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REPORT 5 OF THE BOARD OF TRUSTEES (November 2020)
FDA Conflict of Interest
(Resolution 216-A-18)
(Reference Committee B)

EXECUTIVE SUMMARY

The United States Food and Drug Administration (FDA) utilizes advisory committees to obtain independent expert advice and recommendations on scientific, technical, and policy matters related to FDA-regulated products. There are 50 advisory committees and panels. The FDA's advisory committees are governed by several federal laws and regulations that: (1) establish standards for convening advisory committees; (2) specify criteria for what constitutes a conflict of interest (COI); and (3) outline the requirements for disclosing, assessing, and managing COIs. In addition, the FDA has issued guidance documents interpreting government-wide regulations pertaining to the appearance of COIs as well as guidance related to the public availability of advisor COI disclosures and associated FDA COI waivers.

Despite long-standing federal laws governing COIs and waivers applicable to FDA advisory committee members, there have remained persistent concerns that waivers of COIs negatively impact the trustworthiness and independence of advisory committee recommendations. While there is widespread consensus that COI policies are appropriate and necessary along with a measured approach to granting COI waivers for FDA advisory committee members, there is also concern that an overzealous approach to waivers will undermine the actual or perceived quality of advisory committee recommendations.

The resolve clauses in the resolution generating this report, i.e., Resolution 216-A-18, "[Food and Drug Administration] FDA Conflict of Interest," would have the American Medical Association (AMA) adopt policy that specifies that the FDA should place a greater emphasis on advisory committee member COIs and seek a further reduction in the number of COI waivers granted by the FDA. Existing AMA ethics policy provides a clear set of parameters concerning COIs and waivers regarding clinical practice guidelines development and clinical research that should be utilized to expand upon AMA policy concerning FDA advisory committee member COIs and waivers. Accordingly, the AMA Board of Trustees (Board) recommends extending existing policies to FDA advisory committee member COIs and waivers to underscore the importance of existing FDA laws, regulations, and policies. Since AMA policy does not address concerns that advisory committee members may not be fully disclosing conflicts and independent targeted auditing for sufficiency may be warranted, the Board recommends adopting new policy to that effect.

The Board recognizes that ensuring that COIs do not compromise the integrity of the FDA advisory committee process is paramount. At the same time, the Board understands that there is an on-going, pressing need to fill FDA advisory committee vacancies. Therefore, the Board believes that the AMA should also adopt new policy urging the FDA to streamline the COI process to reduce any unnecessary documentation, administrative barriers, or delays that might hinder the participation of qualified physicians on FDA advisory committees.

Finally, the Board recommends that the AMA adopt new policy stating that the FDA should undertake an evaluation of pay-later conflicts of interest (e.g., where an FDA advisory committee member develops a financial conflict of interest only after his or her initial appointment on the advisory committee has expired) to assess whether these undermine the independence of advisory committee member recommendations and whether policies should be adopted to address this issue.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 5, November 2020

Subject: FDA Conflict of Interest (Resolution 216-A-18)

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

At the 2018 Annual Meeting of the House of Delegates (HOD), Resolution 216-A-18, "[Food and Drug Administration] FDA Conflict of Interest," was referred for report back at the 2019 Annual Meeting. Resolution 216-A-18, sponsored by the Medical Student Section, asked that:

> Our American Medical Association (AMA) advocate (1) that the Food and Drug Administration [(FDA)] place a greater emphasis on a candidate's conflict of interest when selecting members for advisory committees and (2) for a reduction in conflict of interest waivers granted to Advisory Committee candidates.

There was mixed testimony on Resolution 216 during the reference committee. Testimony was offered that disclosure and transparency into conflicts of interest (COI) are important, but on the other hand challenges may exist to find qualified individuals without COIs. Others offered that the FDA should utilize generally accepted COI policies and should limit waivers of such policies for advisory committees. The HOD referred Resolution 216 to the Board of Trustees (Board) for report back at the 2019 AMA Annual Meeting.

During the 2019 Annual Meeting, the Board presented Report 19-A-19, "FDA Conflict of Interest" to the HOD in response to the HOD's referral of Resolution 216. At the 2019 Annual Meeting, the HOD referred Report 19-A-19 back to the Board for further consideration, because the HOD wanted the report to include in the report's recommendations language urging the FDA to reduce administrative burdens associated with, and otherwise streamlining, its advisory committee COI process to facilitate physician participation on its advisory committees, since participation continues to be a challenge. This report, i.e., Board Report 10-A-20, contains the revisions to Board Report 19-A-19 that the HOD requested, and the Board presents this report for the HOD's further consideration.

FDA AND THE ROLE OF ADVISORY COMMITTEES

The FDA utilizes advisory committees to obtain independent expert advice and recommendations on scientific, technical, and policy matters related to FDA-regulated products. There are 50 advisory committees and panels.[1] The recommendations of advisory committees do not bind the FDA. Although the advisory committees include permanent non-voting members who are FDA employees (typically responsible for administering the meetings), the majority are external experts who are considered special government employees (SGEs) while performing their advisory committee duties. The advisory committees cover a range of products.[2]

The FDA's advisory committees are governed by several federal laws and regulations that: (1) establish standards for convening advisory committees; (2) specify criteria for what constitutes a COI; and (3) outline the requirements for disclosing, assessing, and managing COIs. In addition, the FDA has issued guidance documents interpreting government-wide regulations pertaining to the appearance of COIs as well as guidance related to the public availability of advisor COI disclosures and associated FDA waivers. For the most part, the federal laws, regulations, and guidance are generally the same whether a committee advisor is a permanent federal employee or SGE with some exceptions as outlined below. For over a decade, the FDA and Congress have implemented reforms to the FDA's process for assessing COIs, managing COIs including waivers, and public disclosure.[3] Members of the FDA's advisory committees are subject to Federal COI laws (18 USC section 208) as well as government-wide standards of ethical conduct regulations (5 CFR section 2635.502). Even where a member has no financial interests that would require the member to refrain from participating in an advisory committee meeting ("recuse") under Federal COI laws, the member may be disqualified from participation under the government-wide Federal regulation at 5 CFR section 2635.502 if the member has interests or relationships that may create the appearance that the member lacks impartiality on the issue before the advisory committee.

As specified in federal law, the FDA has a process for determining whether to grant a waiver for an advisory committee member with an actual financial COI. The FDA also has guidance outlining how the Agency evaluates whether an advisory committee member has potentially disqualifying interests or relationships that fall into the second category of interests: appearance of a COI. (In this latter case, the regulations provide that an authorization to participate would be issued as opposed to issuance of a waiver.) In both cases, the decision to permit voting, permit participation, or recusal will be made by the FDA.

PROHIBITION AGAINST FINANCIAL COI

Unless granted a waiver, a federal employee may not "personally and substantially participate" in an official capacity in any particular matter which, to the employee's knowledge, the employee or a related person or organization (whose interests are imputed to the employee under 18 USC section 208) has a "financial interest" if the particular matter will have a "direct and predictable effect" on that interest (5 CFR section 2640.103(a)). In this analysis, federal employees include FDA advisory committee members who are considered SGEs. A financial interest is defined as the potential for gain or loss as a result of governmental action on the particular matter which includes stock options, a salary, job offer, indebtedness, and similar interests (5 CFR section 2640.103(b)). Under this law, the financial interests of other, related persons and organizations (as defined in law and statute)[4] are imputed to the employee and may disqualify an employee to the same extent as the employee's own interests. Under the law, a COI arises when the employee participates in an official matter and there is a direct and predictable link between the matters in which the federal employee participates and the employee's financial interests. The link cannot be contingent and dependent on other events.

Process for Reviewing Financial COIs and Granting Waivers

The FDA reviews financial COI disclosures made by potential advisory committee members and the member's expertise with respect to the specific product or policy to be evaluated at a particular meeting. Each adviser is required to certify to the truth and completeness of any information provided.[5] The Agency can issue a waiver to permit participation despite a current conflict or one that ended during the 12 months preceding a meeting consistent with applicable law. The FDA is required by law to apply different standards to SGEs (who constitute the majority of advisory

committee members) and permanent government employees in order to determine if an applicable standard for granting a waiver pursuant to 18 USC section 208 is met.

If the individual is a SGE, the FDA's "determination must be based on a certification that the need for the [SGE's] ... services outweighs the potential for a conflict of interest created by the financial interest involved," (5 CFR section 2640.302). The FDA considers a number of factors, including the type of interest that is creating the disqualification, the relationship of the person whose financial interest is involved to the SGE, the uniqueness of the SGE's qualifications, the difficulty of locating a similarly qualified individual without a disqualifying financial interest, the dollar value of the disqualifying financial interest, and the extent to which the disqualifying financial interest could be affected by the actions of the advisory committee.[6] If the individual is a permanent government employee, the FDA determines whether the member's financial interest is not so substantial as to be deemed likely to affect the integrity of the services provided by that individual. In making this determination, the FDA considers a number of factors, including the type of financial interest that is creating the disqualification, the relationship of the person whose financial interest is involved to the member, the dollar value of the disqualifying financial interest, the nature and importance of the employee's role in the matter, and the need for the employee's services in the particular matter.[7] FDA guidance provides that a common factor to be considered for both categories of advisory committee members is the "need" for the individual's services. In deciding whether there is a need, the FDA will consider: (1) the uniqueness of the member's qualifications; (2) the difficulty locating similarly qualified individuals without a disqualifying financial interest; (3) the value and utility of the member's expertise to the matter being addressed by the committee; and (4) the nature and extent of the disqualifying financial interest.

In addition, the FDA must apply one more standard to members serving on drug or biologic advisory committees that provide scientific advice and recommendations regarding a clinical investigation or marketing approval. For these members, the standard for a waiver to permit voting is whether a waiver is "necessary" to afford the committee "essential expertise."[8] Where a financial COI exists, the FDA determines whether the member may: (1) participate as a non-voting member; or (2) not participate in the advisory committee.[9] Individuals with financial COIs are not permitted to vote as a matter of FDA policy. A waiver may not be granted when the member's own scientific work is involved.[10]

The Food and Drug Administration Amendments Act of 2007 included a provision capping the number of COI waivers the FDA could grant in any given year. Subsequently, this cap was rescinded in the Food and Drug Administration Safety and Innovation Act of 2012.[11] A recent analysis of FDA COI waivers found that in fiscal year (FY) 2012, the waiver rate did not exceed one percent and this was less than in earlier years.[12] Additionally, the FDA reports COI waiver rates of less than one percent for FYs 2013, 2014, 2015, and 2016 on its online FDA-TRACK Advisory Committees Dashboard.[13]

Public Disclosure

The FDA publicly discloses[14] on the Agency's website the type, nature, and magnitude of the financial interests of each advisory committee member who has received a waiver under 18 USC section 208. The FDA also provides the reasons for granting each waiver prior to the advisory committee meeting,[15] including, as appropriate, the public health interest in having the expertise of the member with respect to the particular matter.[16]

APPEARANCE OF A CONFLICT OF INTEREST – PERSONAL AND BUSINESS RELATIONSHIPS

Federal law also contains provisions to help ensure that an employee takes appropriate steps to avoid an appearance of loss of impartiality in the performance of his or her official duties. Under 5 CFR section 2635.502 where an agency employee (including FDA advisory committee members), "knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member" of the employee's household, or knows that a person with whom the employee has a "covered relationship is or represents a party to such matter," and "where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts" to question the employee's impartiality in the matter, the employee should not participate in the matter unless the employee has informed the agency designee of the appearance problem and received authorization from the agency designee. An employee has a "covered relationship" with:

- a person other than a prospective employer with whom the employee has or seeks a business, contractual or other financial relationship that involves other than a routine consumer transaction;
- a person who is a member of the employee's household, or who is a relative with whom the employee has a close personal relationship;
- a person for whom the employee's spouse, parent or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; any person for whom the employee has, within the last year, served as officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee; or
- an organization, other than a political party,[17] in which the employee is an "active participant."[18]

Granting a Section 502 Authorization

If the FDA concludes that an appearance issue exists, a determination is made whether the Agency's interest in the member's participation outweighs the concern that a reasonable person may question the integrity of the Agency's programs and operations. If so, the FDA may grant an authorization (i.e., a waiver) before the meeting to allow the member to participate. The FDA may limit authorization or deny authorization. The Agency takes into consideration a number of factors including, but not limited to: (1) the nature of the relationship involved; (2) the effect that resolution of the matter would have upon the financial interests of the person involved in the relationship; (3) the nature and importance of the member's role in the matter, including the extent to which the member is called upon to exercise discretion in the matter; (4) the sensitivity of the matter; (5) the difficulty of reassigning the matter to another expert; and (6) adjustments that may be made in the member's duties that would reduce or eliminate the likelihood that a reasonable person would question her impartiality.

RESEARCH ON COI AND FDA ADVISORY COMMITTEE RECOMMENDATIONS

Despite long-standing federal laws governing COIs and waivers applicable to FDA advisory committee members, there have remained persistent concerns in the general public that waivers of COIs negatively impact the trustworthiness and independence of advisory committee recommendations. However, the research and investigations into this matter have produced mixed results. In a 2014 study of FDA advisory committee member COIs, a researcher found that, where an advisory committee member had an exclusive financial relationship with the manufacturer

(referred to as a sponsor) of the product under review, the member appeared to be biased in support of the product sponsor.[19] No similar bias was found where members had financial ties to both a sponsor and its competitors.[20] The study author noted that "[t]hese findings point to important heterogeneities in financial ties and suggest that policymakers will need to be nuanced in their management of financial relationships of FDA advisory committee members."[21] In another study, the researchers found little significant evidence that advisory committee members vote in their financial interests.[22] The authors also found that the perverse exclusion of "financially-conflicted members resulted in a sharp drop in average member expertise, and an unintended increase in approval voting." The study authors concluded that "[e]liminating conflicts could sharply reduce the level of expertise of the decision makers and lead to unexpected voting tendencies."[23] More recently, an investigation of FDA advisory committee members COIs has called into question: (1) the completeness of COI disclosures submitted by members; (2) whether the FDA does enough to verify the completeness and accuracy of such disclosures; and (3) whether past or current COI assessments are inadequate as pay-later COIs may play a more significant role in influencing a member's deliberations and vote. Specifically, a 2018 investigation found that, at the time of or in the year leading up to the advisory committee meetings under scrutiny, many of the members received payments or other financial support from the sponsoring drug firm or key competitors for consulting, travel, lectures, or research.[24] The investigators concluded that the FDA did not publicly disclose those ties even though this information was disclosed in scholarly journals.[25] In the same investigation, a review was undertaken of compensation records from drug sponsors to advisory committee members who advised the FDA on whether to approve 28 psychopharmacologic, arthritis, and cardiac or renal drugs between 2008 and 2014.[26] The investigators concluded that there were "widespread after-the-fact payments or research support to panel members."[27] As correctly noted by the investigators: "[t]he agency's safeguards against potential conflicts of interest are not designed to prevent such future financial ties."

AMA POLICY

The AMA has policy addressing COIs applicable to FDA advisory committees (Policy H-100.992, "FDA") as well as ethics policy concerning COIs in the areas of research (Ethics Opinion 7.1.4/ AMA Principles of Medical Ethics: II, IV,V, "Conflicts of Interest in Research") and clinical practice guidelines (Policy H-410.953, "Ethical Considerations in the Development of Clinical Practice Guidelines").

DISCUSSION

The resolve clauses in Resolution 216 would have the AMA adopt policy that specifies that the FDA should place a greater emphasis on advisory committee member COIs and seek a further reduction in the number of COI waivers granted by the FDA. While there is widespread consensus that COI policies are appropriate and necessary along with a measured approach to granting COI waivers for FDA advisory committee members, there is also concern that an overzealous approach to waivers will undermine the actual or perceived quality of advisory committee recommendations. The FDA has reduced the number of waivers granted, but there are conflicting reports with regard to the magnitude of the challenge the Agency faces filling advisory committee vacancies. For example, one article reported that in FY 2017, "218 advisory committee positions of the 600-plus on the FDA's 49 advisory committees had not been filled."[28] Yet, data disclosed by FDA indicates that in FY 2017 there were 64 vacancies out of 564[29] and in FY 2018 there were 57 total vacancies out of 547 members.[30] A 10 percent vacancy is substantially lower than a nearly 50 percent vacancy. Nonetheless, the COI waiver rate has remained consistently below one percent. Lowering this percentage further is reasonably likely to increase vacancies which are hovering at 10 percent.

Existing AMA ethics policy provides a clear set of parameters concerning COIs and waivers regarding clinical practice guidelines development and clinical research that should be utilized to expand upon AMA policy concerning FDA advisory committee member COIs and waivers. Our current AMA policy related to advisory committee members provides that a FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute and evidence of such should be evaluated by the FDA, in consultation with its advisory committees (Policy H-100.992). The policy also provides that the FDA should not let COIs overrule scientific evidence in making policy decisions. Building on the above policy, our AMA has ethics policy noting how minimizing and mitigating COIs in clinical research is imperative to justify and maintain trust in the medical research community (7.1.4, "Conflicts of Interest in Research"). This is equally true for FDA advisory committee member recommendations. This same policy provides that physicians who engage in research should disclose material ties to companies whose products they are investigating or other ties that create real or perceived COIs. Similarly, AMA ethics policy concerning clinical practice guidelines provides that patients, the public, physicians, and other stakeholders must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable (Policy H-410.953). Notably, while Policy H-410.953 specifies that published guidelines/updates are to be developed independent of direct financial support from entities that have an interest in the recommendations, it does specify consideration for COIs (actual and perceived) for individuals associated in the development of the guidelines. The policy states: "ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline." In order to ensure credibility, our AMA policy provides that:

> formal procedures would be adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.

The policy provides for a clear statement of methodology, COI policy and procedures, and disclosures of panel members' COIs. The Board recommends extending the foregoing policies to FDA advisory committee member COIs and waivers to underscore the importance of existing FDA laws, regulations, and policies. And since AMA policy does not address concerns that advisory committee members may not be fully disclosing conflicts and independent targeted auditing for sufficiency may be warranted, the Board recommends adopting new policy to that effect.

The Board recognizes that ensuring that COIs do not compromise the integrity of the FDA advisory committee process is paramount. At the same time, the Board understands that there is an ongoing, pressing need to fill FDA advisory committee vacancies. Therefore, the Board believes that, in accordance with the position outlined above, the AMA should also adopt new policy urging the FDA to streamline the COI process to reduce any unnecessary documentation, administrative barriers, or delays that might hinder the participation of qualified physicians on FDA advisory committees.

Finally, existing policy does not address the impact of pay-later COIs (e.g., where a FDA advisory committee member develops a financial COI only after his or her initial appointment on the advisory committee has expired). Since there is limited research on the topic, this is an important area for the FDA and researchers to more fully evaluate and craft appropriate policy.

RECOMMENDATIONS

In light of these considerations, your Board of Trustees recommends that the following be adopted in lieu of Resolution 216-A-18 and the remainder of this report be filed:

1. That our American Medical Association (AMA) reaffirm Policy H-100.992, "FDA," which supports that FDA conflicts of interest should not overrule scientific evidence in making policy decisions and the FDA should include clinical experts on advisory committees. (Reaffirm HOD Policy)

2. That our AMA adopt the following new policy:

   It is the position of the American Medical Association that decisions of the Food and Drug Administration (FDA) must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that FDA decisions and the recommendations of FDA advisory committees are ethically and scientifically credible and derived through a process that is rigorous, independent, transparent, and accountable. Rigorous policies and procedures should be in place to minimize the potential for financial or other interests to influence the process at all key steps. These should include, but not necessarily be limited to: a) required disclosure of all relevant actual or potential conflicts of interest, both financial and personal; b) a mechanism to independently audit disclosures when warranted; c) clearly defined criteria for identifying and assessing the magnitude and materiality of conflicts of interest; and d) clearly defined processes for preventing or terminating the participation of a conflicted member, and mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when an individual's participation cannot be terminated due to the individual's unique or rare skillset or background that is deemed highly valuable to the process. Further, clear statements of COI policy and procedures, and disclosures of FDA advisory committee members' conflicts of interest relating to specific recommendations, should be published or otherwise made public. Participation on advisory committees should be facilitated through appropriate balancing of the relative scarcity or uniqueness of an individual's expertise and ability to contribute to the process, as compared to the feasibility and effectiveness of mitigation measures. Finally, our AMA urges the FDA to streamline the COI process to the greatest extent possible, thereby eliminating any unnecessary documentation, delays, or administrative barriers to qualified physicians' participation on FDA advisory committees. (New HOD Policy)

3. That our AMA adopt the following new policy:

   It is the position of the American Medical Association that the FDA should undertake an evaluation of pay-later conflicts of interest (e.g., where a FDA advisory committee member develops a financial conflict of interest only after his or her initial appointment on the advisory committee has expired) to assess whether these undermine the independence of advisory

committee member recommendations and whether policies should be adopted to address this issue. (New HOD Policy)

Fiscal Note: Less than $500

REFERENCES

[1] FDA Advisory Committees, Accessed on February 25, 2019
[2] Id. Products include blood, vaccines and other biologics; human drugs; food; medical devices; patient engagement; pediatric; radiation-emitting products; risk communication; science board; toxicological research; veterinary; and tobacco.
[3] See, for example, the FDA Amendments Act (FDAA) of 2007 which mandated that by 2012 no more than thirteen percent of committee advisors per year could receive COI waivers. The FDA reduced the maximum size of financial interests eligible for waivers from a combined financial interest of up to $100,000, to a maximum of $50,000. See also Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees (March 2007); Public Availability of Advisory Committee Members' Financial Interest Information and Waivers-Final Guidance (2014); and, Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees (2016).
[4] Related persons and organizations include: the employee's spouse, minor child, or general partner; an organization or entity for which the employee serves as officer, director, trustee, general partner, or employee; and a person with whom the employee is negotiating for, or has an arrangement concerning, prospective employment.
[5] In preparation for advisory committee meetings involving particular matters, SGEs invited to participate in the meetings are required to report to FDA any financial interests related to the subject matter of the advisory committee meeting. 5 CFR § 2634.904(a)(2). Permanent government employees also report financial interests on a yearly basis and/or just prior to the advisory committee meeting they are planning to attend. 5 CFR §§ 2634.202 and 2634.904(a)(1). The FDA reviews not only the financial interests of a potential advisory committee participant and the individual's immediate family, but also the financial interests, of which the individual has knowledge, of the participant's business partners, organizations for which the individual serves as officer, director, trustee, general partner, or employee, and any prospective employer of the member (if there are ongoing employment negotiations or an agreement regarding future employment). See 18 U.S.C. § 208(a).
[6] 5 CFR 2640.302(b)
[7] 5 CFR 2640.301(b)
[8] Food, Drug, and Cosmetic Act section 505 (n)(4) "Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved."
[9] Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining COI and Eligibility for Participation in FDA Advisory Committees March 2007
[10] Id.
[11] Wood SF, Mador JK. *Science and regulation. Uncapping conflict of interest?* Science (2013)
[12] Lurie P. *Suggestions for Improving Conflict of Interest Processes in the US Food and Drug Administration Advisory Committees—Past Imperfect*. JAMA Intern Med. 2018;178(7):997–998. doi:10.1001/jamainternmed.2018.1324
[13] Report to Congress Food and Drug Administration Safety and Innovation Act, Section 712 (e) of the Federal Food, Drug, and Cosmetic Act, Fiscal Year 2016 Annual Report on FDA Advisory Committee Vacancies and Public Disclosures Accessed on February 27, 2019
[14] The FDA does not publicly disclose financial interest information if it is exempt from disclosure under the Freedom of Information Act or otherwise protected from disclosure by statute or regulation, except if necessary to describe the type, nature, and magnitude of the financial conflict being waived.
[15] This information must be published within specified time frames before advisory committee meetings. Food, Drug, and Cosmetic Act section 712(c).
[16] FDA Guidance on Publication of Financial COI waivers. https://www.fda.gov/RegulatoryInformation/Guidances/ucm391034.htm#_ftn11
[17] Political party as described in 26 U.S.C. 527(e)

[18] Participation is active if, for example, it involves service as an official of the organization or in a capacity similar to that of a committee or subcommittee chairperson or spokesperson, or participation in directing the activities of the organization. In other cases, significant time devoted to promoting specific programs of the organization, including coordination of fundraising efforts, is an indication of active participation. Payment of dues or the donation or solicitation of financial support does not, in itself, constitute active participation.

[19] Pham-Kanter G., Revisiting Financial Conflicts of Interest in FDA Advisory Committees, Milbank Quarterly, September 2014 Volume 92, Issue 3 (pages 446–470), DOI: 10.1111/1468-0009.12073

[20] Id.

[21] Id.

[22] Cooper J., Golec J. Conflicts of Interest on Expert Committees: The Case of FDA Drug Advisory Committees, University of Connecticut School of Business Research Paper No. 17-02, April 2018 Accessed February 24, 2019

[23] Id.

[24] Piller C., You J. Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns, Science Magazine, July 5, 2018 Accessed February 24, 2019

[25] Id.

[26] Id.

[27] Piller C., You J. Hidden conflicts? Pharma payments to FDA advisers after drug approvals spark ethical concerns, Science Magazine, July 5, 2018 Accessed February 24, 2019

[28] Sullivan, T., FDA Conflicts of Interest Rules Means Fewer Experts on Advisory Panels, Policy and Medicine Blog, May 5, 2018 Accessed on February 24, 2019.

[29] FDA website – online Percent of FDA advisory committee member positions vacant at the end of the month Accessed February 27, 2019

[30] FDA website – online Percent of FDA advisory committee member positions vacant at the end of the month Accessed February 27, 2019

APPENDIX: RELEVANT AMA POLICY

Policy H-100.992, "FDA"

(1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.
(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.
(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

E-7.1.4, "Conflicts of Interest in Research"

Increasing numbers of physicians, both within and outside academic health centers, are becoming involved in partnerships with industry to conduct biomedical and health research. As they do so, physicians must be mindful of the conflicts such engagement poses to the integrity of the research and the welfare of human participants. In addition to financial conflicts of interest created by incentives to conduct trials and recruit subjects, physicians must be sensitive to the differing roles of clinician and investigator, which may require them to balance dual commitments to participants and science. This conflict of commitment is particularly acute when a physician-investigator has treated or continues to treat a patient who is eligible to enroll as a participant in a clinical trial the physician is conducting.
Minimizing and mitigating conflicts of interest in clinical research is imperative if the medical community is to justify and maintain trust in the medical research community.
Physicians who engage in research should:
(a) Decline financial compensation that awards in excess of the physician's research efforts and does not reflect fair market value. Physicians should not accept payment solely for referring patients to research studies.
(b) Ensure that the research protocol includes provision for funding participants' medical care in the event of complications associated with the research. A physician should not double-bill a third-party payer for additional expenses related to conducting the trial if he or she has already received funds from a sponsor for those expenses.
(c) As part of the informed consent process, disclose to prospective participants the nature and source of funding and financial incentives offered to the investigators. This disclosure should be included in any written consent materials.
(d) Avoid engaging in any research where there is an understanding that limitations can be placed on the presentation or publication of results by the research sponsor.
(e) Refrain from knowingly participating in a financial relationship with a commercial entity with whom they have a research relationship until the research relationship ends and the research results have been published or otherwise disseminated to the public.
(f) Disclose material ties to companies whose products they are investigating or other ties that create real or perceived conflicts of interest to:
(i) institutions where the research will be carried out;
(ii) organizations that are funding the research;
(iii) any journal or publication where the research results are being submitted.
(g) Physicians who have leadership roles in institutions that conduct biomedical and health research as well as the entities that fund research with human participants should promote the development of guidelines on conflicts of interest that clarify physician-investigators responsibilities.

AMA Principles of Medical Ethics: II,IV,V; The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law. Issued: 2016

Policy H-410.953, “Ethical Considerations in the Development of Clinical Practice Guidelines”

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines help inform physician judgment and decision making by physicians and patients. Clinical practice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, clinical practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable.
To that end, the development or updating of clinical practice guidelines should meet the following expectations:
1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed.
2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations.
3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups.
4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline.
5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided.
6. Guidelines are subject to rigorous, independent peer review.
7. Clear statements of methodology, COI policy and procedures, and disclosures of panel members’ conflicts of interest relating to specific recommendations are published with any guideline or otherwise made public.
8. Guidelines are in the first instance disseminated independent of support from or participation by individuals or entities that have a direct interest in the recommendations.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 6, November 2020

Subject:	Covenants Not to Compete (Resolution 10-A-19)
Presented by:	Russ Kridel, MD, Chair
Referred to:	Reference Committee B

INTRODUCTION

At the 2019 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) considered Resolution 10, "Covenants Not to Compete," introduced by the New Mexico Delegation, which directed:

1. Our American Medical Association consider as the basis for model legislation the New Mexico statute allowing a requirement that liquidated damages be paid when a physician partner who is a part owner in practice is lured away by a competing hospital system.

2. Our AMA ask our Council on Ethical and Judicial Affairs to reconsider their blanket opposition to covenants not to compete in the case of a physician partner who is a part owner of a practice, in light of the protection that liquidated damages can confer to independent physician owned partnerships, and because a requirement to pay liquidated damages does not preclude a physician from continuing to practice in his or her community.

Mixed testimony regarding Resolution 10-A-19 was received by the reference committee. A number of speakers suggested that more information was necessary regarding the issues raised by the resolution and that it should be referred to the Board of Trustees for further study. Testimony also suggested that the Board and not the Council on Ethical and Judicial Affairs (CEJA), was the appropriate entity to study the concerns that prompted the resolution. Individuals testifying also expressed hesitation about both basing model legislation on the New Mexico statute and basing AMA policy on a specific state law. Following the reference committee's recommendation, the HOD referred Resolution 10-A-19 to the Board.

Although Resolution 10-A-19 uses the phrase "Covenants Not to Compete," this report uses "Restrictive Covenants," to be consistent with AMA policy.

Use of the term "partner" or "partners"

While this report uses the terms "partner" or "partners" to refer to physician ownership interests in a group practice, this report's use of these terms should not be interpreted in any way as being limited to physician ownership interests in group practices formed as partnerships. Rather, the term "partner" or "partners" encompasses *any* type of physician ownership interests in a group practice, e.g., as a member in a limited liability corporation, a shareholder in a corporation, a partner in a partnership etc., regardless of the group practice's legal structure.

DISCUSSION

Concerns about Restrictive Covenants' Potential Negative Effects

There is growing concern among many AMA members regarding the negative impact of restrictive covenants. Some AMA members oppose restrictive covenants, in part because of the negative impact that restrictive covenants may have on them and their families if restrictive covenant enforcement compels a physician to move out of his or her community to continue practicing medicine. Members may also be disturbed about the potential negative effects that restrictive covenants may have on patient choice, patient access and the patient-physician relationship.

An Increase in Employed Physicians

The reason restrictive covenants are becoming more problematic for many AMA members is perhaps due to that fact that, for the first time ever, there are more employed physicians than physician-practice owners.[1] Recent state legislative activity is consistent with this trend, as several states have either enacted or amended restrictive covenant statutes applicable to physicians specifically or to health care generally.

Reasons why AMA members may support reasonable restrictive covenants

Other physicians, e.g., owners of physician practices or physician leaders of integrated health systems, may strongly support reasonable restrictive covenants. A reasonable restrictive covenant may, for example, give a medical practice peace of mind about committing the significant resources needed to help a new physician succeed, without having to fear that the physician will then leave, taking patients to a competitor and/or using sensitive information to gain a competitive advantage over his or her former employer. Further, physician practice owners may view reasonable restrictive covenants as necessary to ensure that all of the owners are mutually committed to the joint investments in the equipment and/or facilities that the entire practice must make in order to meet the agreed-upon business plan. CEJA Ethical Opinion 11.2.3.1, entitled, "Restrictive Covenants," does state, in part, that physicians should not agree to restrictive covenants that are unreasonable with respect to geography or duration and that do not make reasonable accommodation for patients' choice of physician. This report presents the entire text of Ethical Opinion 11.2.3.1 in the discussion concerning the second resolve of the resolution.

New Mexico

The New Mexico statute is a relatively recent development, enacted in 2015 and amended in 2017. The New Mexico law is a legislative compromise between physicians who are practice owners and physicians who are employees, acknowledging that there are physicians on both sides of the restrictive covenant issue.

The statute applies to "health care practitioners,"[2] which includes physicians, and to "agreements," which means "a written contract to which a health care practitioner is a party."[3] The New Mexico law states that a restrictive covenant in an agreement that restricts the right of a health care practitioner to provide clinical health care services is "unenforceable upon the termination of: (1) the agreement; (2) a renewal or extension of the agreement; or (3) a health care practitioner's employment with a party seeking to enforce the agreement."[4] Consequently, under the New Mexico statute, a restrictive covenant in an agreement such as an employment or practice partnership agreement, cannot be enforced against a former employee or partner. The law also states that such a provision in an agreement for clinical health care services is void, unenforceable

and against public policy if the provision: (1) makes the agreement subject to the laws of another state; or (2) requires any litigation arising out of the agreement to be conducted in another state.

Although the New Mexico law precludes restrictive covenant enforcement, the party, e.g., a former employer, retains significant rights. First, if a physician has worked for an employer for an initial period of less than three years and then leaves, the employer may require the physician to repay: (1) a loan; (2) relocation expenses; (3) a signing bonus or other remuneration bonus or other remuneration to induce the health care practitioner to relocate or establish a health care practice in a specified geographic area; or (4) recruiting, education, and training expenses. Second, a party may enforce a nondisclosure provision relating to confidential information and trade secrets. Third, the physician or health care practitioner may be required to comply with a non-solicitation provision with respect to patients and employees of the party seeking to enforce the agreement for a period of one year or less after the last date of employment.

The statute achieves a compromise between physicians who are only employees and practice owners by differentiating between the two when it comes to liquidated damages. As noted above, if a physician was an employee who has worked for an employer for an initial period of less than three years and leaves, the former employer can recover (1)-(4) above. This is the statute's way of protecting the former employer financially by enabling it to recover amounts incurred to bring the employee to the community and to help the physician establish a practice. After the initial three-year period, however, the employer cannot recover (1)-(4) because the statute presumes that the employer has, by then, recovered those costs. Further, since monetary recovery is limited to (1)-(4), the former employer may not obligate the physician to pay liquidated damages. By limiting monetary recovery and prohibiting restrictive covenant enforcement, the statute protects the employed physician who may have entered into an employment agreement with little or no bargaining power.

With respect to physician partners, the statute does not allow the practice to enforce a restrictive covenant against a former partner but does permit the practice to require the former partner to pay reasonable liquidated damages. This disparate treatment of physician owners and employees recognizes that physician partners owe duties to one another that do not apply to employed physicians. Unlike employees, a physician partner has a duty to protect other partners, the partnership itself and the large investment that the physician and the other partners have collectively made in the practice. If a practice makes investments that count on an individual partner's continued financial and other commitments to the practice, the New Mexico statute permits, as a matter of fairness, that the departing physician partner pay the practice reasonable liquidated damages if the partner leaves.

First Resolve of Resolution 10-A-19

The Board does not recommend that the AMA develop state model legislation at this time. The Board fully understands, however, that restrictive covenant issues are of great concern to many AMA members and believes that the AMA should provide members with further guidance and resources than currently exist. Accordingly, this report recommends that the AMA develop a state restrictive covenant legislative template, for reasons described below.

Difference Between a Model Bill and a Legislative Template

The AMA Advocacy Resource Center (ARC), the state legislative and regulatory unit of the AMA, makes model bills and state legislative templates available to state and national medical specialty societies to assist in their respective state legislative and regulatory strategy development and

implementation. Model bills are prescriptive in the sense that they present a single, optimal approach to an issue. A model bill usually has little commentary or explanation concerning the underlying rationale for the bill's specific provisions.

A state legislative template, on the other hand, is not prescriptive. A template is an environmental scan of relevant state law and presents multiple legislative options for addressing a topic that is so diverse and complex across the states that the more one-size-fits-all approach that a model bill represents may not be adequate. The ARC has developed legislative templates for a variety of issues including health courts, scope of practice issues, and medical liability reforms, to name a few.

Reasons Favoring a State Legislative Template

The Board has three reasons for recommending the creation of a state legislative template over a model bill.

First, state restrictive covenant statutes are very diverse, differing in terms of issues addressed, e.g., the role, if any, that liquidated damages may play in restrictive covenant analyses. Further complicating the matter is that many states have restrictive covenant-related legal decisions going back years, regardless of whether the state also has a statute on the books. The wide variation in states' legislative and judicial treatment of restrictive covenants can be particularly present when it comes to physician restrictive covenants. This is especially true where temporal and geographic reasonableness, the legitimacy of business interests involved, patient demographics, physician specialty and public policy considerations like patient choice and patient access may differ greatly from one case to another. The Board is concerned that any model legislation may be too specific to be of much use, since a bill would only present one set of legislative solutions to the myriad restrictive covenant issues. Not drafting a model bill would also avoid concerns expressed by reference committee testimony about basing model legislation on a specific state solution, e.g., the New Mexico statute, and AMA policy, more broadly, on one state law.

A legislative template could, on the other hand, capture at least some of the diversity discussed above and offer several options for legislative language and accompanying rationale. Issues covered could include, but not be limited to: identification of legitimate business interests; reasonableness of geographic scope; reasonableness of duration; damages; consideration given to the impact that restrictive covenant enforcement may have on the individual physician; termination events that trigger a restrictive covenant's application; and differing treatment of physician-owners and employees. The template could, of course, discuss key aspects of the New Mexico statute, and present potential solutions based on that law.

Second, restrictive covenants are a highly sensitive issue for AMA members. Many members have very strong opinions for and against restrictive covenants. The Board is concerned that any AMA-initiated model bill would fail to strike the proper balance between competing points of view, assuming a balance could be achieved across a membership that is diverse in a great many respects, e.g., in terms of specialty, geography, practice environment, etc. The Board notes that Policy H-383.987, "Restrictive Covenants in Physician Contracts," states that, "Our AMA will provide guidance, consultation, and model legislation concerning the application of restrictive covenants to physicians upon request of state medical associations and national medical specialty societies." This policy ensures that the AMA's development of any restrictive covenant model bill is informed by guidance that has been fully vetted at the state medical association or national medical specialty society level to ensure that the bill reflects the likely compromises that the association or society has worked out among its members. A state legislative template is, on the other hand, less likely to

invite division among AMA members, since the template would simply provide an environmental scan of the issues raised above and possible legislative options.

Third, with respect to making revisions and updates, a template is more flexible than a model bill. The AMA Council on Legislation (COL) works with AMA ARC staff to develop the AMA's model state bills. The COL approves the final draft of a model bill during one of its quarterly in-person meetings. The COL then submits that draft to the Board for consideration at the next Board meeting. The model bill is only final if the Board approves the bill. Any significant revisions to a model bill must go through the same process. Creating and revising a legislative template does not involve the more formal process that applies to official AMA model state bills. Again, this is because templates are environmental scans providing varying legislative language options rather than constituting a model bill's more definitive approach. Consequently, the AMA has more flexibility when it comes to timely updating its state legislative templates. This flexibility may be particularly important now given state medical associations', national medical specialty societies' and legislatures' increasing attention to restrictive covenants.

Second Resolve of Resolution 10-A-19

The Board does not recommend that the HOD adopt the second resolve in Resolution 10, since that resolve does not accurately reflect CEJA's position concerning restrictive covenants. Ethical Opinion 11.2.3.1, "Restrictive Covenants," states:

> Competition among physicians is ethically justifiable when it is based on such factors as quality of services, skill, experience, conveniences offered to patients, fees, or credit terms.
>
> Covenants-not-to-compete restrict competition, can disrupt continuity of care, and may limit access to care.
>
> Physicians should not enter into covenants that:
>
> a) Unreasonably restrict the right of a physician to practice medicine for a specified period of time or in a specified geographic area on termination of a contractual relationship; and
>
> b) Do not make reasonable accommodation for patients' choice of physician.
>
> Physicians in training should not be asked to sign covenants not to compete as a condition of entry into any residency or fellowship program.

Ethical Opinion 11.2.3.1 does not express a blanket opposition to restrictive covenant agreements, and does not prohibit physicians from using, or agreeing to, restrictive covenants. Ethical Opinion 11.2.3.1 simply states that physicians should not enter into a restrictive covenant that is unreasonable in terms of duration, geographic scope and does not make a reasonable accommodation for patients' choice of physician. Ethical Opinion 11.2.3.1 is consistent with the majority of states where courts will enforce physician restrictive covenants so long as the covenants protect a legitimate business interest, are reasonable with respect to duration and geography and are not otherwise against public policy, of which patient choice may be a consideration in some jurisdictions.[5] Accordingly, the Board does not recommend adopting the second resolve of the resolution.

Nevertheless, given the importance of restrictive covenants to AMA members, the HOD may have an interest in asking CEJA to incorporate into Ethical Opinion 11.2.3.1 the distinction recognized

by the New Mexico law between physician partners and physicians who are only employed. CEJA could, for example, state that partners in a practice have an ethical obligation to protect the practice, their fellow partners, and partners' investment in the practice. CEJA could further recognize that these mutual obligations apply when a partner chooses to leave the practice, e.g., if he or she chooses to work at a competing hospital, entailing that both the physician and the partners owe one another an ethical obligation to treat one another fairly upon the physician's exit. These duties could, depending on the circumstances, obligate the departing physician to compensate the partnership via the payment of reasonable, liquidated damages. Such an addition to Ethical Opinion 11.2.3.1 could further the opinion's emphasis on accommodating patient choice—ensuring that practices are treated fairly upon a partner's exit and enabling the practice to stay financially viable, thus remaining an option for patient choice.

AMA POLICY

In addition to the CEJA Ethical Opinion 11.2.3.1 and Policy H-383.987, other AMA policies discuss restrictive covenants. Policy H-310.929, "Principles for Graduate Medical Education," states that restrictive covenants must not be required of residents or applicants for residency education; and Policy H-225.950, "AMA Principles for Physician Employment," discourages physicians from entering into agreements that restrict the physician's right to practice medicine for a specified period of time or in a specified area upon termination of employment.

AMA EDUCATIONAL RESOURCES

Finally, as noted above, AMA has many resources that educate medical students, physicians-in-training, and physicians about restrictive covenants. For example:

- The AMA Career Planning Resource webpage has a wealth of information discussing physician employment issues, which includes information and tips regarding restrictive covenants. The AMA Career Planning Resource webpage may be accessed at https://www.ama-assn.org/residents-students/career-planning-resource/understanding-employment-contracts.
- The AMA also has two model employment agreements that discuss restrictive covenants: the Annotated Model Physician-Hospital Employment Agreement, 2011 edition: E-Book, free for AMA members at https://commerce.ama-assn.org/store/ui/catalog/productDetail?product_id=prod1240028&sku_id=sku1240037 and the Annotated Model Physician-Group Practice Employment Agreement: E-Book, free for members at https://commerce.ama-assn.org/store/ui/catalog/productDetail?product_id=prod2530052&sku_id=sku2530104. These resources contain model restrictive covenant language for potential physician employees to consider, which may prove useful in the employment negotiation process.
- Finally, AMA ARC staff work extensively on physician employment issues. AMA members are encouraged to contact the Advocacy Resource Center at arc@ama-assn.org, if they would like to obtain more information and resources concerning restrictive covenants.

RECOMMENDATION

In light of these considerations, the Board recommends that the following be adopted in lieu of Resolution 10-A-19 and the remainder of this report be filed:

Our American Medical Association create a state restrictive covenant legislative template to assist state medical associations, national medical specialty societies and physician members as they navigate the intricacies of restrictive covenant policy at the state level. (Directive to Take Action)

Fiscal Note: Less than $5000

REFERENCES

[1] "Updated Data on Physician Practice Arrangements: For the First Time, Fewer Physicians are Owners Than Employees," American Medical Association, Policy Research Perspectives, Carol Kane, PhD. (2019). This resource can be accessed at https://www.ama-assn.org/system/files/2019-07/prp-fewer-owners-benchmark-survey-2018.pdf.
[2] NMSA 1978, § 24-1I-1(B).
[3] NMSA 1978, § 24-1I-1(A).
[4] NMSA 1978, § 24-1I-2(A).
[5] Some states have enacted statutes prohibiting restrictive covenants, either generally or specifically with respect to physicians. States that more generally prohibit restrictive covenants include California, North Dakota, and Oklahoma. States that prohibit physician restrictive covenants include Colorado, Delaware, Massachusetts, New Hampshire, and Rhode Island. These statutes differ with respect to damages.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 7, November 2020

Subject:	Opposition to Involuntary Civil Commitment for Substance Use Disorder (Resolution 22-A-19)
Presented by:	Russ Kridel, MD, Chair
Referred to:	Reference Committee B

INTRODUCTION

At the 2019 Annual Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred Resolution 22-A-19, "Opposition to Involuntary Civil Commitment," introduced by the delegations from Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont, which asked:

> That our American Medical Association oppose involuntary civil commitment without judicial involvement of persons for reasons solely related to substance-use disorder; and
>
> That our AMA work to advance policy and programmatic efforts to address gaps in voluntary substance use treatment services.

Testimony on Resolution 22 was limited and mixed. Some speakers suggested that involuntary civil commitment was sometimes important to help save lives. Other speakers highlighted the positive role that judicial oversight can play for a person with a substance use disorder (SUD). The resolution sponsors noted the role of consent and questionable medical evidence justifying involuntary civil commitment. This report provides an update on the current use of some civil commitment proceedings and a review of relevant AMA policy, and it also makes policy recommendations.

DISCUSSION

Background

Involuntary civil commitment can be broadly described as "a legal intervention by which a judge, or someone acting in a judicial capacity, may order that a person with symptoms of a serious mental disorder, and meeting other specified criteria, be confined in a psychiatric hospital or receive supervised outpatient treatment for some period of time."[1] There are at least three key aspects to consider regarding this definition. First, the fact that an involuntary civil commitment is a legal proceeding that allows the state to intercede into a person's right to liberty for non-criminal reasons. Second, the loss of liberty is predicated on the existence of a mental disorder, and for the purposes of this report, "other specified criteria" includes a SUD. And third, bedrock to the AMA *Code of Medical Ethics* is that "[p]hysicians have civic duties, but medical ethics do not require a physician to carry out civic duties that contradict fundamental principles of medical ethics, such as the duty to avoid doing harm." (*Code of Medical Ethics*. Opinion 9.7.2, Court-Initiated Medical Treatment in Criminal Cases)

The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) says that "[s]ubstance use and mental disorders are closely linked." The 2018 National Survey on Drug Use and Health (NSDUH) presented data that "illicit substance use increases risk for other hazardous substance use and mental illness; and that [m]ental illness is a risk factor for illicit substance use."[2] In 2018, 36 percent of those with a serious mental illness (SMI) received no treatment while more than 20 million Americans had a (SUD), but only 10 percent received any treatment—roughly the same percentage of treatment for those with an SUD and SMI.[3] Detailing the scope of why the treatment gap continues is beyond the scope of the report, but among the predominant factors is the lack of access to health care professionals and appropriate medical services.[4]

Involuntary civil commitment

Proponents of involuntary civil commitment policies for the treatment of a SUD focus on the opportunity to help an individual receive treatment because that individual is a threat to him- or herself and/or others.[5] More than 30 states have a variation of law that allows for involuntary civil commitment for a SUD that variously define the nature of the harm and/or threat. This might include severe incapacitation, lack of decisional capacity, danger to property, abusing while pregnant or a repeated pattern of failing to meet social, financial or occupational responsibilities. The length of the involuntary commitment also can vary from up to one month to an indefinite period of time. The Associated Press reports that use of involuntary civil commitments has increased.[6]

Commentators have highlighted multiple concerns with involuntary civil commitment for SUD, including a lack of infrastructure to ensure that persons involuntarily committed are treated in medical facilities. There also is concern that law enforcement—and not a physician—might be able to initiate an involuntary civil commitment before a judge or magistrate.[7] And if a person is involuntarily committed for a SUD, will treatment be forced upon the person, including the taking of medications to treat withdrawal and/or maintenance medications? Or would such medications be denied to a person? The AMA *Code of Medical Ethics* counsels that physicians should: "Participate only if the procedure being mandated is therapeutically efficacious and is therefore undoubtedly not a form of punishment or solely a mechanism of social control." (*Code of Medical Ethics*. Opinion 9.7.2, Court-Initiated Medical Treatment in Criminal Case) In opposition to a bill allowing for involuntary civil commitment for a SUD, the Massachusetts Medical Society raised further concerns that, "There is no research to suggest that this treatment option will save lives. Therefore, more studies are needed before Massachusetts should institute a law with far-reaching consequences."[8]

While testimony before the HOD indicated that there may be benefits for select individuals, and there are news reports of positive individual outcomes, the studies that have been done on the subject note that dangers of involuntary civil commitment are high. A Massachusetts Department of Public Health review found that persons "who received involuntary treatment were 2.2 times as likely to die of opioid-related overdoses and 1.9 times as likely to die of any cause compared to those with a history of voluntary treatment only."[9] A review of nine studies found:

> There is limited scientific literature evaluating compulsory drug treatment. Evidence does not, on the whole, suggest improved outcomes related to compulsory treatment approaches, with some studies suggesting potential harms. Given the potential for human rights abuses within compulsory treatment settings, non-compulsory treatment modalities should be prioritized by policymakers seeking to reduce drug-related harms.[10]

Some of these abuses have ranged from placing persons civilly committed into the general population in a criminal facility, making persons wear prison garb (e.g. an orange jumpsuit) and forcing detoxification. For comparison, American Society of Addiction Medicine (ASAM) placement criteria for persons with a substance use disorder emphasize:

> [s]eparate placement criteria for adolescents and adults to create comprehensive and individualized treatment plans. Adolescent and adult treatment plans are developed through a multidimensional patient assessment over five broad levels of treatment that are based on the degree of direct medical management provided, the structure, safety and security provided, and the intensity of treatment services provided.[11]

This is not to suggest that all facilities where a person subject to involuntary civil commitment might be placed primarily house criminal subjects or provide substandard care. Rather, the juxtaposition is to highlight the need for in-patient care to rely upon medical standards of care. It is questionable whether a criminal facility can accomplish this.

Also, this does not suggest there is no role for involuntary civil commitment, or that jails cannot play a positive role for providing medical care to those incarcerated,[12] but as testified by members of the HOD, legal, ethical and other safeguards need to be put in place if a person is to lose his or her liberty and is civilly committed without his or her consent. As a threshold matter, it is worth noting that, "The availability of effective, comprehensive, community-based systems of care for persons suffering from serious mental illnesses will diminish the need for involuntary commitment and/or court-ordered treatment,"[13] according to the National Alliance of Mental Illness (NAMI). That is, using jails as stand-ins for medically-based treatment centers would not be necessary if there were sufficient public support and resources for community-based care for mental illness and SUDs. And it should be clear that while jails and prisons can and do provide medical care, a correctional facility's core purpose is to imprison, not treat patients.

NAMI's policy position further highlights elements to balance patient autonomy with the proper role of the judicial system when considering involuntary civil commitment. This includes ensuring a person potentially subject to involuntary civil commitment receive an expeditious hearing, medical decisions be made by medical professionals—and not courts—and that, "Involuntary inpatient and outpatient commitment and court-ordered treatment should be used as a last resort and only when it is believed to be in the best interests of the individual." This also includes ensuring the individual has an opportunity to oppose the involuntary commitment.[14]

The patient's right to be a part of the medical decision-making process is central to an effective patient-physician relationship. The ability to make decisions is central to the issues in this report. Among the detailed recommendations put forward by the American Psychiatric Association Council on Psychiatry and Law, "States authorizing involuntary outpatient commitment should provide due process protections equivalent to those afforded patients subject to involuntary hospitalization."[15]

An update on AMA efforts to advance policy and programmatic efforts to address gaps in voluntary substance use treatment services

The AMA, through its ongoing state and federal advocacy as well as its work through the AMA Opioid Task Force, continues its efforts to address gaps in evidence-based treatment for mental health and substance use disorders. At the state level, in the past two years, the AMA has helped advance and enact state laws in more than one dozen states to remove prior authorization for medications to help treat opioid use disorder—commonly referred to as medication assisted

treatment (MAT). The AMA's work in this area has included technical support to state medical societies, development of model state legislation and presentations by AMA leadership and staff to influential stakeholders such as the National Governors Association, National Association of Insurance Commissioners (NAIC), National Academies of Sciences, Engineering and Medicine, as well as the U.S. Congress.[16]

In 2019, the AMA also released with Manatt Health a "National Roadmap on State-Level Efforts to End the Opioid Epidemic," which highlighted best practices from multiple states on areas including reducing the treatment gap. While it is beyond the scope of this report to detail all of the best practices, with respect to reducing the treatment gap, the AMA-Manatt Health report[17] highlighted examples such as:

- The Pennsylvania state insurance commissioner helping forge a voluntary agreement with the Commonwealth's major commercial payers to remove prior authorization for MAT;
- The Colorado Division of Insurance implementing a law establishing an office of the ombudsman to assist state residents in accessing behavioral health care;
- The establishment of Centers of Excellence in Pennsylvania as part of hub-and-spoke models of care to help promote evidence-based care; and
- Community-based collaborative practice models led by the North Carolina Medical Society to enhance access to physicians and other health care professionals.

The AMA also continues its advocacy with partners such as the American Psychiatric Association (APA), ASAM and others in support of mental health and substance use disorder parity oversight and enforcement. In February 2020, after sustained advocacy in partnership with the APA, the NAIC approved a new charge for a newly formed Mental Health Parity and Addiction Equity Act (MHPAEA) Working Group that will continue to raise the importance of parity enforcement in the states. The AMA will continue to work with the NAIC and others as they develop parity-specific recommendations and actions.

With respect to payment reform to support increased access to treatment services, the AMA worked with the ASAM to develop a concept paper for an alternative payment model to support a team-based approach to office-based management of treatment for opioid use disorder (OUD), called "Patient-Centered Opioid Addiction Treatment model" (P-COAT). This model concept provided the foundation for Section 6042 of the SUPPORT Act, which requires the U.S. Centers for Medicare & Medicaid Services to implement a demonstration project supporting treatment of Medicare patients with OUD consistent with the comprehensive biopsychosocial model of care in the P-COAT approach. The P-COAT model also formed the basis for AMA and ASAM advocacy on a new Medicare payment policy that, effective in 2020, provides a bundled payment for office-based treatment of OUD. As AMA and ASAM recommended, the bundled payments include a higher payment for the first month of treatment to cover the cost of developing and getting the patient engaged in a treatment plan and educating the patient about self-management of their condition, and monthly payments of about $367 for as long as the patient remains in treatment. The payments support development of a treatment plan, care coordination, individual and group therapy and counseling for patients with OUD, with the cost of medications used in treatment paid separately.

The AMA has also been working to eliminate the requirement for physicians to get a special waiver from the U.S. Drug Enforcement Administration (DEA) in order to prescribe buprenorphine for the treatment of OUD. The AMA has supported legislation introduced in the U.S. House of Representatives that would eliminate this requirement and has met with senior Administration officials to seek the Administration's support for this policy change.

The AMA was encouraged by the Centers for Disease Control and Prevention's (CDC) recognition that its opioid prescribing guidelines have been misapplied and have had serious unintended consequences. CDC recently embarked on an effort to update its guidelines and the AMA has strongly cautioned the agency to heed the advice of the U.S. Department of Human and Health Services' Pain Management Task Force that patients with painful conditions need to be treated as individuals and that one-size-fits-all approaches must be avoided.

The AMA also has repeatedly urged the DEA to update its rules for electronic prescribing of controlled substances, especially outdated multifactor authentication rules. Regardless, even though federal law required an update in 2019, the DEA has not yet done so. This is important because federal law requires e-prescribing controlled substances starting in 2021.

AMA POLICY

The AMA has both Ethics and HOD policy on the areas covered in this report. The AMA *Code of Medical Ethics (the Code)* makes clear that*:*

> Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. (*Code of Medical Ethics*. Opinion 2.1.1, Informed Consent)

The Code also covers situations when a patient may lack decision-making capacity. In those situations, the Code reiterates that, "Respect for patient autonomy is central to professional ethics and physicians should involve patients in health care decisions commensurate with the patient's decision-making capacity." (*Code of Medical Ethics*. Opinion 2.1.2, Decisions for Adult Patients Who Lack Capacity) The Code further advises:

> Even when a medical condition or disorder impairs a patient's decision-making capacity, the patient may still be able to participate in some aspects of decision making. Physicians should engage patients whose capacity is impaired in decisions involving their own care to the greatest extent possible, including when the patient has previously designated a surrogate to make decisions on his or her behalf. (*Code of Medical Ethics*. Opinion 2.1.2, Decisions for Adult Patients Who Lack Capacity)

For situations involving children and adolescents, the Code also suggests respect not only for the parent's (or guardian's) responsibility, but also the need to include children in the decision-making process. The Code advises that:

> Respect and shared decision making remain important in the context of decisions for minors. Thus, physicians should evaluate minor patients to determine if they can understand the risks and benefits of proposed treatment and tailor disclosure accordingly. The more mature a minor patient is, the better able to understand what a decision will mean, and the more clearly the child can communicate preferences, the stronger the ethical obligation to seek minor patients' assent to treatment. (*Code of Medical Ethics*. Opinion E-2.2.1, Pediatric Decision Making)

The Code further provides that, "Except when immediate intervention is essential to preserve life or avert serious, irreversible harm, physicians and parents/guardians should respect a child's refusal to assent, and when circumstances permit should explore the child's reason for dissent." (*Code of Medical Ethics*. Opinion E-2.2.1, Pediatric Decision Making)

Finally, the Code provides that, "All individuals have a fundamental right to be free from unreasonable bodily restraint." It further explains that, "At times, however, health conditions may result in behavior that puts patients at risk of harming themselves. In such situations, it may be ethically justifiable for physicians to order the use of chemical or physical restraint to protect the patient." These times must be governed by the physician's professional judgment. The Code goes on to state "In certain limited situations, when a patient poses a significant danger to self or others, it may be appropriate to restrain the patient involuntarily. In such situations, the least restrictive restraint reasonable should be implemented and the restraint should be removed promptly when no longer needed." (*Code of Medical Ethics*. Opinion 1.2.7, Use of Restraints)

AMA policy also is clear on the benefits of shared decision-making, including support for "[p]rotecting the patient-physician relationship by continuing to advocate for: the obligation of physicians to be patient advocates." (Policy H-165.837, "Protecting the Patient-Physician Relationship") AMA policy also emphasizes the need for patients to be active partners in their health care, including support for "[t]he concept of voluntary use of shared decision-making processes and patient decision aids as a way to strengthen the patient-physician relationship and facilitate informed patient engagement in health care decisions." (Policy H-373.997, "Shared Decision-Making")

Finally, as briefly quoted in the body of the report, the Code provides important considerations for physicians' actions in court-initiated medical treatments. While the policy cited above mainly focuses on the rights of prisoners in a criminal setting, the Code provides guidance for physicians who do participate in court-initiated medical treatments. In addition to the discussion above, the Code includes the provision that:

> Physicians who provide care under court order should be able to conclude, in good conscience and to the best of his or her professional judgment, that to the extent possible the patient voluntarily gave his or her informed consent, recognizing that an element of coercion that is inevitably present. When treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, an independent physician or a panel of physicians not responsible to the state should confirm that voluntary consent was given. (*Code of Medical Ethics*. Opinion 9.7.2, Court-initiated Medical Treatment in Criminal Cases)

RECOMMENDATIONS

The Board recommends that Resolution 22-A-19 be amended by addition and deletion and the remainder of the report be filed.

1. That our American Medical Association oppose civil commitment proceedings for patients with a substance use disorder unless: a) A physician or mental health professional determines that civil commitment is in the patient's best interest consistent with the AMA *Code of Medical Ethics*; b) Judicial oversight is present to ensure that the patient can exercise his or her right to oppose the civil commitment; c) The patient will be treated in a medical or other health care facility that is staffed with medical professionals with training in mental illness and addiction, including medications to help with withdrawal and other symptoms as prescribed by his or her physician; and d) The facility is separate and distinct from a correctional facility. (New HOD Policy)

2. That our AMA continue its work to advance policy and programmatic efforts to address gaps in voluntary substance use treatment services. (Directive to Take Action)

Fiscal Note: Less than $500

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[2] The National Survey on Drug Use and Health: 2018. Presentation by Elinore F. McCance-Katz, MD, PhD Assistant Secretary for Mental Health and Substance Use. Substance Abuse and Mental Health Services Administration. U.S. Department of Health and Human Services. Available at https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/Assistant-Secretary-nsduh2018-presentation.pptx

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[11] "What is the ASAM Criteria." American Society of Addiction Medicine. https://www.asam.org/Quality-Science/the-asam-criteria/about

[12] "The Repurposing of the American Jail," Jessica Pishko. *The Atlantic*. November 19, 2019. Albany Sherriff Craig Apple converted 25 cells in a county correctional facility to allow for the provision of medication-assisted treatment for inmates, but this is primarily still for those convicted of a crime.

[13] National Alliance on Mental Illness. Legal Issues. Available at https://www.nami.org/About-NAMI/Policy-Platform/9-Legal-Issues

[14] Id.

[15] Resource Document on Involuntary Outpatient Commitment and Related Programs of Assisted Outpatient Treatment. American Psychiatric Association Council on Psychiatry and Law. Approved by the Joint Reference Committee, October 2015. Note: The APA included the following disclaimer: "The findings, opinions, and conclusions of this report do not necessarily represent the views of the officers, trustees, or all members of the American Psychiatric Association. Views expressed are those of the authors."

[16] Susan R. Bailey, MD, President-elect, AMA Board of Trustees. Statement of the American Medical Association to the U.S. House of Representatives Committee on Oversight and Reform Re: Medical Experts: Inadequate Federal Approach to Opioid Treatment and the Need to Expand Care. June 19, 2019. Available at https://docs.house.gov/meetings/GO/GO00/20190619/109654/HHRG-116-GO00-Wstate-BaileyS-20190619.pdf

[17]f National Roadmap on State-Level Efforts to End the Opioid Epidemic. American Medical Association and Manatt Health. September 2019. Available at www.end-opioid-epidemic.org/national-roadmap

REPORT 13 OF THE BOARD OF TRUSTEES (November 2020)
Merit-based Incentive Payment System (MIPS) Update
(Reference Committee B)

EXECUTIVE SUMMARY

At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred two resolutions, and at the 2019 Annual Meeting, a third resolution was referred, for a combined Board of Trustees (Board) Report at the 2019 Interim Meeting related to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Each of the resolutions asks for a repeal or significant change to the Merit-Based Incentive Payment System (MIPS). Our AMA worked closely with Centers for Medicare & Medicaid Services' (CMS) and Congress on implementation of the MIPS program, on necessary technical fixes, and has continued advocacy on MIPS implementation. Despite these efforts, the three resolutions highlight the serious challenges physician practices face under the MIPS program.

Our AMA understands that there is significant frustration with the MIPS program and continues to vigorously advocate that both CMS and Congress make needed changes. Our AMA continues to advocate that Congress provide physicians with positive Medicare payment updates, extend the $500 million positive payment adjustment for exceptional performance in MIPS that is not subject to budget neutrality, and extend alternative payment models (APMs) payments to provide physicians with additional resources to help transition to APMs. The COVID-19 pandemic has only increased the hardship on physician practice and underscores the need for positive payment updates this year.

Our AMA should have the ability to support legislation that would provide physicians with positive payment updates that could shift the budget neutrality dynamic of the current MIPS program. Consistent with existing AMA policy, the new recommendation contained in this report is that our AMA support legislation that ensures Medicare physician payment is sufficient to safeguard beneficiary access to care, replaces or supplements budget neutrality in MIPS with incentive payments, or implements positive annual physician payment updates.

The new recommendation to support replacing or supplementing budget neutrality will allow flexibility to review and consider legislation without being too narrowly defined that we overlook an opportunity to improve the MIPS program in another, impactful way.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 13, November 2020

Subject: Merit-based Incentive Payment System (MIPS) Update

Presented by: Russ Kridel, MD, Chair

Referred to: Reference Committee B

At the 2018 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) referred two resolutions, and at the 2019 Annual Meeting, a third resolution was referred, for a combined Board of Trustees (Board) Report at the 2019 Interim Meeting related to the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The first resolution, Resolution 206-I-18, "Repealing Potential Penalties Associated with MIPS," was introduced by the Florida Delegation and asks that:

> Our American Medical Association advocate to repeal all potential penalties associated with the MIPS program.

The second resolution, Resolution 231-I-18, "Reducing the Regulatory Burden in Health Care," was introduced by the Pennsylvania Delegation and asks that:

> Our American Medical Association work to support the repeal of the Merit-Based Incentive Payment System (MIPS); and that upon repeal of MIPS, our AMA oppose any federal efforts to implement any pay-for-performance programs unless such programs add no significant regulatory or paperwork burdens to the practice of medicine and have been shown, by evidence-based research, to improve the quality of care for those served.

The third resolution, Resolution 243-A-19, "Improving the Quality Payment Program and Preserving Patient Access," was introduced by the Texas Delegation and asks that:

> Our American Medical Association strongly advocate for Congress to make participation in MIPS and alternative payment models (APMs) under the Quality Payment Program (QPP) completely voluntary, that our AMA strongly advocate for Congress to eliminate budget neutrality in MIPS and to finance incentive payments with supplemental funds that do not come from Medicare Part B payment cuts to physicians and other clinicians, and that our AMA call on the Centers for Medicare and Medicaid Services (CMS) to provide a transparent, accurate, and complete Quality Payment Program Experience Report on an annual basis so physicians and medical societies can analyze the data to advocate for additional exemptions, flexibilities, and reductions in reporting burdens, administrative hassles, and costs.

The reference committee heard mixed testimony on Resolutions 206, 231, and 243. Some testified that MIPS should be repealed, as many practices that serve Medicare beneficiaries cannot sustain additional reductions in their Medicare payments. Others testified that our AMA should continue working with Congress and the Administration to ensure that all physician practices, regardless of

size or specialty, have the opportunity to succeed in the QPP. Also, there was significant testimony that our AMA should continue advocating to simplify and improve the MIPS program and increase the number and variety of APMs available to physicians.

BACKGROUND

Our AMA was supportive when Congress replaced the flawed, target-based sustainable growth rate (SGR) formula with a new payment system under MACRA. Scheduled payment cuts prior to the implementation of MACRA exceeded 20 percent. Those cuts would have had a devastating impact on physician practices and patient access to care. Under MACRA, the SGR formula was replaced with specified payment updates for 2015 through 2019, and for 2026 and beyond. MACRA also created an opportunity to address problems found in existing physician reporting programs, including the chance to earn incentives. In addition, the law sought to promote innovation by encouraging new ways of providing care through APMs.

Our AMA worked closely with CMS and Congress on implementation of the MIPS program, and AMA advocacy efforts resulted in a policy allowing physicians who reported on one measure, one time, for one patient to avoid a penalty in the first year. This transition period allowed many physician practices to be successful in the first performance year of MIPS, with 93 percent of eligible clinicians receiving a modest positive payment adjustment and nearly three-quarters qualifying for an additional exceptional performance bonus. (Notably, the exceptional performance bonus is funded at $500 million annually in the MACRA statute and is not budget neutral.)

Following the first year of the MIPS program, our AMA was also successful in getting Congress to make needed technical changes to MACRA in the Bipartisan Budget Act of 2018. These changes helped many practices avoid penalties that they likely would otherwise have incurred under the MIPS program. Specifically, our AMA worked with Congress to exclude Medicare Part B drug costs from MIPS payment adjustments, as including these additional items and services created significant inequities in the administration of the program. In addition, our AMA helped achieve changes that allow CMS to reweight the Cost performance category to not less than 10 percent for the third, fourth, and fifth years of MIPS, instead of increasing it to 30 percent as the law previously required, and to set the performance threshold for three additional years instead of basing it on the mean or median of previous MIPS scores.

As a result of these efforts, CMS has continued to gradually implement the MIPS program. Based on the second performance period in calendar year 2018, 97 percent of eligible clinicians received a modest positive payment adjustment in 2020 with 84 percent qualifying for an additional exceptional performance bonus.

DISCUSSION

Ongoing AMA Advocacy Efforts

Since the enactment of MACRA, our AMA has worked closely with both Congress and CMS to promote a smooth implementation of the QPP. Despite these efforts, Resolutions 206, 231, and 243 illustrate that the implementation of a new quality and payment program for physicians is a major undertaking and significant improvements to the program are still needed. As is noted in the resolutions, numerous improvements must still be made to the MIPS program, including more accurate risk adjustment for cost and quality measures, timelier program feedback for physicians, and a more cohesive program structure. In addition, physician practices, especially small and rural physician practices, cannot shift to new payment models without adequate resources.

In an effort to address these outstanding issues, our AMA has convened MIPS and APM workgroups made up of representatives from across the physician community, which have developed creative solutions to improve the QPP. Feedback from the MIPS and APM workgroups, as well as other state and specialty medical societies, has led our AMA to focus its efforts to improve the QPP on several key issues: replacing the Medicare physician pay freeze with a stable revenue source that allows physicians to sustain their practice; replacing or supplementing budget neutrality provisions; extending the Advanced APM payments for an additional six years; simplifying the MIPS scoring system and creating a more meaningful MIPS program; expanding exceptions and flexibilities during the COVID-19 pandemic; and ensuring small and rural practices have the opportunity to succeed.

Implement Annual Positive Physician Payment Updates

Resolution 206 notes that many physician practices cannot sustain additional reductions in their Medicare payments. Our AMA agrees, and while MACRA included modest positive payment updates in the Medicare Physician Fee Schedule, it left a gap from 2020 through 2025, during which there are no updates at all. Following this six-year freeze, the law specifies physician payment updates of 0.75 percent or 0.25 percent for physicians participating in APMs or MIPS.

Our AMA recognizes that these payment updates are not sufficient, particularly while physicians are investing resources to shift to new payment models and provide quality patient care during the COVID-19 pandemic. Therefore, our AMA has advocated that Congress pass legislation providing physicians with positive payment updates beginning in 2020. As the COVID-19 pandemic continues to confront the nation, our AMA is calling on Congress to protect patient access to medical care and preserve the viability of physician practices across the country by implementing a positive payment update and providing additional financial assistance to physicians. Our AMA is working on a survey to determine the financial impact the COVID-19 pandemic is having on physician practices and the results are expected in September. We anticipate the results will support our AMA's advocacy for Medicare payment improvements.

Medicare physician payment will also be impacted by budget neutrality requirements in implementation of the AMA Current Procedural Terminology (CPT) Editorial Panel coding framework and AMA Specialty Society Relative Value Scale Update Committee (RUC) recommended values for office and outpatient visits starting January 1, 2021. Our AMA strongly supports implementation of CMS' new office visit policy and believes it will lead to significant administrative burden reduction and better describe and recognize the resources involved in office visits as they are performed today. However, we are deeply concerned that the corresponding budget neutrality cuts are deeply problematic during or immediately after the COVID-19 pandemic, during which physician practices have experienced severe reductions in revenue.

Physicians who do not report office visit codes, including radiologists, pathologists, and hospitalists, face estimated 2021 payment cuts of 8 percent solely due to budget neutrality. Specialties, including general surgeons, critical care physicians, anesthesiologists, and emergency physicians, face estimated cuts ranging from 5 percent to 7 percent. The budget neutrality driven cuts also will reduce the positive impacts of the office visit changes for primary care physicians, oncologists, pediatricians, and other specialties for whom the office visits are a high proportion of their services.

Our AMA, joined more than one hundred national specialty societies and health care professional organizations, in urging the U.S. Department of Health & Human Services (HHS) Secretary to use its authorities and flexibilities under the public health emergency to implement the office visit

increases and waive the requirement for CMS to adjust Medicare physician payments for budget neutrality when it implements the office visit coding and payment changes that it has finalized for 2021. Our AMA is pursuing all avenues for waiving budget neutrality, including Congressional action.

The Board strongly supports advocating for positive payment updates, which are needed to provide physicians a margin to maintain their practices, as well as transition to more efficient models of care delivery and provide relief to physician practices confronting the COVID-19 pandemic.

Extend APM Payments

In addition to providing positive physician payment updates, Congress and the Administration must work to provide physicians with adequate resources to move into new payment models. One goal of MACRA, in addition to the MIPS program, was to provide physicians with a path to transition into new, innovative APMs that could allow physicians to be paid for services that add value to patient care.

To help facilitate this transition, Congress provided a five percent incentive payment for physicians who participate in Advanced APMs during the first six years of the program. Unfortunately, through the first three participation years, very few physicians had the opportunity to earn this incentive payment due to the small number of Advanced APMs approved by CMS. While our AMA is working closely with numerous physician groups, as well as the Center for Medicare & Medicaid Innovation (CMMI), to develop and test physician-led APMs, it will take time to implement the number of APMs needed to allow most physicians a realistic opportunity to participate in these models. Therefore, our AMA is urging Congress to extend the Advanced APM incentive payments to provide support to physicians as they transition to new payment models. The Board strongly supports efforts to ensure there are voluntary APMs available for physicians in all specialties and practices of all sizes.

Impact of Budget Neutrality

The Board strongly supports providing physicians with the resources necessary to improve quality and patient care. The Board is therefore concerned about reports from numerous physicians who have worked diligently to comply with the numerous MIPS requirements, yet have ended up investing more in health information technology and care management processes than they received through their resulting MIPS incentive payment. The negative return on investment from MIPS participation is a serious problem. Also, several witnesses have testified in reference committee that funding positive MIPS incentive payments with penalties imposed on practices that do not score above the MIPS performance threshold exacerbates this problem for smaller practices. The Board supports language in Resolution 243-A-19 noting that physicians need dedicated funding for MIPS incentive payments in order to ensure physicians have the capital they need to move into models that provide patients with the utmost value. Basing positive payment adjustments on penalties also creates uncertainty in the program, which further discourages practices from making the up-front investments needed to transition to value-based payment and care delivery models.

MIPS incentive payments for performance years 2019 through 2022 are based on a combination of budget neutrality and dedicated annual funding. Congress provided $500 million for each of the first six years of MIPS to fund additional adjustments for exceptional performance. The first two years of MIPS payment adjustments (2019 and 2020) were funded largely by the $500 million annual allocation due to the gradual implementation of MIPS which resulted in very few penalties.

One option for supplementing budget neutral incentive payments is to seek an extension of the $500 million pool, which expires after year six of MIPS.

While supporting the elimination of budget neutrality in the MIPS program, the Board also understands that this is a complex issue that would involve some difficult trade-offs. It would be extremely difficult to secure funding from Congress both for positive MIPS incentive payments, which would help practices that participate in MIPS and exceed the MIPS performance threshold, and funding for positive conversion factor updates, which would help all practices that care for fee-for-service Medicare patients, including small practices that are excluded from MIPS, because they are below the low-volume threshold. In addition, physicians in large practices have generally obtained higher MIPS scores than those in smaller practices, so this policy is more likely to help large practices than smaller practices. Partially or fully eliminating MIPS budget neutrality may also make it more difficult to achieve adoption of AMA recommendations to improve the MIPS program, because Congress and the Administration would view any increase in the number of physicians able to succeed in MIPS as increasing federal spending.

Despite these concerns, the Board determined that replacing or supplementing the budget neutrality requirements in MIPS with incentive payments would help support physicians as they continue to work to comply with the program. Therefore, the Board supports MIPS incentive payments not limited by budget neutrality requirements to provide physicians a margin to transition into more efficient models of care delivery.

Simplifying and Streamlining MIPS

Our AMA has repeatedly urged CMS to reduce burden and complexity and make MIPS more clinically relevant for physicians and patients. As noted in Resolution 243, many physicians must report MIPS measures that are not linked to improved clinical care for their patients. Studies suggest the cost of reporting quality metrics is considerable.[1] Our AMA is engaged in a research study to determine the cost to physician practices of creating the infrastructure needed to participate in MIPS and of collecting and reporting data. Through interviews with practice leaders and administrators, our AMA aims to understand the costs (e.g., software, staff, practice leaders, and consultants) associated with MIPS participation for practices of different sizes and specialties and in different regions of the country, as well as practice leader views about MIPS.

Our AMA's MIPS workgroup has developed detailed recommendations that would make the MIPS program more cohesive and allow physicians to select more relevant measures to report. Our AMA has urged CMS to streamline the MIPS program by allowing physicians to focus their participation around a specific episode of care, clinical condition, or public health priority. By allowing physicians to focus on activities that fit into their workflow and address their patient populations' needs, rather than segregated measures divided into four disparate MIPS categories, the program would be more likely to improve quality of care for patients and be more meaningful for physicians.

In the 2020 Medicare Physician Payment Schedule final rule, CMS outlined the MIPS Value Pathways (MVPs) approach, which responds to some of the recommendations made to CMS by the AMA after significant consultation with specialty and state medical societies. Physicians in MVPs would focus their MIPS participation on a set of measures tailored to an episode of care or condition starting in the 2021 performance period. The MVPs framework would also provide enhanced data and feedback to physicians. Our AMA and specialty societies are working with CMS to develop MVPs that are relevant to physicians and their patients and expect more details to be included in future rulemaking. Our AMA continues to work with CMS to ensure MVP

participation is voluntary, less burdensome, and incentivizes physicians to opt into this new framework.

Our AMA has also urged Congress to allow CMS the flexibility to base scoring on multi-category measures to make MIPS more clinically meaningful, reduce silos between each of the four MIPS categories, and create a more unified program. Our AMA's goal is to help the Administration develop an approach that allows physicians to spend less time on reporting and more time with patients and on improving care. The Board strongly supports the efforts to unify MIPS reporting while also making it more meaningful for physicians.

Support for Small and Rural Practices

As noted in Resolution 231, our AMA agrees that small physician practices could be disproportionately impacted by penalties under MIPS. In 2017, the national mean and median scores for all MIPS eligible clinicians were 74.01 and 88.97 points. However, the mean and median scores for small practices were 43.46 and 37.67. In 2018, small practice scores increased, although they remain lower than the national mean and median, which were 86.96 and 99.63. The 2018 mean and median scores for small practices were 65.69 and 81.16. Our AMA agrees that the lower scores achieved by small practices illustrate the need for our AMA to continue advocating for changes to MACRA that will help small practices and solo practitioners.

In order to help small practices become more successful in the MIPS program, our AMA has engaged in advocacy efforts in multiple areas. First, our AMA has been a strong supporter of the low-volume threshold exemption which was increased and now excludes physicians with allowed charges of $90,000 or less, 200 or fewer unique Medicare patients, or 200 or fewer covered professional services to Medicare Part B beneficiaries from the MIPS program. Our AMA has also supported MIPS policies including reduced reporting requirements for small practices in the Quality performance category, hardship exemptions from the Promoting Interoperability performance category for qualifying small practices, bonus points for small practices, and technical assistance grants to help small and rural practices succeed in the program. Finally, our AMA is advocating for a legislative change that would allow CMS to develop separate thresholds for small and large practices, so that small physician practices are compared to practices with similar resources. The Board agrees that additional changes are needed to ensure small and rural practices have the opportunity to succeed in the MIPS program.

Flexibility During the COVID-19 Public Health Emergency

Since the HHS Secretary declared a public health emergency (PHE) due to the 2019 novel coronavirus on Jan. 27, 2020, our AMA has worked constantly with CMS to identify issues and make recommendations to ensure physicians are able to continue to meet the needs of patients while confronting and slowing the spread of the virus. In response to our concerns about relieving MIPS reporting burdens, CMS automatically held harmless from penalties every eligible clinician who did not submit any MIPS data for 2019 and extended the deadline for physicians and groups who wished to opt into MIPS.

CMS recently announced expanded hardship exceptions due to COVID-19 for the 2020 MIPS performance period. Physicians will have the option to opt-out completely or partially from MIPS by completing a hardship exception application through the end of the year. For example, a practice may submit a hardship application and indicate that they do not want to be scored on Cost and Quality and have their score calculated based on just Promoting Interoperability and Improvement

Activities. Alternatively, practices may submit a hardship application and opt-out of all four performance categories and be held harmless from a 2022 payment adjustment.

Our AMA is pleased CMS took our recommendation to create flexible reporting options in 2020 with the option to reweight any or all of the MIPS performance categories. The flexibilities should assist with allowing practices to focus their attention on caring for patients during the pandemic and reduce administrative burden. Our AMA continues to monitor the impact COVID-19 is having on practices and advocate to CMS for the appropriate relief and to ensure CMS liberally grants hardship requests due to the COVID-19 PHE. It is also our understanding that CMS QPP.CMS.GOV website is in the process of being updated with the 2020 policy and should reflect the announcement along with additional educational materials in late summer. The information currently posted on the website is regarding the 2019 MIPS COVID-19 policy. CMS has also indicated that additional information on MIPS COVID-19 policy will be included in upcoming rulemaking. The Board strongly supports efforts to minimize MIPS reporting burdens and allow greater flexibility during this pandemic.

Other Advocacy Efforts

In addition to these major program changes, our AMA also continues to urge CMS and Congress to address more nuanced issues in the QPP such as:

- Stabilizing the performance threshold until program improvements are tested and implemented;
- Revamping the Virtual Group option to encourage small practices to participate;
- Improving risk adjustment methodologies to account for social risk factors;
- Reducing the number of quality measures a physician must report under the Quality performance category;
- Maintaining a minimum point floor for physicians reporting on quality measures that meet the data completeness threshold, regardless of performance on the measure;
- Eliminating the requirement that physicians must report on an outcome or high priority measure and eliminating the requirement to report on all-payer data;
- Developing a phased approach for removing "topped-out" measures from MIPS and improving the benchmark methodology;
- Aligning the MIPS and Physician Compare calculation methodologies;
- Maintaining the Cost performance category weight while new episode-based cost measures are developed and piloted;
- Modifying the threshold levels of APM participation required to be eligible for the APM incentive payments;
- Securing adoption of physician-focused payment models with realistic targets for improving patient health outcomes and generating savings;
- Eliminating the Total Cost of Care and Medicare Spending Per Beneficiary measures within the Cost performance category as improved episode-based cost measures are developed;
- Allowing physicians to attest to their use of Certified Electronic Health Record Technology (CEHRT) in the Promoting Interoperability performance category;
- Reducing the number of measures physicians are required to report in the Promoting Interoperability performance category; and
- Providing credit for the use of health information technology beyond CEHRT.

As illustrated by the list above, our AMA has spent significant staff time working with both Congress and CMS to improve the QPP. Our AMA has specifically been advocating persistently for MIPS to be more meaningful to physicians and less administratively burdensome, and to increase the number of available APMs. Our AMA advocacy team meets regularly with both CMS

officials and Congressional staff to work to improve MIPS and the APM pathway for physicians and will continue to do so going forward.

Among the concerns raised with seeking repeal of the MIPS penalties at this time is that the cost would need to be offset and would potentially come at the expense of bonuses or across the board cuts in physician payments, which would impact physicians who are currently exempt from MIPS, such as small practices. Another concern is that repealing penalties associated with MIPS or repealing the entire program at this time could result in an alternative quality payment program that may be less desirable. Furthermore, such a shift in our AMA's advocacy position would effectively preclude our AMA from continuing our advocacy efforts with state and specialty medical societies in support of the Administration's and Congress' efforts to advance successful, innovative payment models as well as the technologies needed to support such models.

AMA POLICY

Our AMA has numerous existing policies on MACRA including Policies D-395.999, D-395.998, H-390.838, D-390.950, and D-390.949. Together, these policies direct our AMA to work with CMS to advocate for improvements to MIPS, a reduction in MIPS requirements for all physicians, an exemption to MIPS for small practices, a period of stability in the MIPS program to allow for testing and stability and additional flexibilities for fragile practices. AMA policy also supports our advocacy to increase the number and variety of APMs available to physicians, extend the Advanced APM incentive payments to provide support to physicians as they transition to new payment models, and modify the threshold levels of APM participation required to be eligible for the APM incentive payments (Policies H-385.913, H-450.931, and H-385.908).

CONCLUSION

Our AMA understands that there is significant frustration with the MIPS program and continues to vigorously advocate that both CMS and Congress make needed changes. In addition to urging CMS to make additional improvements to the MIPS program, our AMA is joined with many state and specialty medical societies making it a priority to advocate that Congress provide physicians with positive Medicare payment updates, extend the $500 million positive payment adjustment for exceptional performance in MIPS that is not subject to budget neutrality, and extend APM payments to provide physicians with additional resources to help transition to APMs. The Board believes that the lack of positive updates from 2020 to 2025 severely threatens physicians' ability to sustain their practices, especially while at the same time implementing quality improvements. Our AMA will work with due purpose to seek positive updates as we continue to reduce MIPS burdens.

While the Board recognizes that the QPP needs improvement, we also acknowledge that the MIPS program continues to be refined. Detailed results from the 2017 and 2018 performance years reflect MIPS' gradual implementation as most physicians were able to achieve high scores and earn a positive payment adjustment. Results from at least the 2019 and 2020 performance periods will be impacted by the COVID-19 pandemic and hardship exceptions will be in place to provide relief. Implementation of a new quality and payment program is a significant undertaking and requires an iterative process with constant evaluation and improvement.

In addition to our current policy, the Board believes that our AMA should have the ability to support legislation that would provide physicians with positive payment updates that could shift the budget neutrality dynamic of the current MIPS program. The Board understands that eliminating the budget neutrality requirements of the MIPS program is a complex issue and that there are many

ways to achieve that goal. Therefore, we offer a recommendation to support replacing or supplementing budget neutrality, which will allow us flexibility to review and consider legislation without being too narrowly defined that we overlook an opportunity to improve the MIPS program in another way.

Therefore, the Board recommends, consistent with existing AMA policy, that our AMA continue its work with CMS and Congress to improve the MIPS program, increase APM opportunities for physicians, and provide additional resources for physician practices through positive updates and APM payments. Given that the repeal of MACRA could result in a more burdensome quality program with no opportunity to earn incentives and lower payment updates for physicians, we recommend not advocating for the repeal of MIPS penalties or the MIPS program at this time. However, the Board will continue to monitor the QPP's impact and burden on physicians, and if improvements to the program are not sufficient, we will reevaluate our advocacy policies and position in the future.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolutions 206-I-18, 231-I-18, and 243-A-19 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) support legislation that ensures Medicare physician payment is sufficient to safeguard beneficiary access to care, replaces or supplements budget neutrality in MIPS with incentive payments, or implements positive annual physician payment updates. (Directive to Take Action)

2. That our AMA reaffirm Policy D-395.999, "Reducing MIPS Reporting Burden," Policy D-395.998, "Opposed Replacement of the Merit-Based Incentive Payment System with the Voluntary Value Program," Policy H-390.838, "MIPS and MACRA Exemption," Policy D-390.950, "Preserving a Period of Stability in Implementation of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA)," Policy D-390.949, "Preserving Patient Access to Small Practices Under MACRA," Policy H-385.913, "Physician-Focused Alternative Payment Models," Policy H-385.913, "Physician-Focused Alternative Payment Models," Policy H-450.931, "Moving to Alternative Payment Models," and Policy H-385.908, "Physician-Focused Alternative Payment Models: Reducing Barriers." (Reaffirm HOD Policy)

Fiscal Note: Less than $500

REFERENCES

[1] Casalino LP, Gans D, Weber R, Cea M, Tuchovsky A, Bishop TF, Miranda Y, Frankel BA, Ziehler KB, Wong MM, Evenson TB. U.S. Physician Practices Spend More than $15.4 Billion Annually to Report Quality Measures (March 2016). *Heath Affairs* 35:3 https://doi.org/10.1377/hlthaff.2015.1258

EXISTING AMA POLICY

Policy D-395.999, "Reducing MIPS Reporting Burden"
Our AMA will work with the Centers for Medicare and Medicaid Services (CMS) to advocate for improvements to Merit-Based Incentive Payment System (MIPS) that have significant input from practicing physicians and reduce regulatory and paperwork burdens on physicians. In the interim, our AMA will work with CMS to shorten the yearly MIPS data reporting period from one-year to a minimum of 90-days (of the physician's choosing) within the calendar year.

Policy D-395.998, "Opposed Replacement of the Merit-Based Incentive Payment System with the Voluntary Value Program"
1. Our AMA will oppose the replacement of the Merit-Based Incentive Payment System (MIPS) with the Voluntary Value Program (VVP) as currently defined.
2. Our AMA will study the criticisms of the Merit-Based Incentive Payment System (MIPS) program as offered by proponents of the VVP to determine where improvement in the MIPS program needs to be made.
3. Our AMA will continue its advocacy efforts to improve the MIPS program, specifically requesting: (a) true EHR data transparency, as the free flow of information is vital to the development of meaningful outcome measures; (b) safe harbor protections for entities providing clinical data for use in the MIPS program; (c) continued infrastructure support for smaller practices that find participation particularly burdensome; (d) adequate recognition of and adjustments for socioeconomic and demographic factors that contribute to variation in patient outcomes as well as geographic variation; and (e) limiting public reporting of physician performance to those measures used for scoring in the MIPS program.
4. Our AMA will determine if population measures are appropriate and fair for measuring physician performance.

Policy H-390.838, "MIPS and MACRA Exemption"
Our AMA will advocate for an exemption from the Merit-Based Incentive Payment System (MIPS) and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) for small practices.

Policy D-390.950, "Preserving a Period of Stability in Implementation of the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA)"
1. Our AMA will advocate that Centers for Medicare and Medicaid Services (CMS) implement the Merit-Based Payment Incentive Payment System (MIPS) and Alternative Payment Models (APMs) as is consistent with congressional intent when the Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act (MACRA) was enacted.
2. Our AMA will advocate that CMS provide for a stable transition period for the implementation of MACRA, which includes assurances that CMS has conducted appropriate testing, including physicians' ability to participate and validation of accuracy of scores or ratings, and has necessary resources to implement provisions regarding MIPS and APMs.
3. Our AMA will advocate that CMS provide for a stable transition period for the implementation of MACRA that includes a suitable reporting period.

Policy D-390.949, "Preserving Patient Access to Small Practices Under MACRA"
1. Our AMA will urge the Centers for Medicare and Medicaid Services to protect access to care by significantly increasing the low volume threshold to expand the MACRA MIPS exemptions for small practices (on a voluntary basis), and to further reduce the MACRA requirements for ALL physicians' practices to provide additional flexibility, reduce the reporting burdens and administrative hassles and costs.
2. Our AMA will advocate for additional exemptions or flexibilities for physicians who practice in health professional shortage areas.
3. Our AMA will determine if there are other fragile practices that are threatened by MACRA and seek additional exemptions or flexibilities for those practices.

Policy H-385.913, "Physician-Focused Alternative Payment Models"
1. Our AMA recognizes that the physician is best suited to assume a leadership role in transitioning to alternative payment models (APMs).
2. Our AMA supports that the following goals be pursued as part of an APM:
A. Be designed by physicians or with significant input and involvement by physicians;
B. Provide flexibility to physicians to deliver the care their patients need;
C. Promote physician-led, team-based care coordination that is collaborative and patient-centered;
D. Reduce burdens of Health Information Technology (HIT) usage in medical practice;
E. Provide adequate and predictable resources to support the services physician practices need to deliver to patients, and should include mechanisms for regularly updating the amounts of payment to ensure they continue to be adequate to support the costs of high-quality care for patients;
F. Limit physician accountability to aspects of spending and quality that they can reasonably influence;
G. Avoid placing physician practices at substantial financial risk;
H. Minimize administrative burdens on physician practices; and
I. Be feasible for physicians in every specialty and for practices of every size to participate in.
3. Our AMA supports the following guidelines to help medical societies and other physician organizations identify and develop feasible APMs for their members:
A. Identify leading health conditions or procedures in a practice;
B. Identify barriers in the current payment system;
C. Identify potential solutions to reduce spending through improved care;
D. Understand the patient population, including non-clinical factors, to identify patients suitable for participation in an APM;
E. Define services to be covered under an APM;
F. Identify measures of the aspects of utilization and spending that physicians can control;
G. Develop a core set of outcomes-focused quality measures including mechanisms for regularly updating quality measures;
H. Obtain and analyze data needed to demonstrate financial feasibility for practice, payers, and patients;
I. Identify mechanisms for ensuring adequacy of payment; and
J. Seek support from other physicians, physician groups, and patients.
4. Our AMA encourages CMS and private payers to support the following types of technical assistance for physician practices that are working to implement successful APMs:
A. Assistance in designing and utilizing a team approach that divides responsibilities among physicians and supporting allied health professionals;
B. Assistance in obtaining the data and analysis needed to monitor and improve performance;
C. Assistance in forming partnerships and alliances to achieve economies of scale and to share tools, resources, and data without the need to consolidate organizationally;

D. Assistance in obtaining the financial resources needed to transition to new payment models and to manage fluctuations in revenues and costs; and
E. Guidance for physician organizations in obtaining deemed status for APMs that are replicable, and in implementing APMs that have deemed status in other practice settings and specialties.
5. Our AMA will continue to work with appropriate organizations, including national medical specialty societies and state medical associations, to educate physicians on alternative payment models and provide educational resources and support that encourage the physician-led development and implementation of alternative payment models.

Policy H-450.931, "Moving to Alternative Payment Models"
1. As physician payment moves to pay-for-value, our American Medical Association will help physician practices with the following: (a) physician practices need support and guidance to optimize the quantity and content of physician work under alternative payment models; (b) address physicians' concerns about the operational details of alternative payment models to improve their effectiveness; (c) to succeed in alternative payment models, physician practices need data and resources for data management and analysis; and (d) harmonize key components of alternative payment models across multiple payers, especially performance measures to help physician practices respond constructively.
2. Our AMA will, in partnership with other appropriate physician organizations, work with the Centers for Medicare & Medicaid Services to establish an appropriate timetable for implementation of pay-for-value models that takes into account the physician community's readiness to assume two-sided risk (up-side and down-side risk).

Policy H-385.908, "Physician-Focused Alternative Payment Models: Reducing Barriers"
1. Our AMA encourages physicians to engage in the development of Physician-Focused Payment Models by seeking guidance and refinement assistance from the Physician-Focused Payment Model Technical Advisory Committee (PTAC).
2. Our AMA will continue to urge CMS to limit financial risk requirements to costs that physicians participating in an APM have the ability to influence or control.
3. Our AMA will continue to advocate for innovative ways of defining financial risk, such as including start-up investments and ongoing costs of participation in the risk calculation that would alleviate the financial barrier to physician participation in APMs.
4. Our AMA will work with CMS, the Office of the National Coordinator for Health Information Technology (ONC), PTAC, interested medical societies, and other organizations to pursue the following to improve the availability and use of health information technology (IT):
a. Continue to expand technical assistance;
b. Develop IT systems that support and streamline clinical participation;
c. Enable health IT to support bi-directional data exchange to provide physicians with useful reports and analyses based on the data provided;
d. Identify methods to reduce the data collection burden; and
e. Begin implementing the 21st Century Cures Act.
5. Our AMA will work with CMS, PTAC, interested medical societies, and other organizations to design risk adjustment systems that:
a. Identify new data sources to enable adequate analyses of clinical and non-clinical factors that contribute to a patient's health and success of treatment, such as disease stage and socio-demographic factors;
b. Account for differences in patient needs, such as functional limitations, changes in medical conditions compared to historical data, and ability to access health care services; and

c. Explore an approach in which the physician managing a patient's care can contribute additional information, such as disease severity, that may not be available in existing risk adjustment methods to more accurately determine the appropriate risk stratification.
6. Our AMA will work with CMS, PTAC, interested medical societies, and other organizations to improve attribution methods through the following actions:
a. Develop methods to assign the costs of care among physicians in proportion to the amount of care they provided and/or controlled within the episode;
b. Distinguish between services ordered by a physician and those delivered by a physician;
c. Develop methods to ensure a physician is not attributed costs they cannot control or costs for patients no longer in their care;
d. Explore implementing a voluntary approach wherein the physician and patient agree that the physician will be responsible for managing the care of a particular condition, potentially even having a contract that articulates the patient's and physician's responsibility for managing the condition; and
e. Provide physicians with lists of attributed patients to improve care coordination.
7. Our AMA will work with CMS, PTAC, interested medical societies, and other organizations to improve performance target setting through the following actions:
a. Analyze and disseminate data on how much is currently being spent on a given condition, how much of that spending is potentially avoidable through an APM, and the potential impact of an APM on costs and spending;
b. Account for costs that are not currently billable but that cost the practice to provide; and
c. Account for lost revenue for providing fewer or less expensive services.

REPORT OF THE BOARD OF TRUSTEES

B of T Report 14, November 2020

Subject:	Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities (Resolution 201-I-19)
Presented by:	Russ Kridel, MD, Chair
Referred to:	Reference Committee B

INTRODUCTION

At the American Medical Association's (AMA) 2019 Interim Meeting, the House of Delegates (HOD) referred Resolution 201-I-19, "Advocating for the Standardization and Regulation of Outpatient Addiction Rehabilitation Facilities," introduced by the Medical Student Section, which asks: "That our American Medical Association advocate for the expansion of federal regulations of outpatient addiction rehabilitation centers in order to provide patient and community protection in line with evidence-based care." Testimony on Resolution 201 was mixed. Testimony was provided that raised significant concerns related to additional federal regulations proffered by Resolution 201. Additional testimony offered several amendments and substitute language proposals to strengthen the resolution. Believing that further study was warranted, the HOD referred Resolution 201. This report recommends new policy and reaffirms existing policy in lieu of the adoption of Resolution 201.

DISCUSSION

Background

Despite sharp reductions in opioid prescriptions, increases in the use of state prescription drug monitoring programs, increases in naloxone, and other signs of progress, the nation is now experiencing a more deadly and complicated drug overdose epidemic. According to the AMA's Opioid Task Force 2020 Progress Report, released July 21, 2020, while physicians have reduced opioid prescriptions by 37 percent between 2014 and 2019, illicitly manufactured fentanyl, fentanyl analogues, and stimulants (e.g., methamphetamine, cocaine) are now killing more Americans than ever. The use of these illicit drugs has surged, and their overdose rate increased by 10.1 percent and 10.8 percent, respectively. The changing landscape of the epidemic poses challenges for the health care system, which must pivot to treat people in danger of overdose from all drugs.

One of the primary challenges in ending the nation's drug overdose epidemic remains the inability of most patients to obtain evidence-based care for a substance use disorder. While the Affordable Care Act (ACA) and the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) in combination have addressed some of the coverage and access gaps, the National Survey on Drug Use and Health for 2017 and 2018, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), has found that over 90 percent of those 12 and older with an illicit drug use disorder did not receive treatment. The number of drug overdoses will continue to rise

unless more is done to help the more than two million Americans with an untreated substance use disorder.

Resolving the issue of capacity to treat all patients who require it, however, faces several barriers. While network adequacy laws require a sufficient number of addiction medicine and psychiatric physicians in a patient's network, health insurance companies are falling far short of their obligation, and enforcement of these requirements often is lacking. Moreover, many payers are failing to comply with state and federal mental health and substance use disorder parity laws.

Removing the barriers for patients to receive evidence-based treatment is critical to helping end the epidemic. AMA advocacy in this area has been substantial and multipronged, focusing on removing barriers to evidence-based care, encouraging more physicians to become trained to provide buprenorphine in-office to help treat opioid use disorder, and advocating for payers to increase network capacity and demonstrate compliance with mental health and substance use disorder parity laws. The AMA is working at the state and federal levels to strengthen network adequacy requirements and enforcement and promote meaningful oversight and enforcement of mental health and substance use disorder parity laws. In addition, the AMA has advocated against health insurance company tactics to delay and deny access to evidence-based treatment for opioid use disorder through the use of prior authorization requirements and other barriers for medications to treat opioid use disorder (MOUD), the gold standard for treating opioid use disorder. Barriers include the reluctance among some providers and individuals to use MOUD, stigma, administrative obstacles, and lack of sufficient treatment facilities and addiction medicine specialists or physicians who treat patients with an OUD. The AMA has partnered with the American Psychiatric Association, American Society of Addiction Medicine (ASAM), and many other organizations in the Federation to simultaneously address these issues.

Congressional Action

According to SAMHSA, due to the increased demand for opioid treatment, substance use treatment centers are a multi-billion-dollar industry. As noted in Resolution 201, media outlets have reported cases of fraud and abuse in this industry. Multiple federal law enforcement agencies, including the Federal Trade Commission (FTC), the Federal Bureau of Investigation (FBI), and the Department of Labor's Employee Benefits Security Administration (EBSA), have conducted investigations uncovering fraudulent acts regarding substance use treatment services and products, especially involving insurance fraud. Under the Federal Trade Commission Act (15 U.S.C. §§41 et seq.), the FTC has the authority to prohibit false or deceptive claims and may seek a judicial order levying civil penalties on violators. The FDA and FTC have sent joint warning letters to companies illegally marketing unapproved opioid cessation products claiming to treat opioid addiction and withdrawal. In addition, several states, including New York, have cracked down on fraudulent operators and federal prosecutors have brought lawsuits in California and Florida.

In 2018, as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271—the SUPPORT for Patients and Communities Act, or the SUPPORT Act), Congress took action against fraudulent treatment centers. Sections 8021-8023 of the SUPPORT Act include the Opioid Addiction Recovery Fraud Prevention Act, which prohibits any unfair or deceptive acts regarding substance use disorder treatment services or products. The provision makes these practices unlawful under section 18 of the Federal Trade Commission Act (15 U.S.C. §57a). The provision effectively authorizes the FTC to seek civil penalties against opioid treatment programs and products that make false or deceptive claims regarding their cost, price, efficacy, performance, benefit, risk, or safety. The bill also

authorizes state attorneys general, or other state officials, to bring civil actions for violations. The AMA supported these provisions.

The Board commends the laudable goal underlying Resolution 201. However, in considering the many comments received on this resolution, we find most compelling the many comments by those who testified before the reference committee that the problem is not lack of regulation but lack of enforcement of laws. As noted above, state and federal laws already govern outpatient treatment facilities. Federal regulations can often interfere with evidence-based medicine—e.g., the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain issued by the CDC—and the Board agrees that standardized evidence-based federal regulations are not the right approach. The Board also notes that medical specialties, such as ASAM and the American Psychiatric Association, have guidelines and standards to help ensure the provision of evidence-based care in treatment facilities for in-patient and out-patient care.

The Board has determined that more evaluation of existing programs and outcomes is needed. Billions of dollars have been spent by the federal government in support of state-level grant programs to provide care for those with a substance use disorder or co-occurring mental disorder. Many of these programs are certainly saving lives, but there may be others that are not as effective. The SUPPORT Act took an important step toward ensuring such evaluation in section 7171, which requires the Secretary to review entities that receive federal funding to provide SUD treatment services. The review is required to include certain specified elements about the entity's history, population served, and treatment capacity. The Secretary is required, within two years of enactment, to develop and submit a plan to Congress to direct appropriate resources to entities that provide SUD treatment services in order to address inadequacies in services or funding identified through the required review. When released, this report will help in determining which of the many federally funded programs are working and should be continued and which should either be improved or denied future funding. The AMA looks forward to highlighting those evidence-based, best practices demonstrated to help increase access to treatment for those with an OUD.

Moreover, we remain concerned that relying on short-term grants that depend on the annual appropriations process in Congress does not provide long-term certainty for states in terms of planning for programs and resources or accessibility to treatment and continuity of care for individuals seeking substance use disorder treatment. A short-term grant would not allow most states to recruit, for example, addiction medicine specialists or psychiatrists to underserved areas if there is only a short-term commitment for that medical professional. Recruiting a physician (and his or her family) to relocate with a promise of only a 6- or 12-month commitment is problematic, to say the least. Sustained funding and a comprehensive framework to prevent and treat all substance use disorders is necessary as the epidemic evolves and overdose fatalities involving illicit opioids, stimulants (e.g., methamphetamine), heroin, and cocaine increase.

One such proposal, which the AMA supports, is the "Comprehensive Addiction Resources Emergency (CARE) Act" (S. 1365/H.R. 2569), introduced by Senator Elizabeth Warren (D-MA) and the late Representative Elijah E. Cummings (D-MD). The CARE Act is modeled directly on the Ryan White Comprehensive AIDS Resources Emergency Act, which was passed by Congress in 1990 to provide significant new funding to help state and local governments combat the HIV/AIDS epidemic. The CARE Act is designed to support local decision making and federal research and programs to prevent drug use while funding evidence-based treatments and recovery support services. The bill would provide $100 billion over 10 years, the type of long-term funding that could really help to turn-around the substance-use epidemic. While this bill has not moved forward during this Congressional session, your Board believes it serves as an excellent model for a framework in the future.

AMA POLICY

Our AMA has longstanding and extensive policy on addiction and substance use disorder treatment. Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction," which was reaffirmed by the HOD at the 2019 Interim Meeting, provides in part that our AMA "will: (a) 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; and (b) develop a public awareness campaign to increase awareness that medical treatment of substance use disorder with medication-assisted treatment is a first-line treatment for this chronic medical disease."

Likewise, AMA policy provides that "our AMA (1) will continue to seek and participate in partnerships designed to foster awareness and to promote screening, diagnosis, and appropriate treatment of substance misuse and substance use disorders; (2) will renew efforts to: (a) have substance use disorders addressed across the continuum of medical education; (b) provide tools to assist physicians in screening, diagnosing, intervening, and/or referring patients with substance use disorders so that they have access to treatment; (c) develop partnerships with other organizations to promote national policies to prevent and treat these illnesses, particularly in adolescents and young adults; and (d) assist physicians in becoming valuable resources for the general public, in order to reduce the stigma and enhance knowledge about substance use disorders and to communicate the fact that substance use disorder is a treatable disease; and (3) will support appropriate federal and state legislation that would enhance the prevention, diagnosis, and treatment of substance use disorders." (Policy H-95.922, "Substance Use and Substance Use Disorders").

Current AMA policy also broadly covers parity issues, including support for "health care reform that meets the needs of all Americans, including people with mental illness and substance use/addiction disorders and will advocate for the inclusion of full parity for the treatment of mental illness and substance use/addiction disorders in all national health care reform legislation." (Policy H-165.888, "Evaluating Health System Reform Proposals") (Also see Policy D-180.998, "Insurance Parity for Mental Health and Psychiatry" and Policy H-185.974, "Parity for Mental Illness, Alcoholism, and Related Disorders in Medical Benefits Programs").

With respect to third-party payers, our AMA opposes federal, state, third-party and other laws, policies, rules and procedures, including those imposed by pharmacy benefit managers working for Medicaid, Medicare, TRICARE, and commercial health plans, that would limit a patient's access to medically necessary pharmacological therapies for opioid use disorder, whether administered in an office-based opioid treatment setting or in a federal regulated Opioid Treatment Program, by imposing limitations on the duration of treatment, medication dosage or level of care. (Policy H-95.944, "Third-Party Payer Policies on Opioid Use Disorder Pharmacotherapy").

More generally, with regard to federal drug policy, "our AMA, in an effort to reduce personal and public health risks of drug abuse, urges the formulation of a comprehensive national policy on drug abuse, specifically advising that the federal government and the nation should: (1) acknowledge that federal efforts to address illicit drug use via supply reduction and enforcement have been ineffective; (2) expand the availability and reduce the cost of treatment programs for substance use disorders, including addiction; (3) lead a coordinated approach to adolescent drug education; (4) develop community-based prevention programs for youth at risk; (5) continue to fund the Office of National Drug Control Policy to coordinate federal drug policy; (6) extend greater protection against discrimination in the employment and provision of services to drug abusers; (7) make a long-term commitment to expanded research and data collection; (8) broaden the focus

of national and local policy from drug abuse to substance abuse; and (9) recognize the complexity of the problem of substance abuse and oppose drug legalization." (Policy H-95.981, "Federal Drug Policy in the United States").

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 201-I-19, and that the remainder of the report be filed.

1. That our AMA advocate for the expansion of federal grants in support of treatment for a substance use disorder to states that are conditioned on that state's adoption of law and/or regulation that prohibit drug courts, recovery homes, sober houses, correctional settings, and other similar programs from denying entry or ongoing care if a patient is receiving medication for an opioid use disorder or other chronic medical condition. (Directive to Take Action)

2. That our AMA advocate for sustained funding to states in support of evidence-based treatment for patients with a substance use disorder and/or co-occurring mental disorder, such as that put forward by the American Society of Addiction Medicine, American Academy of Addiction Psychiatry, American Psychiatric Association, American Academy of Child and Adolescent Psychiatry and other professional medical organizations. (Directive to Take Action)

3. That our AMA reaffirm Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction." (Reaffirm HOD Policy)

4. That our AMA reaffirm Policy H-95.922, "Substance Use and Substance Use Disorders." (Reaffirm HOD Policy)

5. That our AMA reaffirm H-95.981, "Policy Federal Drug Policy in the United States." (Reaffirm HOD Policy).

Fiscal Note: Less than $5000

REPORT OF THE BOARD OF TRUSTEES

B of T Report 16, November 2020

Subject:	Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings, BOT Report 2-I-19
Presented by:	Russ Kridel, MD, Chair
Referred to:	Reference Committee B

INTRODUCTION

At the 2019 Interim Meeting of the AMA House of Delegates, Board of Trustees (BOT) Report 2, "Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings," was considered for adoption.

Board Report 2-I-19 recommended:

> That our American Medical Association (AMA) support further research into how primary care practices can implement MAT into their practices and disseminate such research in coordination with primary care specialties;
>
> That our AMA support efforts to expand primary care services to patients receiving methadone maintenance therapy (MMT) for patients receiving care in an Opioid Treatment Program or via office-based therapy; and
>
> That the AMA Opioid Task Force increase its evidence-based educational resources focused on MMT and publicize those resources to the Federation. (Directive to Take Action)

Testimony on Board Report 2-I-19 generally supported the recommendations, but there was conflicting testimony related to Recommendation 2. Recommendations 1 and 3 were adopted. This report discusses the issues raised by Recommendation 2 and presents additional recommendations.

DISCUSSION

Background

Board Report 2-I-19 discussed the history and efficacy of methadone maintenance treatment (MMT) in great detail, including the increase in Opioid Treatment Programs (OTPs) offering MMT; the medication's efficacy in treating opioid use disorder; and the various state and federal requirements regulating the provision of MMT. Board Report 2-I-19 also reviewed examples of clinical research and practice in providing MMT in primary care settings, "that have demonstrated benefits of having MMT provided in a primary care setting outside of a traditional OTP." BOT Report 2 explained, however, that the examples were, "highly structured and still must comply with state and federal rules (including who can dispense, take-home rules for stable patients, patient monitoring, strict record-keeping, etc.) governing the provision of MMT." It is worth further

highlighting that testimony pointed out the limited nature of the research, and the studies did not involve large groups of patients. The patients in the studies, moreover, were highly selected; with low acuity; without significant untreated psychiatric comorbidity; and had been stable in treatment for at least one year. In addition, the primary care practices in the studies each had a close ongoing relationship with the community OTP, and there was not the option of the physicians in the primary care setting to provide buprenorphine, which was approved by the U.S. Food and Drug Administration (FDA) for use in treating opioid use disorder in 2002.[1]

The Board provides this additional context to emphasize both the positive nature of the pilot programs but also to make clear that they were provided as examples rather than suggesting the MMT primary care practice pilot programs should be the rule or able to be replicated in all situations. The Board appreciates the opportunity to clarify the issues and present a discussion and recommendations to further support increased access to evidence-based care.

There are other barriers to MMT, including the fact that MMT remains one of the most highly stigmatized forms of treatment to treat opioid use disorder (OUD). Previous studies make clear how patients who receive MMT, "experience prejudice, stereotypes, and discrimination from friends and family, coworkers and employers, healthcare workers, and others."[2] This stigma is one of the root causes why those with an OUD may not seek treatment. In addition, because MMT is highly regulated by multiple layers of state and federal government, patients encounter multiple additional barriers, including a lack of access in rural areas[3] and the common requirement to drive or travel long distances to an OTP.[4] Dosing restrictions/requirements and other administration and/or legal barriers limit the ability of jails, prisons and Federally Qualified Health Centers (FQHCs) to provide MMT to particularly vulnerable and marginalized populations. It is beyond the scope of this report, but important to note that the AMA, American Society of Addiction Medicine (ASAM) and other medical organizations strongly support removing barriers to treatment for OUD in correctional settings.[5] Furthermore, some states place additional restrictions on the number of OTPs allowed to operate in a state or have burdensome requirements for an OTP to open.[6] Each of these barriers—whether stigma, social determinants, statute or rule—potentially limit a patient's ability to receive MMT and could also hinder that patient from receiving any care, including primary care as discussed above. At the same time, the Board recognizes that there is an appropriate role for clinical and other guidance to ensure the safety of patients. The focus of this report is not to delve into every potential barrier but to point out, broadly, that there are opportunities for further advocacy to identify, evaluate and either support or oppose policies that impede the provision of primary care services in an OTP, as well as the provision of MMT itself.

At a minimum, better coordination with primary care and MMT services would help increase access to evidence-based care for an OUD. Better support and training for family physicians, for example, to assess, diagnose and refer patients with an OUD to an OTP for MMT or other appropriate care, is supported by evidence.[7] While beyond the scope of this report, clinical research also is widely available to help primary care physicians with dosing and other clinical issues raised by the use of buprenorphine and/or MMT.[8,9] The AMA also has placed additional resources regarding methadone on the AMA drug overdose epidemic microsite, including information and research from the American Association of Treatment for Opioid Dependence,[10] American Academy of Family Physicians,[11] ASAM,[12] American College of Physicians[13] and the Providers Clinical Support System.[14] The AMA will continue to update the microsite with relevant information as provided by our Federation partners.

Physicians who might be interested to include MMT in primary care practices should be aware, for example, of some of the costs that their practices would incur under current federal requirements to operate an OTP.[15] Practices would need to meet specifications to assure that the stocked methadone

and the practice site are secure. Credentialed staff would need to be present to administer medication. Systems would need to be in place to monitor patients for adherence, ensure stock of medication and keep records with accountability to the U.S. Drug Enforcement Administration (DEA). The Board recognizes that these requirements are not insignificant and may be cost prohibitive. In addition, the Board points out the many different therapeutic and patient safety issues raised during the I-19 Interim Meeting concerning dosing, methadone's narrow therapeutic index, side effects and other issues.[16]

The issue at hand, however, is not whether patients currently receiving MMT, or those who might benefit from MMT, should also receive primary care services. The issue is how to best ensure that patients who are receiving MMT, or would benefit from receiving MMT, *also* receive primary care services. As noted in Board Report 2-I-19 and above, this entails multiple aspects, including removing barriers to MMT. There is no question that patients receiving MMT would benefit from receiving primary care services and the AMA remains committed to supporting efforts for patients receiving care in an OTP to also receive primary care services. This must be an evidence-based approach[17] done in compliance with applicable state and federal regulations. If the evidence demonstrates that patients can safely receive MMT in office-based settings, and the provision of such care is done in accordance with the highest standards of medical evidence and clinical research, the AMA wants to ensure that it supports policies that advance patient care.

It follows that the Board recommends further research into evidence-based initiatives to support the integration of primary care services into OTPs. This includes working with our partners at the American Society of Addiction Medicine, American Psychiatric Association, American Academy of Addiction Psychiatry, American Academy of Family Physicians and other medical societies to better understand and identify examples and best practices of how primary care services have been integrated into OTPs and addiction medicine practices. Additional stakeholders, including the American Association for the Treatment of Opioid Dependence, will likely be able to provide helpful information on evidence-based initiatives—as well as barriers—to integrate primary care services in OTPs and practices providing care for substance use disorders.

As stated above, the Board recognizes that the costs, requirements, etc. may make including MMT in primary care practices challenging and as such, the Board understands that not all primary care practices are able to or would be able to provide MMT. Yet, at a time when more Americans than ever are dying from illicitly manufactured fentanyl, fentanyl analogs and heroin—and prescription opioid-involved mortality remains at more than 11,000 deaths per year—the AMA believes all efforts must be made to increase access to evidence-based care. This is in line with recommendations from the National Academy of Medicine (NAM), which recommends the need for the DEA and U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) to "explore methadone delivery models that can increase access to this lifesaving medication."[18] The NAM authors call for additional use of pilot programs to evaluate best practices as well as the need for health insurance companies, Medicaid, and Medicare to "eliminate policies that disincentivize clinicians from providing medications and limit or delay access to treatment." The call for further research and removal of administrative and financial barriers are items the AMA strongly supports.

The AMA will continue its work to remove utilization management barriers to patients with an OUD from receiving evidence-based care. This includes AMA advocacy to: (1) urge states to include all medications used to treat OUD on the lowest cost-sharing tier of a health insurer's or pharmacy benefit management company formulary;[19] (2) support for state Medicaid agencies to include methadone on the state preferred drug list; (3) support for innovative proposals such as mobile units to provide MMT;[20] and broad support for increased flexibility for OTPs to provide take-home dosing and other policies during the COVID-19 pandemic.[21] It bears repeating that the

AMA believes the focus must be on increasing access to MMT *and* primary care. The AMA does not see the value in debating the specific mechanisms by which physicians can do this effectively so long as they do so safely and in accordance with best clinical practice and medical evidence. This approach will help remove stigma and increase access to MMT and primary care. AMA policy strongly supports physicians exercising the clinical judgment to care for their patients according to the highest standards that the medical profession brings to all other medical conditions. This is true for MMT and any other type of treatment proven effective for a medical disease.

The Board, therefore, recommends that the AMA provide further support for primary care services and MMT, including continued support for clinical research and other evidence to guide safe clinical practice, as well as new recommendations to remove barriers and increase access to evidence-based care.

AMA POLICY

The AMA opposes "the stigma associated with patients suffering from persistent pain and/or substance use disorders, including addiction." (Policy D-95.981, "Improving Medical Practice and Patient/Family Education to Reverse the Epidemic of Nonmedical Prescription Drug Use and Addiction") The AMA broadly supports MMT, the evolving nature of evidence supporting MMT, education on MMT as well as removing barriers to MMT. (Policy H-95.957, "Methadone Maintenance in Private Practice") Specifically, Policy H-95.957 "supports the position that 'medical' methadone maintenance may be an effective treatment for the subset of opioid dependent patients who have attained a degree of behavioral and social stability under standard treatment and thereby an effective measure in controlling the spread of infection with HIV and other blood-borne pathogens but further research is needed; encourages additional research that includes consideration of the cost of 'medical' methadone maintenance relative to the standard maintenance program (for example, the cost of additional office security and other requirements for the private office-based management of methadone patients) and relative to other methods to prevent the spread of blood-borne pathogens among intravenous drug users; supports modification of federal and state laws and regulations to make newly approved anti-addiction medications available to those office-based physicians who are appropriately trained and qualified to treat opiate withdrawal and opiate dependence in accordance with documented clinical indications and consistent with sound medical practice guidelines and protocols; and urges that guidelines and protocols for the use of newly approved anti-addiction medications be developed jointly by appropriate national medical specialty societies in association with relevant federal agencies and that continuing medical education courses on opiate addiction treatment be developed by these specialty societies to help designate those physicians who have the requisite training and qualifications to provide therapy within the broad context of comprehensive addiction treatment and management."

The AMA also broadly supports efforts to increase access to OTPs in areas where they are needed most. (Policy H-95.921, "Exclusive State Control of Methadone Clinics") This includes an ongoing commitment by the AMA to support and promote education relating to MMT. (Policy D-120.985, "Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone") The policy includes "how primary care practices can implement medication-assisted treatment (MAT) into their practices and disseminate such research in coordination with primary care specialties." (Policy D-95.968, "Support the Elimination of Barriers to Medication-Assisted Treatment for Substance Use Disorder") AMA policy also supports how "[f]inancial incentives should enhance the provision of high quality, cost-effective medical care." (Policy H-285.951, "Financial Incentives Utilized in the Management of Medical Care") Finally, there is extensive

support in current policy for removing administrative barriers for the provision of evidence-based care. (Policy H-320.939, "Prior Authorization and Utilization Management Reform")

RECOMMENDATIONS

The Board recommends that the following be adopted in lieu of the second recommendation of Board Report 2-I-19, and that the remainder of the report be filed:

1. That our AMA research current best practices and support pilot programs and other evidence-based efforts to expand and integrate primary care services for patients receiving methadone maintenance treatment. (New HOD Policy)

2. That our AMA support further research to help define the population of patients who may be safely treated with methadone maintenance treatment via primary care office-based therapy. (New HOD Policy)

3. That our AMA urge all payers, including health insurance companies, pharmacy benefit management companies, and state and federal agencies, to reduce prior authorization and other administrative burdens and to enhance the provision of primary care, counseling, and other medically necessary services for patients being treated with methadone maintenance treatment. (Directive to Take Action)

Fiscal Note: Less than $500

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[1] "Buprenorphine." U.S. Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/medication-assisted-treatment/treatment/buprenorphine

[2] Earnshaw V, Smith L, Copenhaver M. Drug Addiction Stigma in the Context of Methadone Maintenance Therapy: An Investigation into Understudied Sources of Stigma. Int J Ment Health Addict. 2013;11(1):110-122. doi:10.1007/s11469-012-9402-5

[3] Lack of access in rural areas was cited in testimony by family physician residents at the 2019 meeting of the American Academy of Family Physicians in adopting a resolution to support increased access to MMT. See "Residents Focus Discussions on Training, Patient Care," July 31, 2019. Available at https://www.aafp.org/news/education-professional-development/20190731nc-rescongress.html

[4] Joudrey PJ, Edelman EJ, Wang EA. Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States. JAMA. 2019;322(13):1310–1312. doi:10.1001/jama.2019.12562

[5] See, for example AMA and Vermont Medical Society strong support for strong support for Senate Bill 166, An act relating to the provision of medication-assisted treatment for inmates. Feb. 21, 2018. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-2-21-AMA-VMS-Letter-in-support-of-VT-SB-166-FINAL.pdf. Also see American Society of Addiction Medicine public policy statement on Treatment of OUD in Correctional Settings. Available at https://www.asam.org/docs/default-source/public-policy-statements/2020-statement-on-treatment-of-oud-in-correctional-settings.pdf?sfvrsn=ff156c2_2

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[7] Opioid Use Disorder: Medical Treatment Options, Am Fam Physician. 2019 Oct 1;100(7):416-425., https://www.aafp.org/afp/2019/1001/p416.html

[8] Salisbury-Afshar E. Buprenorphine Maintenance vs. Methadone Maintenance or Placebo for Opioid Use Disorder. Am Fam Physician. 2015;91(3):165-166.

[9] Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database Syst Rev. 2014;(2):CD002207. Published 2014 Feb 6. doi:10.1002/14651858.CD002207.pub4

[10] American Association of Treatment for Opioid Dependence. Frequently Asked Questions. Available at http://www.aatod.org/opioid-education/frequently-asked-questions/

[11] See https://end-overdose-epidemic.org/resources/?_societies_associations=american-academy-of-family-physicians

[12] See https://end-overdose-epidemic.org/resources/?_societies_associations=american-society-of-addiction-medicine

[13] See https://end-overdose-epidemic.org/resources/?_societies_associations=american-college-of-physicians

[14] See https://end-overdose-epidemic.org/resources/?_other_organizations=pcss

[15] See, broadly, the certification and accreditation requirements for Opioid Treatment Programs. U.S. Substance Abuse and Mental Health Services Administration. Available at https://www.samhsa.gov/medication-assisted-treatment/certification-opioid-treatment-programs

[16] National Center for Biotechnology Information. PubChem Database. Methadone, CID=4095, https://pubchem.ncbi.nlm.nih.gov/compound/Methadone (accessed on July 23, 2020)

[17] See, for example, the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. American Society of Addiction Medicine. Available at https://www.asam.org/docs/default-source/quality-science/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2

[18] Madras, B. K., N. J. Ahmad, J. Wen, J. Sharfstein, and the Prevention, Treatment, and Recovery Working Group of the Action Collaborative on Countering the U.S. Opioid Epidemic. NAM Perspectives. Discussion Paper, Washington, DC. https://doi.org/10.31478/202004b

[19] This is one of several recommendations contained in the AMA-Manatt Health publication, *National Roadmap on State-Level Efforts to End the Opioid Epidemic: Leading-edge Practices and Next Steps*. September 2019. Available at https://end-overdose-epidemic.org/wp-content/uploads/2020/05/AMA-Manatt-National-Roadmap-September-2019-FINAL.pdf

[20] AMA letter to Uttam Dhillon, Acting Administrator, Drug Enforcement Administration, U.S. Department of Justice. RE: RIN 1117-AB43/Docket No. DEA-459 Registration Requirements for Narcotic Treatment

Programs with Mobile Components. April 27, 2020. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-4-27-Letter-to-Dhillon-re-NTP-Mobile.pdf

[21] AMA letter to Elinore F. McCance-Katz, MD, PhD, Assistant Secretary for Mental Health and Substance Use, U.S. Department of Health and Human Services. April 13, 2020. Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2020-4-13-Letter-to-McCance-Katz-at-SAMHSA-re-OTP-Telemed-.pdf

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 201
(November 2020)

Introduced by: Illinois

Subject: Permitting the Dispensing of Stock Medications for Post Discharge Patient Use and the Safe Use of Multi-dose Medications for Multiple Patients

Referred to: Reference Committee B

Whereas, A topical stock-item medication is an unlabeled ointment or drop that the hospital operating room (OR), or Emergency Room (ER), or Ambulatory Surgical Treatment Center (ASTC) staff has on stand-by or is retrieved from a dispensing system for a specified patient for use during a procedure or visit; and

Whereas, Topical stock-item agents are charged to the patient, but unused medication often gets discarded when the patient is discharged, even if the medication is recommended for post-discharge care to aid in the patient's healing; and

Whereas, Because regulations governing the ability to dispense the remaining portion of stock-item medications for post-discharge use can be unclear or appear overly burdensome, many facilities do not allow the practice; and

Whereas, Patients may need to purchase duplicate agents for post-discharge use, increasing patient cost and creating medication waste; and

Whereas, Similar issues of cost inefficiencies and medical waste arise with the use of medications such as multiuse eye drops that are only allowed for single-patient use, but could safely be used in multiple patients; and

Whereas, The Joint Commission has previously approved specific policies and procedures implemented by the Utah Valley Regional Medical Center for the use of multidose eye drops in multiple patients; therefore be it

RESOLVED, That our American Medical Association work with the Food and Drug Administration, national specialty societies, state medical societies and/or other interested parties to ensure that legislative and regulatory language permits the practice of dispensing stock-item medications to individual patients upon discharge in accordance with labeling and dispensing protocols that help ensure patient safety, minimize duplicated patient costs, and reduce medication waste. (Directive to Take Action)

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

Received: 07/17/20

Reference:

Using multi dose eye drops in a health care setting: a policy and procedural approach to safe and effective treatment of patients. Jensen MK, et al. JAMA Ophthalmology 2014. https://jamanetwork.com/journals/jamaophthalmology/article-abstract/1901216

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 202
(November 2020)

Introduced by: New York

Subject: Cares Act Equity and Loan Forgiveness in the Medicare Accelerated Payment Program

Referred to: Reference Committee B

Whereas, In enacting the CARES Act, Congress established a number of programs to assist physicians, hospitals and other care providers to address the devastating drop in patient revenue during the height of the Covid-19 pandemic; and

Whereas, The CARES Act includes $175 billion in relief funds for hospitals and other healthcare providers who are or have been providing testing and treatment for individuals with possible or actual cases of COVID-19; and

Whereas, The initial distributions from this relief fund have only gone to hospitals, physicians and other healthcare providers who have received Medicare payments; and

Whereas, Some specialty physician practices, because of the nature of their patient population, including some primary care specialties such as pediatrics who certainly may provide testing and treatment for individuals with possible or actual COVID-19, may not receive Medicare payments; and

Whereas, Even where payments were made to physicians from this fund, it was often for minimal amounts compared to funds received by health systems; and

Whereas, According to the Department of Health and Human Services (HHS) website, Rural Distribution payments were made to rural acute care general hospitals and Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), and Community Health Centers (CHCs) located in rural areas (Hospitals and RHCs will each receive a minimum base payment plus a percent of their annual expenses). The base payment will account for RHCs with no reported Medicare claims, such as pediatric RHCs, and CHCs lacking expense data, by ensuring that all clinical, non-hospital sites receive a minimum level of support no less than $100,000, with additional payment based on operating expenses. Rural acute care general hospitals and CAHs will receive a minimum level of support of no less than $1,000,000, with additional payment based on operating expenses; and

Whereas, The Paycheck Protection Program (PPP) forgivable loan program established in the CARES Act has provided awards to many community physician practices, but concerns remain regarding the limitations on the use of the funds; and

Whereas, The Medicare Advanced Payment Program (MAPP) was suspended by CMS on April 26, despite its use by many physicians and the lifeline it provided for many physician practices during the Covid-19 pandemic; therefore be it

RESOLVED, That our American Medical Association and the federation of medicine work to improve and expand various federal stimulus programs (e.g., the CARES Act and MAPP) in order to assist physicians in response to the Covid-19 pandemic, including:

- Restarting the suspended Medicare Advance payment program, including significantly reducing the re-payment interest rate and lengthening the repayment period;

- Expanding the CARES Act health care provider relief pool and working to ensure that a significant share of the funding from this pool is made available to physicians in need regardless of the type of patients treated by those physicians; and

- Reforming the Paycheck Protection Program, to ensure greater flexibility in how such funds are spent and lengthening the repayment period (Directive to Take Action); and be it further

RESOLVED, That, in the setting of the COVID-19 pandemic, our AMA advocate for additional relief to physicians via loan forgiveness for medical school educational debt. (Directive to Take Action)

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

Received: 06/18/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 203
(November 2020)

Introduced by: New York

Subject: COVID–19 Emergency and Expanded Telemedicine Regulations

Referred to: Reference Committee B

Whereas, The world is facing a global health crisis through the pandemic spread of the coronavirus COVID-19 and as a consequence the health and safety of the people of the United States are uncertain; and

Whereas, The disease poses a heightened risk to immunocompromised individuals and other vulnerable populations including the elderly, those with chronic lung disease, heart disease, cancer, and/or diabetes; and

Whereas, The COVID–19 pandemic has created situations where persons are instructed NOT to go to their physicians' offices if experiencing cough with fever unless they are in a high risk situation or experiencing shortness of breath and are told to present to the emergency department of a hospital in such cases; and it is the medical community and community health centers which serve a vital role in the maintenance of health and prevention of disease; and

Whereas, On March 4, 2020, Congress voted to approve an emergency coronavirus spending bill of $8.3 billion to address this growing health crisis; and

Whereas, Physicians and other medical providers must be enabled to respond to the growing need for medical services including during mandatory quarantine and voluntary isolation and physicians have adopted and adapted to the use of telemedicine as a tool for caring for their patients; and

Whereas, Technology is available to patients and physicians alike to allow for personalized advice and management through various means including telephonic and video communications (telemedicine), and the utilization of telemedicine for geographic areas where access to physicians and other health care providers is not readily accessible has become increasingly important, indeed many patients find telemedicine to be more convenient and satisfying for some of their healthcare needs; and

Whereas, Since the means are available for patient care in these situations, physicians and others should be paid for their services when using such telemedicine technology; and

Whereas, Telemedicine has become an effective tool in reducing inappropriate use of emergency room and ambulance services for evaluation of acute illness and this is especially true during the Covid-19 pandemic; therefore be it

RESOLVED, That, with the expanded use of telemedicine during the Covid-19 pandemic, our American Medical Association continue to advocate for a continuation of coverage for the full-spectrum of technologies that were made available during the pandemic and that physicians be reimbursed by government and private payers for time and complexity (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate that the current emergency regulations for improved access to and payment for telemedicine services be made permanent with respect to payment parity and use of commonly accessible devices for connecting physicians and patients, without reference to the originating site, while ensuring qualifications of duly licensed physicians to provide such services in a secure environment (Directive to Take Action); and be it further

RESOLVED, That our AMA propose that all insurance carriers provide coverage for telemedicine visits with any physician licensed and registered to practice in the United States. (Directive to Take Action)

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

Received: 06/18/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 204
(November 2020)

Introduced by: Resident and Fellow Section

Subject: Studying Physician Supervision of Allied Health Professionals Outside of Their Fields of Graduate Medical Education

Referred to: Reference Committee B

Whereas, Advanced practice providers and allied health professionals are required under the laws of many states to be supervised to some degree by a physician; and

Whereas, News reports and articles note instances of thoracic surgeons and obstetrician/gynecologists supervising social workers in the provision of group therapy[1] and plastic surgeons supervising physician assistants who advertise themselves as "dermatologists"[2]; and

Whereas, Widely known anecdotal evidence suggests numerous advanced practice providers practicing in various fields while being nominally supervised by physicians not trained in those fields; and

Whereas, Physicians without appropriate training supervising advanced practice providers outside of their expertise defeats the purpose of scope-of-practice laws and endangers patients; therefore be it

RESOLVED, That our American Medical Association conduct a systematic study to collect and analyze publicly available physician supervision data from all sources to determine how many allied health professionals are being supervised by physicians in fields which are not a core part of those physicians' completed residencies and fellowships. (Directive to Take Action)

Fiscal Note: Estimated cost of $100,000 to implement resolution.

Received: 08/25/20

References:
1. Ornstein C and ProPublica. Illinois leads Medicare billings for group therapy. Chicago Tribune. 13 Jul 2014. https://www.chicagotribune.com/lifestyles/health/ct-medicare-group-therapy-met-20140713-story.html. Accessed 18 Sep 2019.
2. Al-agba N. The P.A. Problem: Who You See and What You Get. The Healthcare Blog. 24 Nov 2017. https://thehealthcareblog.com/blog/2017/11/24/the-p-a-problem/. Accessed 18 Sep 2019.

RELEVANT AMA POLICY:

Principles Guiding AMA Policy Regarding Supervision of Medical Care Delivered by Advanced Practice Nurses in Integrated Practice H-360.987
Our AMA endorses the following principles: (1) Physicians must retain authority for patient care in any team care arrangement, e.g., integrated practice, to assure patient safety and quality of care. (2) Medical societies should work with legislatures and licensing boards to prevent dilution of the authority of physicians to lead the health care team. (3) Exercising independent medical judgment to select the drug of choice must continue to be the responsibility only of physicians. (4) Physicians should recognize physician assistants and advanced practice nurses under physician leadership, as effective physician extenders and valued members of the health care

team. (5) Physicians should encourage state medical and nursing boards to explore the feasibility of working together to coordinate their regulatory initiatives and activities. (6) Physicians must be responsible and have authority for initiating and implementing quality control programs for nonphysicians delivering medical care in integrated practices.
Citation: BOT Rep. 23, A-96; Reaffirmation A-99; Reaffirmed: Res. 240, and Reaffirmation A-00; Reaffirmed: CMS Rep. 6, A-10; Reaffirmed: BOT Rep. 9, I-11; Reaffirmation A-12; Reaffirmed: BOT Rep. 16, A-13

Practice Agreements Between Physicians and Advance Practice Nurses and the Physician to Advance Practice Nurse Supervisory Ratio H-35.969
Our AMA will: (1) continue to work with the Federation in developing necessary state advocacy resource tools to assist the Federation in: (a) addressing the development of practice agreements between practicing physicians and advance practice nurses, and (b) responding to or developing state legislation or regulations governing these practice agreements, and that the AMA make these tools available on the AMA Advocacy Resource Center Web site; and (2) support the development of methodologically valid research comparing physician-APRN practice agreements and their respective effectiveness.
Citation: BOT Rep. 28, A-09; Reaffirmed: BOT Rep. 09, A-19

Physician Assistants and Nurse Practitioners H-160.947
Our AMA will develop a plan to assist the state and local medical societies in identifying and lobbying against laws that allow advanced practice nurses to provide medical care without the supervision of a physician. The suggested Guidelines for Physician/Physician Assistant Practice are adopted to read as follows (these guidelines shall be used in their entirety):
(1) The physician is responsible for managing the health care of patients in all settings.
(2) Health care services delivered by physicians and physician assistants must be within the scope of each practitioner's authorized practice, as defined by state law.
(3) The physician is ultimately responsible for coordinating and managing the care of patients and, with the appropriate input of the physician assistant, ensuring the quality of health care provided to patients.
(4) The physician is responsible for the supervision of the physician assistant in all settings.
(5) The role of the physician assistant in the delivery of care should be defined through mutually agreed upon guidelines that are developed by the physician and the physician assistant and based on the physician's delegatory style.
(6) The physician must be available for consultation with the physician assistant at all times, either in person or through telecommunication systems or other means.
(7) The extent of the involvement by the physician assistant in the assessment and implementation of treatment will depend on the complexity and acuity of the patient's condition and the training, experience, and preparation of the physician assistant, as adjudged by the physician.
(8) Patients should be made clearly aware at all times whether they are being cared for by a physician or a physician assistant.
(9) The physician and physician assistant together should review all delegated patient services on a regular basis, as well as the mutually agreed upon guidelines for practice.
(10) The physician is responsible for clarifying and familiarizing the physician assistant with his/her supervising methods and style of delegating patient care.
Citation: BOT Rep. 6, A-95; Reaffirmed: Res 240 and Reaffirmation A-00; Reaffirmed: Res. 213, A-02; Modified: CLRPD Rep. 1, A-03; Reaffirmed: BOT Rep. 9, I-11; Reaffirmed: Joint CME-CMS Rep., I-12; Reaffirmed: BOT Rep. 16, A-13

Regulation of Advanced Practice Nurses H-35.964
1. AMA policy is that advanced practice registered nurses (APRNs) should be subject to the jurisdiction of state medical licensing and regulatory boards for regulation of their performance of medical acts.
2. Our AMA will develop model legislation to create a joint regulatory board composed of members of boards of medicine and nursing, with authority over APRNs.
Citation: BOT Action in response to referred for decision Amendment B-3 to Res. 233 A-17

Guidelines for Integrated Practice of Physician and Nurse Practitioner H-160.950
Our AMA endorses the following guidelines and recommends that these guidelines be considered and quoted only in their entirety when referenced in any discussion of the roles and responsibilities of nurse practitioners: (1) The physician is responsible for the supervision of nurse practitioners and other advanced practice nurses in all settings.
(2) The physician is responsible for managing the health care of patients in all practice settings.
(3) Health care services delivered in an integrated practice must be within the scope of each practitioner's professional license, as defined by state law.
(4) In an integrated practice with a nurse practitioner, the physician is responsible for supervising and coordinating care and, with the appropriate input of the nurse practitioner, ensuring the quality of health care provided to patients.
(5) The extent of involvement by the nurse practitioner in initial assessment, and implementation of treatment will depend on the complexity and acuity of the patients' condition, as determined by the supervising/collaborating physician.
(6) The role of the nurse practitioner in the delivery of care in an integrated practice should be defined through mutually agreed upon written practice protocols, job descriptions, and written contracts.
(7) These practice protocols should delineate the appropriate involvement of the two professionals in the care of patients, based on the complexity and acuity of the patients' condition.
(8) At least one physician in the integrated practice must be immediately available at all times for supervision and consultation when needed by the nurse practitioner.
(9) Patients are to be made clearly aware at all times whether they are being cared for by a physician or a nurse practitioner.
(10) In an integrated practice, there should be a professional and courteous relationship between physician and nurse practitioner, with mutual acknowledgment of, and respect for each other's contributions to patient care.
(11) Physicians and nurse practitioners should review and document, on a regular basis, the care of all patients with whom the nurse practitioner is involved. Physicians and nurse practitioners must work closely enough together to become fully conversant with each other's practice patterns.
Citation: CMS Rep. 15 - I-94; BOT Rep. 6, A-95; Reaffirmed: Res. 240, A-00; Reaffirmation A-00; Reaffirmed: BOT Rep. 28, A-09; Reaffirmed: BOT Rep. 9, I-11; Reaffirmed: Joint CME-CMS Rep., I-12; Reaffirmed: BOT Rep. 16, A-13

Health Workforce H-200.994
The AMA endorses the following principle on health manpower: Both physicians and allied health professionals have legal and ethical responsibilities for patient care, even though ultimate responsibility for the individual patient's medical care rests with the physician. To assure quality patient care, the medical profession and allied health professionals should have continuing dialogue on patient care functions that may be delegated to allied health professionals consistent with their education, experience and competency. Citation: (BOT Rep. C, I-81; Reaffirmed: Sunset Report, I-98; Modified: CME Rep. 2, I-03; Reaffirmed: CME Rep. 2, A-13)

Health Care Quality Improvement Act of 1986 Amendments H-275.965
The AMA supports modification of the federal Health Care Quality Improvement Act in order to provide immunity from federal antitrust liability to those medical staffs credentialing and conducting good faith peer review for allied health professionals to the same extent that immunity applies to credentialing of physicians and dentists.
Citation: (Res. 203, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation A-05; Reaffirmed: BOT Rep. 10, A-15)The AMA supports modification of the federal Health Care Quality Improvement Act in order to provide immunity from federal antitrust liability to those medical staffs credentialing and conducting good faith peer review for allied health professionals to the same extent that immunity applies to credentialing of physicians and dentists. Citation: (Res. 203, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmation A-05; Reaffirmed: BOT Rep. 10, A-15)

Protecting Physician Led Health Care H-35.966
Our American Medical Association will continue to work with state and specialty medical associations and other organizations to collect, analyze and disseminate data on the expanded use of allied health professionals, and of the impact of this practice on healthcare access (including in poor, underserved, and rural communities), quality, and cost in those states that permit independent practice of allied health professionals as compared to those that do not. This analysis should include consideration of practitioner settings and patient risk-adjustment. Citation: Res. 238, A-15; Reaffirmed: BOT Rep. 20, A-17;

Education Programs Offered to, for or by Allied Health Professionals Associated with a Hospital H-35.978
The AMA encourages hospital medical staffs to have a process whereby physicians will have input to and provide review of education programs provided by their hospital for the benefit of allied health professionals working in that hospital, for the education of patients served by that hospital, and for outpatient educational programs provided by that hospital. Citation: (BOT Rep. B, A-93; Adopts Res. 317, A-92; Reaffirmed: CME Rep. 2, A-03; Reaffirmed: CME Rep. 2, A-13)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 205
(November 2020)

Introduced by: Virginia, American Association of Clinical Urologists, West Virginia, North Carolina, New Jersey, South Carolina, Mississippi, Louisiana, American Urological Association, Maryland

Subject: Telehealth Post SARS-COV-2

Referred to: Reference Committee B

Whereas, The Coronavirus Preparedness and Response Supplemental Appropriations Act signed into law March 6, 2020 waives certain Medicare telehealth payment requirements during the Public Health Emergency (PHE) and allows beneficiaries in all areas of the country to receive telehealth services, including at home[1]; and

Whereas, Telehealth has allowed for the continuation of necessary healthcare in a secure and safe manner during this pandemic; and

Whereas, Patients, depending on their location, age, and/or socioeconomic status, may face barriers to accessing telehealth services due to inadequate access to technology, unreliable broadband coverage, and/or lack of familiarity with technology[2]; and

Whereas, Our AMA has enacted policies, such as Policy D-480.965 which support increased coverage and reimbursement for telehealth services; and

Whereas, Prior to COVID-19, the varied, confusing, and cumbersome rules/regulations made telehealth difficult for the practicing physician to incorporate into their practice; and

Whereas, Both patients and their physicians now have enthusiastically adopted telehealth services and technology; therefore be it

RESOLVED, That our American Medical Association advocate to facilitate the widespread adoption of telehealth services in the practice of medicine for physicians or physician-led teams post SARS-COV-2 (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage the Centers for Medicare and Medicaid Services, health insurance industry, and Federal/State government agencies to adopt uniform, clear regulations as well as equitable coverage and reimbursement mechanisms that promote physician-led telehealth services (New HOD Policy); and be it further

RESOLVED, That our AMA advocate for equitable access to telehealth services especially for the most at risk and under resourced patient populations and communities. (Directive to Take Action)

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

Received: 06/08/20

References:
[1] Robeznieks, A. (March 2020). Key Changes Made to Telehealth Guidelines to Boost COVID-10 Care. American Medical Association. Retrieved from https://www.ama-assn.org/delivering-care/public-health/key-changes-made-telehealth-guidelines-boost-covid-19-care
[2] Velasquex, D., & Mehrota, A. (May 2020). Ensuring the Growth of Telehealth During COVID-19 Does Not Exacerbate Disparities in Care. HealthAffairs. Retrieved from https://www.healthaffairs.org/do/10.1377/hblog20200505.591306/full/.

RELEVANT AMA POLICY

Reimbursement for Telehealth D-480.965

Our AMA will work with third-party payers, the Centers for Medicare and Medicaid Services, Congress and interested state medical associations to provide coverage and reimbursement for telehealth to ensure increased access and use of these services by patients and physicians. Citation: Res. 122, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 206
(November 2020)

Introduced by: Georgia

Subject: Strengthening the Accountability of Health Care Reviewers

Referred to: Reference Committee B

Whereas, Health care insurance companies and pharmacy benefits managers use of prior authorization is a mechanism to manage health care for patients; and

Whereas, The reviewers of these procedures are contracted by these corporations and, thus, may be located in areas throughout the United States; and

Whereas, It is well documented that the standard of care throughout the United States may vary depending on location, facilities, and population amongst many other criteria; and

Whereas, When a physician receives a decision for a proposed test or approval of treatment, there is no information on the person making the decision, including their experience or qualifications, prior to review to ensure a proper evaluation is carried out; and

Whereas, The decision of the reviewer not to approve a procedure or treatment may cause delay in the diagnosis or treatment that could be harmful to the patient; and

Whereas, Any decision rendered by the reviewer is not subject to independent peer review which would make the reviewer accountable for their decisions; and

Whereas, These reviewers are not subject to any investigation by the medical board in the state where the care occurs to explain their medical decision for any untoward event; and

Whereas, Practicing physicians today are always subject to review in this era of value-based care by hospitals, insurance companies, and CMS, yet reviewers are not; therefore be it

RESOLVED, That our American Medical Association advocate for legislation to require physicians contracted by health insurers or pharmacy benefit managers to possess an active license in the states where they review prior authorizations and be subject to the rules, statutes, medical board, and peer review of the state in which the prior authorization request is made (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for the repeal of the Employee Retirement Income Security Act (ERISA) as it pertains to prior authorization decisions. (Directive to Take Action)

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

Received: 09/28/20

RELEVANT AMA POLICY

External Grievance Review Procedures H-320.952
Our AMA establishes an External Grievance procedure for all health plans including those under the Affordable Care Act (ACA) with the following basic components:
(1) It should apply to all health carriers and Accountable Care Organizations;
(2) Grievances involving adverse determinations may be submitted by the policyholder, their representative, or their attending physician;
(3) Issues eligible for external grievance review should include, at a minimum, denials for (a) medical necessity determinations; and (b) determinations by carrier that such care was not covered because it was experimental or investigational;
(4) Internal grievance procedures should generally be exhausted before requesting external review;
(5) An expedited review mechanism should be created for urgent medical conditions;
(6) Independent reviewers practicing in the same state should be used whenever possible;
(7) Patient cost sharing requirements should not preclude the ability of a policyholder to access such external review;
(8) The overall results of external review should be available for public scrutiny with procedures established to safeguard the confidentiality of individual medical information;
(9) External grievance reviewers shall obtain input from physicians involved in the area of practice being reviewed. If the review involves specialty or sub-specialty issues the input shall, whenever possible, be obtained from specialists or sub-specialists in that area of medicine.
Citation: Res. 701, I-98; Reaffirmation I-99; Reaffirmation A-00; Reaffirmed: CMS Rep. 6, A-10; Reaffirmed: Res. 709, A-12; Modified: Res. 712, A-13; Reaffirmed in lieu of: Res. 242, A-17; Reaffirmation: I-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 207
(November 2020)

Introduced by: New York

Subject: AMA Position on All Payer Database Creation

Referred to: Reference Committee B

Whereas, Organized medicine worked hard to push for the creation of the FAIRHEALTH database, an independent database of charges; and

Whereas, Private health insurers are now pushing for legislation to create alternate databases at the state and federal levels known as an All Payer Database; and

Whereas, The All Payer Database will reflect payments from all payers and as such will be heavily weighted towards poor payments for physicians such as Medicare and Medicaid which are generally lower payments than issued by commercial and self-insured plans; and

Whereas, Much of this information is already available; and

Whereas, The private insurers interest in such a database is to use it to replace the FAIRHEALTH database and justify lower payments to physicians; and

Whereas, Much of the payment data for hospitals is not reliable because hospitals frequently pay employed physicians at a much higher rate than the professional collections; therefore be it

RESOLVED, That our American Medical Association advocate that any All Payer Database should also provide true payments that hospitals are making to their employed physicians, not just the amount of payment that the insurer is making on the physician's behalf to the hospital. (Directive to Take Action)

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

Received: 10/09/20

RELEVANT AMA POLICY

Price Transparency D-155.987

1. Our AMA encourages physicians to communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status (e.g., self-pay, in-network insured, out-of-network insured) of the patient or other relevant information where possible.
2. Our AMA advocates that health plans provide plan enrollees or their designees with complete information regarding plan benefits and real time cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.
3. Our AMA will actively engage with health plans, public and private entities, and other stakeholder groups in their efforts to facilitate price and quality transparency for patients and physicians, and help ensure that entities promoting price transparency tools have processes in place to ensure the accuracy and relevance of the information they provide.
4. Our AMA will work with states and the federal government to support and strengthen the development of all-payer claims databases.
5. Our AMA encourages electronic health records vendors to include features that assist in facilitating price transparency for physicians and patients.
6. Our AMA encourages efforts to educate patients in health economics literacy, including the development of resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.
7. Our AMA will request that the Centers for Medicare and Medicaid Services expand its Medicare Physician Fee Schedule Look-up Tool to include hospital outpatient payments.
Citation: CMS Rep. 4, A-15; Reaffirmed in lieu of: Res. 121, A-16; Reaffirmed in lieu of: Res. 213, I-17; Reaffirmed: BOT Rep. 14, A-18; Reaffirmed in lieu of: Res. 112, A-19; Modified: Res. 213, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 208
(November 2020)

Introduced by: New York

Subject: Insurance Claims Data

Referred to: Reference Committee B

Whereas, Insurance company claims data is a repository of public health information, utilization information, practice patterns, and other important information; and

Whereas, The insurers utilize their claims data in order to develop policy, coverage determinations, and pricing; and

Whereas, The insurers obtain the data from both at risk plans and plans for which they act in the capacity of Third-Party Administrator (TPA); and

Whereas, Insurers typically do not share this data, asserting that it is proprietary; and

Whereas, Asymmetry of information is an impediment to more robust health policy, better and more responsive health policy, more cost-effective policy and new entrants into the insurance marketplace; therefore be it

RESOLVED, That our American Medical Association seek legislation and regulation to promote open sharing of de-identified health insurance claims data. (Directive to Take Action)

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

Received: 10/09/20

RELEVANT AMA POLICY

Work of the Task Force on the Release of Physician Data H-406.990

Release of Claims and Payment Data from Governmental Programs

The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data only when it preserves access to health care and is used to provide accurate physician performance assessments.

Raw claims data used in isolation have significant limitations. The release of such data from government programs must be subject to safeguards to ensure that neither false nor misleading conclusions are derived that could undermine the delivery of appropriate and quality care. If not addressed, the limitations of such data are significant. The foregoing limitations may include, but are not limited to, failure to consider factors that impact care such as specialty, geographic location, patient mix and demographics, plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution.

Raw claims and payment data resulting from government health care programs, including, but not limited to, the Medicare and Medicaid programs should only be released:

1. when appropriate patient privacy is preserved via de-identified data aggregation or if written authorization for release of individually identifiable patient data has been obtained from such patient in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and applicable regulations;
2. upon request of physicians [or their practice entities] to the extent the data involve services that they have provided;
3. to law enforcement and other regulatory agencies when there is reasonable and credible reason to believe that a specific physician [or practice entity] may have violated a law or regulation, and the data is relevant to the agency's investigation or prosecution of a possible violation;
4. to researchers/policy analysts for bona fide research/policy analysis purposes, provided the data do not identify specific physicians [or their practice entities] unless the researcher or policy analyst has (a) made a specific showing as to why the disclosure of specific identities is essential; and, (b) executed a written agreement to maintain the confidentiality of any data identifying specific physicians [or their practice entities];
5. to other entities only if the data do not identify specific physicians [or their practice entities]; or
6. if a law is enacted that permits the government to release raw physician-specific Medicare and/or Medicaid claims data, or allows the use of such data to construct profiles of identified physicians or physician practices. Such disclosures must meet the following criteria:
(a) the publication or release of this information is deemed imperative to safeguard the public welfare;
(b) the raw data regarding physician claims from governmental healthcare programs is:
(i) published in conjunction with appropriate disclosures and/or explanatory statements as to the limitations of the data that raise the potential for specific misinterpretation of such data. These statements should include disclosure or explanation of factors that influence the provision of care including geographic location, specialty, patient mix and demographics, health plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution, in addition to other relevant factors.
(ii) safeguarded to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data.
(c) any physician profiling which draws upon this raw data acknowledges that the data set is not representative of the physicians' entire patient population and uses a methodology that ensures the following:
(i) the data are used to profile physicians based on quality of care provided - never on utilization of resources alone - and the degree to which profiling is based on utilization of resources is clearly identified.
(ii) data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties.
(iii) the data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians.
(d) any governmental healthcare data shall be protected and shared with physicians before it is released or used, to ensure that physicians are provided with an adequate and timely opportunity to review, respond and appeal the accuracy of the raw data (and its attribution to individual physicians) and any physician profiling results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release.
Citation: BOT Rep. 18, A-09; Reaffirmed: BOT Rep. 09, A-19; Modified: Speakers Rep., A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 209
(November 2020)

Introduced by: New York

Subject: Physician Tax Fairness

Referred to: Reference Committee B

Whereas, In 2018, President Trump signed the Tax Cuts and Jobs Act; and

Whereas, This legislation includes a tax break for owners of certain pass-through entities, many of which include physician practices structured as such and can include S corporations, partnerships and some limited liability companies; and

Whereas, This may benefit those who earn below the threshold of $207,500 or less for a single filer (where the deduction phases out when taxable income exceeds $157,500) or $415,000 or less for a married couple filing jointly (where the deduction phases out starting at $315,000); and

Whereas, The new tax law disallows this 20% deduction for taxpayers with income above the threshold in specified service businesses which are defined as those in which the principal asset is the reputation or skill of the owners and which category includes physicians; and

Whereas, Many physicians, especially those in two physician households, will not qualify under the new tax law, and combined with the decrease in the deductions allowed for state and local taxes, home mortgage, etc., many physicians have been adversely affected and will pay more in taxes; and

Whereas, The effect of this law will be a continued trend of decreased physician self-employment and thus overall lower physician reimbursement; therefore be it

RESOLVED, That our American Medical Association lobby that physicians be excluded from being considered a specified service business as defined by the Internal Revenue Service. (Directive to Take Action)

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

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 210
(November 2020)

Introduced by: New York

Subject: Prohibit Ghost Guns

Referred to: Reference Committee B

Whereas, Homemade, difficult to trace firearms are increasingly turning up at crime scenes; and

Whereas, The most important part of a gun is the lower receiver - the 'chassis' of the weapon, the part housing vital components such as the hammer and trigger; and

Whereas, Under federal law, the lower receiver is considered a firearm - while other gun components do not require a background check for purchase; and

Whereas, Dozens of companies sell what are known as "80%" lower receivers - ones that are 80% finished, lack a serial number and can be used to make a homemade gun; and

Whereas, The Gun Control Act (1968) and the Brady Gun Violence Prevention Act (1993) allow for homemade weapons; and

Whereas, Ghost guns don't have any unique markings and therefore present black holes to police investigators; and

Whereas, Ghost guns provide an easy avenue for people banned from owning guns to obtain them; and

Whereas, According to the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) 30% of all weapons recovered by the bureau in California were homemade; and

Whereas, These weapons have been connected with mass shootings, police shootouts and arms trafficking; therefore be it

RESOLVED, That our American Medical Association support state and federal legislation and regulation that would subject homemade weapons to the same regulations and licensing requirements as traditional weapons. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/09/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 211
(November 2020)

Introduced by: American Academy of Family Physicians, American College of Obstetricians and Gynecologists, American College of Physicians, Infectious Diseases Society of America, Oregon

Subject: Creating a Congressionally-Mandated Bipartisan Commission to Examine the U.S. Preparations for and Response to the COVID-19 Pandemic to Inform Future Efforts

Referred to: Reference Committee B

Whereas, The United States has been the apparent epicenter of the global COVID-19 pandemic and subsequent concerns arising about the United States' capabilities to mount a strategically formulated and concerted response with regards to: effective testing strategies, timely directives on appropriate utilization of social distancing directives, evidence-supported efforts to maintain strategic stockpiles of Personal Protective Equipment (PPE) and ventilators; and

Whereas, Due to the complex interplay of local, state, and national agencies in pandemic response, traditional academic institutions may not have the authority or resources to acquire all information needed to effectively study and evaluate the United States' preparedness and immediate response to the COVID-19 pandemic; and

Whereas, In recent historic national crisis - namely the September 11, 2001 terrorist attacks - congressional leaders established the 9-11 commission which was an independent bipartisan effort to prepare a full and complete account of the circumstances surrounding the September 11, 2001 terrorist attacks, including preparedness for and the immediate response to the attacks; and

Whereas, Commissioning a similar broad-reaching task force under the direction of The United States Congress to complete a comprehensive review and report on the United States' preparedness and immediate response to the COVID-19 pandemic will inform preparation and response to future pandemics; therefore be it

RESOLVED, That our American Medical Association advocate for passage of federal legislation to create a congressionally-mandated bipartisan commission composed of scientists, physicians with expertise in pandemic preparedness and response, public health experts, legislators and other stakeholders, which is to examine the U.S. preparations for and response to the COVID-19 pandemic, in order to inform future public policy and health systems preparedness (Directive to Take Action); and be it further

RESOLVED, That, in advocating for legislation to create a congressionally-mandated bipartisan commission, our AMA seek to ensure key provisions are included, namely that the delivery of a specific end product (i.e., a report) is required by the commission by a certain period of time, and that adequate funding be provided in order for the commission to complete its deliverables. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000
Received: 10/13/20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 212
(November 2020)

Introduced by: American College of Rheumatology, American Academy of Dermatology, American Academy of Neurology, American Academy of Ophthalmology, Association for Clinical Oncology, Georgia, Society for Investigative Dermatology, American College of Gastroenterology, New Jersey

Subject: Copay Accumulator Policies

Referred to: Reference Committee B

Whereas, Copay assistance funds are intended to help patients afford and maintain their medication; and

Whereas, Commercial payers have implemented copay accumulator polices that prevent copay assistance funds from being applied towards a patient's deductible; and

Whereas, Copay accumulator policies allow payers to collect the full amount of the copay assistance provided to the patient and also collect the full amount of the deductible directly from the patient to the financial detriment of the patient; and

Whereas, Copay accumulator policies negatively impact a patient's ability to afford the medications that have been prescribed by their physician by depriving them of the intended cost-savings designed to make the medication more affordable for the individual patient; and

Whereas, Copay assistance funds are often exhausted in the middle of a plan year, leaving patients to pay their full deductible out-of-pocket or discontinue their medication; and

Whereas, The largest commercial insurer in the United States will require physicians to report copay assistance data beginning January 1, 2021 for the express purpose of preventing the application of copay funds toward the patient deductible, thereby placing physicians in conflict with the welfare of their patients and violating the *AMA Code of Medical Ethics*; and

Whereas, It is of the highest urgency during this time of economic uncertainty and public health emergency that payers avoid policies that increase out-of-pocket costs so that patients can continue to afford their medication to improve outcomes and reduce associated morbidity and mortality; and

Whereas, In the current public health emergency it is of the highest urgency to ensure that patients can continue to afford their medications to avoid the dangerous and potentially fatal complications that are associated with COVID-19 infections and the presence of uncontrolled, or poorly controlled, comorbidities; and

Whereas, Even in the absence of the current public health emergency payers should not be permitted to collect copay assistance funds and also collect the full deductible to the patient's financial detriment; therefore be it

RESOLVED, That our American Medical Association with all haste directly engage and advocate for the adoption of proposed state legislation or regulation that would ban copay accumulator policies in state regulated health care plans, including Medicaid (Directive to Take Action); and be it further

RESOLVED, That our AMA with all haste directly engage and advocate for the adoption of proposed federal legislation or regulation that would ban copay accumulator policies in federally regulated ERISA plans. (Directive to Take Action)

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

Received: 10/14/20

RELEVANT AMA POLICY

Co-Pay Accumulators D-110.986
1. Our AMA will develop model state legislation regarding Co-Pay Accumulators for all pharmaceuticals, biologics, medical devices, and medical equipment.
Citation: Res. 205, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 213
(November 2020)

Introduced by: American College of Allergy, Asthma and Immunology

Subject: Pharmacies to Inform Physicians When Lower Cost Medication Options are on Formulary

Referred to: Reference Committee B

Whereas, Physicians often write prescriptions for medications not knowing that the patient's insurance formulary offers a similar medication in the same class at a lower cost; and

Whereas, Many patients can't afford their medication because the copay is too high so they leave the pharmacy without picking up the medication; and

Whereas, Pharmacists are not required to inform the physician of the availability of a lower-cost option when one is available on the formulary; and

Whereas, Medical offices expend a great deal of time and non-reimbursed expense reviewing formularies for patients and communicating back and forth with physicians, pharmacists, and patients; and

Whereas, Healthcare costs could be reduced by solving this problem; therefore be it

RESOLVED, That our American Medical Association support legislation or regulatory action to require that in the event a patient cannot afford the medication prescribed, either because it is not on the formulary or it is priced higher than other medications on the formulary, the pharmacist must communicate to the prescriber a medication option in the same class prescribed with the lowest out-of-pocket cost to the patient. (New HOD Policy)

Fiscal Note: Minimal - less than $1,000

Received: 10/16/20

RELEVANT AMA POLICY

Prescription Drug Plans and Patient Access D-330.910
Our AMA will explore problems with prescription drug plans, including issues related to continuity of care, prior authorization, and formularies, and work with the Centers for Medicare and Medicaid Services and other appropriate organizations to resolve them.
Citation: Res. 135, A-14; Reaffirmed: CMS Rep. 05, A-19

Integration of Drug Price Information into Electronic Medical Records / Barriers to Price Transparency / Bidirectional Communication for EHR Software and Pharmacies / Health Plan, Pharmacy, Electronic Health Records Integration D-478.963
Our AMA will collaborate with other interested stakeholders to: (1) explore (a) current availability and accessibility of EHR, pharmacy and payer functionalities that enable integration of price, insurance coverage, formulary tier and drug utilization management policies, and patient cost information at the point of care, (b) at what levels barriers exist to this functionality or access, and (c) what is currently

being done to address these barriers; and (2) develop and implement a strategic plan for improving the availability and accessibility of real-time prescription cost information at the point of care.
Citation: BOT Rep. 14, A-18

Price of Medicine H-110.991
Our AMA: (1) advocates that pharmacies be required to list the full retail price of the prescription on the receipt along with the co-pay that is required in order to better inform our patients of the price of their medications; (2) will pursue legislation requiring pharmacies, pharmacy benefit managers and health plans to inform patients of the actual cash price as well as the formulary price of any medication prior to the purchase of the medication; (3) opposes provisions in pharmacies' contracts with pharmacy benefit managers that prohibit pharmacists from disclosing that a patient's co-pay is higher than the drug's cash price; (4) will disseminate model state legislation to promote drug price and cost transparency and to prohibit "clawbacks"; (5) supports physician education regarding drug price and cost transparency, manufacturers' pricing practices, and challenges patients may encounter at the pharmacy point-of-sale; and (6) work with relevant organizations to advocate for increased transparency through access to meaningful and relevant information about medication price and out-of-pocket costs for prescription medications sold at both retail and mail order/online pharmacies, including but not limited to Medicare's drug-pricing dashboard.
Citation: CMS Rep. 6, A-03; Appended: Res. 107, A-07; Reaffirmed in lieu of: Res. 207, A-17; Appended: Alt. Res. 806, I-17; Reaffirmed: BOT Rep. 14, A-18; Appended: CMS Rep. 07, A-18; Reaffirmation: A-19; Appended: Res. 126, A-19

Private Health Insurance Formulary Transparency H-125.979
1. Our AMA will work with pharmacy benefit managers, health insurers, and pharmacists to enable physicians to receive accurate, real-time formulary data at the point of prescribing.
2. Our AMA supports legislation or regulation that ensures that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, that formulary information be specific as to generic versus trade name and include copay responsibilities, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term.
3. Our AMA will develop model legislation (a) requiring insurance companies to declare which drugs on their formulary will be covered under trade names versus generic, (b) requiring insurance carriers to make this information available to consumers by October 1 of each year and, (c) forbidding insurance carriers from making formulary deletions within the policy term.
4. Our AMA will promote the following insurer-pharmacy benefits manager - pharmacy (IPBMP) to physician procedural policy: In the event that a specific drug is not or is no longer on the formulary when the prescription is presented, the IPBMP shall provide notice of covered formulary alternatives to the prescriber promptly so that appropriate medication can be provided to the patient within 72 hours.
5. Drugs requiring prior authorization, shall be adjudicated by the IPBMP within 72 hours of receipt of the prescription.
6. Our AMA (a) promotes the value of online access to up-to-date and accurate prescription drug formulary plans from all insurance providers nationwide, and (b) supports state medical societies in advocating for state legislation to ensure online access to up-to-date and accurate prescription drug formularies for all insurance plans.
7. Our AMA will continue its efforts with the National Association of Insurance Commissioners addressing the development and management of pharmacy benefits.
8. Our AMA will develop model state legislation on the development and management of pharmacy benefits.
Citation: Sub. Res. 724, A-14; Appended: Res. 701, A-16; Appended: Alt. Res. 806, I-17; Reaffirmed: CMS Rep. 07, A-18; Reaffirmed: BOT Rep. 20, A-19; Reaffirmed: CMS Rep. 05, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 214
(November 2020)

Introduced by: Obesity Medicine Association

Subject: Increase Advocacy Efforts in Support of the Treat and Reduce Obesity Act

Referred to: Reference Committee B

Whereas, People living with obesity (BMI ≥ 30) are at high risk of suffering adverse health consequences when infected with COVID-19[i]; and

Whereas, The cornerstone of evidence-based obesity treatment is intensive lifestyle intervention (ILI); and

Whereas, Obesity has been recognized by our AMA as a disease[ii]; and

Whereas, Pharmacotherapy for obesity has been proven to safely and effectively double to triple the odds of losing 5-10% body weight, an amount that has been proven to prevent diabetes, improve blood pressure and decrease health care costs[iii]; and

Whereas, Providing people living with obesity these evidence-based tools will lower their risk of severe health consequences should they contract COVID-19; and

Whereas, Medicare does not allow payment for any anti-obesity medication (AOM) due to an out-of-date policy, which prohibits Medicare from covering any “drugs for weight loss or weight gain.”; and

Whereas, There are many evidence-based, effective and safe treatment options for obesity including intensive lifestyle intervention[iv,v,vi], pharmacotherapy[vii], and surgery[viii]; and

Whereas, Medicare restricts payment for ILI to primary care providers in the primary care setting, a setting where it is seldom offered. For this reason, this benefit is scarcely being used; and

Whereas, Our AMA "will work with national specialty and state medical societies to advocate for patient access to and physician payment for the full continuum of evidence-based obesity treatment modalities (such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions);"[ix] and

Whereas, Our AMA has already advocated for the Treat and Reduce Obesity Act (TROA - H.R. 1530, a bipartisan bill)[x] since the 114th Congress, having sent multiple letters in support, legislation that would eliminate the Medicare Part D prohibition on weight loss medications and allow other qualified health care providers such as registered dietitians and social workers to provide behavioral treatment; and

Whereas, TROA has been introduced to each Congress since 2012, yet in spite of these advocacy efforts, TROA has not been passed leaving millions of Medicare recipients living with obesity without access to the evidence-based treatments that can lower their Body Mass Index to reduce their risk from obesity and their risk of a deadly health consequence from COVID-19; therefore be it

RESOLVED, That our American Medical Association increase advocacy efforts towards the passage of the Treat and Reduce Obesity Act. (Directive to Take Action)

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

Received: 10/19/20

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[i] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
[ii] AMA policy H-440.842
[iii] Milken Institute Report. http://www.milkeninstitute.org/publications/view/833. Accessed 1/15/2018
[iv] https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/obesity-in-adults-screening-and-management, accessed 1/15/2018
[v] Centers for Medicare and Medicaid Services (CMS), November 29th, 2011
[vi] Jensen MD et al. *J Am Coll Cardiol*. 2014;63(25 pt B):2985-3023
NIH / NHLBI, October 2000
[vii] https://doi.org/10.1210/jc.2015-1782, accessed 1/15/2018
[viii] http://www.nejm.org/doi/full/10.1056/NEJMoa066254#t=article, accessed 1/15/2018
[ix] Addressing Obesity D-440.954
[x] https://www.congress.gov/bill/116th-congress/house-bill/1530/text?r=8&s=1