegates at the 2018 Annual Meeting the results of its study on models used to provide childcare services, how these services are organized, and the various funding mechanisms. This report, which is presented for the information of the House, provides background on child care services in health care and the implications of access to child care for physicians, as well as results of a study conducted by the AMA and other relevant research.

Policy D-315.976, "Ownership of Patient Data," calling for a study on the use of patient information by hospitals, was adopted at the 2017 Annual Meeting. The requested study was fulfilled by Board of Trustees Report 21-A-18, "Ownership of Patient Data," an informational report that noted our AMA's active engagement with the Department of Health and Human Services, the Office of the Inspector General and the Office of the National Coordinator based on policies covering all aspects of patient record maintenance, access and control. The policy will be rescinded.

D-315.976, "Ownership of Patient Data"

Our AMA will undertake a study of the use and misuse of patient information by hospitals, corporations, insurance companies, or big pharma, including the impact on patient safety, quality of care, and access to care when a patient's data is withheld from his or her physician, with report back at the 2018 Annual Meeting.

Also adopted at the 2017 Annual Meeting was Policy D-405.982, "Management of Physician and Medical Student Stress," which requested a report on various regulatory burdens placed on physicians. Your Board of Trustees presented an informational report, BOT Report 36-A-18, "Management of Physician and Medical Student Stress" that fulfilled the request. Therefore the directive will be rescinded.

D-405.982, "Management of Physician and Medical Student Stress"

Our AMA will produce a report on administrative and regulatory burdens placed on physicians, residents and fellows, and medical students, and pursue strategies to reduce these burdens.

CHANGES IN TERMINOLOGY

The following policy statements were updated to comport with AMA style and usage in references to continuing medical education credit for the AMA Physician's Recognition Award. PolicyFinder now employs an italic typeface and the trademark (™) symbol in references to *AMA PRA Category 1 Credit™* or *AMA PRA Category 2 Credit™*. The prior version of PolicyFinder did not allow these features. We point this out primarily to alert members of the House to the correct usage. It also happens that this year is the 50th Anniversary of the AMA Physician's Recognition Award and Credit System.

The affected policies are:

- H-275.924, "Maintenance of Certification"
- H-295.926, "Support for Development of Continuing Education Programs for Primary Care Physicians in Non-Academic Settings"
- H-300.955, "Restructuring of Continuing Medical Education Credits"
- H-300.974, "Unification of Continuing Education Credits"

- H-300.977, "Revisions to the Physician's Recognition Award"

The changes outlined above do not reset the sunset clock and will be implemented when this report is filed.