REPORTS OF THE BOARD OF TRUSTEES

The following reports, 1–29, were presented by Barbara L. McAneny, MD, Chair:

1. FUNDING OF AMA REGION AND SECTION DELEGATES/ALTERNATES (RESOLUTION 612-A-14)

Reference committee hearing: see report of Reference Committee F.

HOUSE ACTION: RECOMMENDATION ADOPTED

(RESOLUTION 612-A-14 NOT ADOPTED) AND

REMAINDER OF REPORT FILED

Resolution 612-A-14, "Funding of AMA Region and Section Delegates/Alternates," introduced by the New York Delegation and referred by the House of Delegates (HOD) asked:

That our American Medical Association (AMA) provide hotel accommodations during the Annual and Interim meetings at no cost to the medical student region delegates and alternates and the resident physician section delegates and alternates; and

That our AMA reimburse the region and section delegates and alternates for their transportation to and from the meeting; and

That the state and specialty societies which have section and region delegates elected from their memberships will continue to provide meals and other miscellaneous reimbursements to these members of the AMA HOD as they are financially able.

Testimony heard before the HOD resulted in referral of this item since this resolution is complex enough to warrant study and could have unintended consequences.

BACKGROUND

At the 2000 Interim Meeting, the HOD adopted BOT Report 19-I-00, which codified a mechanism to increase medical student representation in the House. Using the Medical Student Section (MSS) Regional structure, student delegates were added to the House on the basis of one seat for every 2,000 medical student members in each of the seven regions. At the time, this increased the number of delegates by 20 members and included the recommendation that "state societies are strongly encouraged to provide full financial support to student delegates elected from the Regions."

Subsequently, a similar representational structure was established for the Resident and Fellow Section (RFS) at the 2006 Annual Meeting. Board of Trustees Report 20-A-06 recommended that the AMA establish a mechanism for additional delegate representation of residents and fellows at a one to 2,000 member ratio. The report specified that "the endorsing society is strongly encouraged to provide full financial support to its resident and fellow delegate(s); however, if the endorsing society is unable to fund the resident or fellow, it is ultimately the responsibility of the delegate to obtain funding."

Both reports specifically advocated for the integration of students and residents into established delegations, which would give the students and residents the opportunity to learn about the AMA structure and the issues facing physicians from more experienced delegates. Such a structure provides an opportunity to establish important relationships to help prepare younger members to become active physician participants in both the HOD and their requisite state societies.

DISCUSSION

Resolution 612-A-14 calls upon our AMA to fund transportation and housing for the Annual and Interim Meetings for medical student regional delegates and alternates and the resident physician sectional delegates and alternates.

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State and specialty societies, which have sectional and regional delegates elected from their memberships, would continue to provide meals and other miscellaneous reimbursements.

The current structure, wherein medical student regional delegates and resident and fellow sectional delegates sit with their state societies, carefully balances increased and proportional student and resident representation in the HOD while ensuring a structure that provides mentoring opportunities for students and residents and integrates them into existing leadership structures. States receive value and representation from the regional and sectional delegates on their delegations by increasing membership for purposes of determining delegate count while providing value to the students and residents.

Should these regional and sectional delegates be funded directly by the AMA, they would likely no longer sit with their state or specialty societies. In that instance, the medical student and resident and fellow sections could conceivably become their own, independent delegations consisting of 48 and 38 delegates and alternates respectively. This reorganization of delegates would make the students and residents the first and third largest delegations in the HOD. The integration of students and residents into the formalized state and specialty delegations is critical to achieving the benefits of mentorship and participation. The creation of "stand alone" student and resident and fellow delegations would preclude the mentoring opportunities afforded to those who participate as delegates through their state delegations.

Our AMA has a historical commitment to supporting the broader activities of the MSS and RFS. Currently, our AMA provides student and resident representation on the Board of Trustees, AMA councils, section governing councils, section activities, one delegate and alternate from each section, membership on advisory boards, support for meetings and conference calls, and full staff and other expertise necessary to conduct business throughout the year.

CONCLUSION

Our AMA greatly values the MSS and RFS' active participation in policymaking and other section activities and provides substantial support for the costs associated with governing activities. One of the greatest advantages of being a regional or sectional delegate is the opportunity to be a part of respective state societies and specialty delegations. The most appropriate way to gain the benefit of both AMA and Federation support is to maintain the current financial structure for section representation.

RECOMMENDATION

The Board of Trustees recommends that Resolution 612-A-14 not be adopted and the remainder of the report be filed.

2. NEW SPECIALTY ORGANIZATIONS REPRESENTATION IN THE HOUSE OF DELEGATES

Reference committee hearing: see report of <u>Reference Committee on Amendments to Constitution and Bylaws</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

See Policy D-600.984

The Board of Trustees and the Specialty and Service Society (SSS) considered the applications of the American Association for Geriatric Psychiatry and the American Society of Breast Surgeons for national medical specialty organization representation in the American Medical Association (AMA) House of Delegates (HOD). The applications were first reviewed by the AMA SSS Rules Committee and presented to the SSS Assembly for consideration.

The applications were considered using criteria developed by the Council on Long Range Planning and Development and adopted by the House (Policy G-600.020). A summary of the guidelines is attached under Exhibit Δ

Organizations seeking admission were asked to provide appropriate membership information to the AMA. That information was analyzed to determine AMA membership, as required under criterion 3. A summary of this information is attached to this report as Exhibit B.

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In addition, organizations must submit a letter of application in a designated format. This format lists the above-mentioned guidelines followed by the organization's explanation of how it meets each criteria.

Before a society is eligible for admission to the House of Delegates, it must participate in the SSS for three years. The American Association for Geriatric Psychiatry was admitted to the SSS in 2012, and the American Society of Breast Surgeons was admitted to the SSS in 2009. Both organizations have been members in good standing since they were admitted.

Review of the materials and discussion during the SSS meeting at the 2014 Interim Meeting indicated that American Association for Geriatric Psychiatry and the American Society of Breast Surgeons meet the criteria for representation in the House of Delegates.

RECOMMENDATIONS

The Board of Trustees recommends that the American Association for Geriatric Psychiatry and the American Society of Breast Surgeons be granted representation in the AMA House of Delegates and the remainder of this report be filed.

EXHIBIT A - Guidelines for Representation In and Admission To the House of Delegates

National Specialty Societies

- 1) The organization must not be in conflict with the constitution and bylaws of the American Medical Association by discriminating in membership on the basis of race, religion, national origin, sex, or handicap.
- 2) The organization must (a) represent a field of medicine that has recognized scientific validity; and (b) not have board certification as its primary focus, and (c) not require membership in the specialty organization as a requisite for board certification.
- 3) The organization must meet one of the following criteria:
 - 1,000 or more AMA members;
 - At least 100 AMA members and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA; or
 - Have been represented in the House of Delegates at the 1990 Annual Meeting and that twenty percent (20%) of its physician members who are eligible for AMA membership are members of the AMA.
- 4) The organization must be established and stable; therefore it must have been in existence for at least 5 years prior to submitting its application.
- 5) Physicians should comprise the majority of the voting membership of the organization.
- 6) The organization must have a voluntary membership and must report as members only those who are current in payment of dues, have full voting privileges and are eligible to hold office.
- 7) The organization must be active within its field of medicine and hold at least one meeting of its members per year.
- 8) The organization must be national in scope. It must not restrict its membership geographically and must have members from a majority of the states.
- 9) The organization must submit a resolution or other official statement to show that the request is approved by the governing body of the organization.
- 10) If international, the organization must have a US branch or chapter, and this chapter must be reviewed in terms of all of the above guidelines.

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Responsibilities of National Medical Specialty Organizations

- 1. To cooperate with the AMA in increasing its AMA membership.
- To keep its delegate to the House of Delegates fully informed on the policy positions of the organizations so that the delegate can properly represent the organization in the House of Delegates.
- 3. To require its delegate to report to the organization on the actions taken by the House of Delegates at each meeting.
- 4. To disseminate to its membership information to the actions taken by the House of Delegates at each meeting.
- 5. To provide information and data to the AMA when requested.

EXHIBIT B - Summary Membership Information

Organization	AMA Membership of C Total Eligible Me	U
American Association for Geriatric Psychiatry	187 of 880	21%
American Society of Breast Surgeons	605 of 2,714	22%

3. AUDITOR'S REPORT

Reference committee hearing: see report of <u>Reference Committee F.</u>

HOUSE ACTION: FILED

The Consolidated Financial Statements for the years ended December 31, 2014 and 2013 and the Independent Auditor's report have been included in a separate booklet, titled "2014 Annual Report." This booklet is included in the Handbook mailing to members of the House of Delegates and will be discussed at the Reference Committee F hearing.

4. AMA 2016 DUES

Reference committee hearing: see report of Reference Committee F.

HOUSE ACTION: RECOMMENDATION ADOPTED REMAINDER OF REPORT FILED

See Policy G-635.130

Our American Medical Association (AMA) last raised its dues in 1994. In recent years, AMA has invested to improve the value of membership. As our AMA's membership benefits portfolio is modified and enhanced, management will continuously evaluate dues pricing to ensure optimization of the membership value proposition.

RECOMMENDATION

2016 Membership Year

The Board of Trustees recommends no change to the dues levels for 2016, that the following be adopted and that the remainder of this report be filed:

Regular Members	\$ 420
Physicians in Their Second Year of Practice	\$ 315
Physicians in Military Service	\$ 280
Physicians in Their First Year of Practice	\$ 210
Semi-Retired Physicians	\$ 210
Fully Retired Physicians	\$ 84

Physicians in Residency Training	\$ 45
Medical Students	\$ 20

5. 2014 GRANTS AND DONATIONS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

This informational financial report details all grants or donations received by the American Medical Association during 2014.

American Medical Association Grants & Donations For the Year Ended December 31, 2014 Amounts in thousands

Funding Institution	Project		ount eived
Agency for Healthcare Research and Quality (subcontracted through Medical College of Wisconsin) Centers for Medicare & Medicaid Services (subcontracted	Pediatric Measurement Center of Excellence	\$	116
through Brandeis University) Centers for Medicare & Medicaid Services (subcontracted	Episode Grouper for Medicare Project ARRA HITECH Eligible Professional Clinical Quality		228
through Mathematica Policy Research, Inc.) Centers for Medicare & Medicaid Services (subcontracted	Measures		197
through YMCA) National Institute on Drug Abuse (subcontracted through	Diabetes Prevention Program Substance Use Screen and Brief Counseling Composite		88
Booz Allen Hamilton, Inc.) Substance Abuse & Mental Health Services Administration (subcontracted through American Academy of Addiction	Electronic Clinical Quality Measure Development		198
Psychiatry) Government Funding	Prescribers' Clinical Support System for Opioid Use		39 866
American Academy of Otolaryngology Head and Neck Surgery - Foundation American College of Cardiology Foundation	Development and Identification of PQRS Measures for Otolaryngology Quality Measures for Peripheral Arterial Disease and		4
	Cardiac Rehabilitation		110
American College of Emergency Physicians	Quality Measures to Enhance Emergency Care		110
American College of Rheumatology American College of Rheumatology	Quality Measures for Rheumatoid Arthritis Development of Gout eMeasures		27 15
American College of Rheumatology American College of Surgeons	National Quality Forum (NQF) Cardiovascular Measure		13
Timetreal Conege of Surgeons	Endorsement Maintenance Cycle		31
American Medical Association Foundation National Foundation for The Centers for Disease Control	Accelerating Change in Medical Education Initiative		35
and Prevention, Inc. Nonprofit Contributors	Measure Specifications for Hepatitis C	_	25 357
Contributions less than \$5,000 Other Contributors	International Medical Graduates Section Reception	_	9 9
Total Grants and Donations		\$	1,232

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6. MEDICAL INFORMATION AND ITS USES (RESOLUTION 213-A-14)

Reference committee hearing: see report of <u>Reference Committee B</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

IN LIEU OF RESOLUTION 213-A-14 AND REMAINDER OF REPORT FILED

See Policy H-406.987

At the 2014 Annual Meeting, the House of Delegates (HOD) referred Resolution 213-A-14, "Medical Information and Its Uses," for report back at the 2015 Annual Meeting. This resolution was introduced by the Illinois Delegation and asked that:

Our American Medical Association work with federal agencies involved in the collection, receipt, and transfer of physician and patient data, including but not limited to demographic, financial, and encounter information, to make publicly known the aggregate information that is being gathered, and to which entities the information is being distributed or sold.

In addition to this resolution, the HOD also adopted new policy at the 2014 Annual Meeting that directly relates to health care data transparency. Policy H-406.993 states that:

Our American Medical Association (AMA) continue to work with the Centers for Medicare & Medicaid Services (CMS) to identify appropriate modifications to improve the usefulness and accuracy of any existing or future provider-specific data released by that agency; and

Our AMA engage with data experts and other stakeholders to develop guiding principles on the data and transparency efforts that should be pursued in order to assist physicians to improve the quality of care and reduce costs.

In response to this new policy, our AMA Board of Trustees approved a recommendation by our AMA Council on Legislation to establish a workgroup consisting of council members, select physicians with data expertise, and AMA staff to focus on health care data transparency. The specific intent of this workgroup was to develop guiding principles on the data and transparency efforts that should be pursued in order to improve care quality and reduce costs.

This report provides background on the current state of health care data transparency, including AMA efforts devoted to promoting innovative uses of health care data that benefit physicians and improve care for patients. Based on the work done by the AMA convened Data Transparency Workgroup, the report seeks to adopt the workgroup's principles that outline: 1) Transparency Objectives and Goals; 2) Data Transparency Resources; and 3) Challenges to Transparency.

BACKGROUND: AVAILABILITY AND USES OF HEALTH CARE DATA

Large amounts of health care information are now publicly accessible and being widely used by a variety of stakeholders to make judgments about health care quality and cost. The following provides a brief overview of the different transparency activities currently being pursued. These ongoing efforts include actions by the federal government, states, insurers, providers, and others, many of which are already at the stage of publishing and publicly reporting on health care data. Our AMA has closely monitored and engaged with these entities and will continue to seek opportunities to work alongside these stakeholders to improve data transparency efforts.

Federal Government – Release of Data

Support for greater transparency in health care data is bipartisan and being pursued at all levels of the federal government. Starting in 2009, President Barack Obama identified transparency and data sharing as one of the four key components of his Open Government Initiative that charges the leaders of all executive agencies and departments with developing plans to increase transparency, participation and collaboration in all federal

government activities. This has prompted federal agencies to publish information about the collection, storage and use of their data.

In keeping with this effort, CMS has made Medicare hospital charge data and physician claims data publicly available. While in the past CMS made data available to researchers and through Freedom of Information Act (FOIA) requests, 2014 marked the first time the agency broadly released physician charge data to the public. This data release covered more than 880,000 medical professionals based on services from 2012, and includes averages and standard deviations in submitted charges, allowed amounts, and Medicare payments, as well as a count of the number of services provided and unique beneficiaries treated. CMS released this initial data set via large Excel spreadsheets that provided little context or explanation, which ultimately resulted in some misreporting. Despite these problems, our AMA expects CMS to publish additional claims and other data in the near future, which may provide additional years and more detailed information on care cost and quality. CMS has also collected both process and outcome measures for several years, mainly through quality reporting mandates, and is in the process of publishing some of this data through its Physician Compare website.

Congress also included data transparency provisions in the Affordable Care Act that established the Qualified Entity (QE) program.³ QEs are entities that have significant experience working with health care data and are certified by CMS to prepare public reports using this information. Currently, QEs are working to combine Medicare claims data with claims data from other payers to create a comprehensive picture of the performance of hospitals, physicians and other health care providers.⁴ These entities have established large health care datasets and are seeking to expand the QE program to allow for non-public reports that can directly focus on individual practice challenges, such as costs, hospital readmissions and other improvement activities.

States – Combining and Collecting Data

Building off of the broad federal data release efforts, states are developing all-payer claims databases (APCDs) that take the federal information and combine it with other data sources. Specifically, these files contain comprehensive datasets derived from medical claims, pharmacy claims, eligibility files, provider files, and dental claims from both private and public payers. Access, release, and usage rules of this data depend on the state; however, this information is already being utilized for various purposes, including public health research, provider evaluation, and the creation of cost comparison tools. Approximately 12 states have established APCDs and six additional states have expressed interest in developing their own APCD in the near future.

In addition, numerous Regional Health Improvement Collaboratives have been established in communities across the country. These organizations are, by definition, multi-stakeholder and often have physicians in leadership positions. Collaboratives are currently collecting and reporting on various measures of quality and cost, as well as establishing quality improvement tools and programs for physicians and other providers.

Insurers and Employers – Focus on Price Transparency

Health insurers and employers have previously used health care data to create physician profiling programs and "efficiency ratings." In developing these programs, AMA advocacy has worked to vigorously challenge efforts that simply measure cost of care without regard to quality, including a significant victory in New York where our AMA, the Medical Society of the State of New York, and then New York Attorney General Andrew Cuomo collaborated to develop strict guidelines that insurers must follow for such programs.

Beyond profiling tools, insurers are devoting new efforts to develop price transparency tools. One of the largest price transparency initiatives is being led by the Health Care Cost Institute (HCCI) in connection with Aetna, Humana, Kaiser Permanente, and UnitedHealth Group. This effort seeks to create a free payment database that will be available to the public. The database will aggregate cost and utilization data from commercial health plans, Medicare, Medicare Advantage, and Medicaid along with quality and other information to help compare costs for consumers. The public tool is expected to be available in early 2015, followed by additional tools available only to participating plan enrollees with patient-specific information.

Many other commercial insurers are also offering transparency tools to enrollees. While most focus mainly on cost data, some provide information on adverse events and other outcomes. The following are a sampling of such efforts:

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 Aetna maintains several web-based tools that provide enrollees with facility-specific cost information for common procedures, physician-specific indicators based on adverse events, 30-day hospital readmission rates, and overall efficiency ratings based on the use of medical services and volume.

- WellPoint offers enrollees two cost tools: Anthem Care Comparison, a web-based tool that provides the total estimated costs for nearly 39 specific medical procedures at local hospitals; and Treatment Cost Advisor, which provides average costs for medical procedures based on age, gender, and location.
- Cigna offers several cost and quality tools that enable members to compare hospitals for treatment outcomes and calculate real-time medication pricing according to the member's health plan.
- UnitedHealth offers a designation program that identifies physicians across 21 specialties and highlights compliance with nationally accepted, evidence-based guidelines for quality care.

The Council on Medical Service Report 4-A-15, "Price Transparency," also discusses issues related specifically to price transparency, including barriers to achieving full price transparency and possible ways to expand the availability of health care pricing information.

Providers – Enhancing Care Quality

While other stakeholders are focused on releasing large sets of data, this information typically is not relevant unless placed into context through data analytics and information on the quality of care. Physicians and other providers are beginning to use health care data alongside quality information to improve care decision-making. For example, hospitals have employed data analytics to identify patients who are likely candidates for interventions to better manage their health conditions. Data models sort patients by the complexity of their conditions and identify factors that signal those who are targets for potential problems such as unfilled prescriptions or non-adherence to medical recommendations. By identifying these patients before they are discharged, providers can mitigate potentially negative outcomes and prevent future hospitalizations, all of which could improve care and reduce costs.

Other providers are piloting Apple's HealthKit to improve the collection of patient data. HealthKit serves as a hub that enables health and fitness apps to connect with one another. As described by Apple, physicians could use this tool to monitor patients who suffer from chronic conditions by gathering data from various web-based sources, including glucose measurement tools, fitness/diet applications (or apps), and even Wi-Fi connected scales. To facilitate this gathering and sharing of data, Apple has announced a collaboration with electronic health record (EHR) companies Epic, Cerner Corp. and Athenahealth Inc., to connect hundreds of physicians to the HealthKit platform. Other products in development by Google and Samsung Electronics are just starting to reach out to medical partners to pilot their systems.

Achieving care improvements through health care data, however, requires a more robust data framework. Physicians have cited problems accessing relevant quality data, requiring months of work to merge, clean, and organize patient information from multiple sources, including external insurance claims, financial records, and EHRs. There is also a lack of standardization across datasets that can lead to complications when trying to track patients across care settings. Finally, physicians have cited concerns that data capture and other initiatives will add to administrative burden and create additional complexities as well as costs that divert attention away from patient care.

EXISTING AMA DATA TRANSPARENCY POLICY

Our AMA has previously adopted extensive policy on physician data transparency; however, it was created at a time when most of this information was not widely available. Accordingly, the existing policy primarily focused on safeguards against releasing this information without addressing opportunities to use and improve this information.

Specifically, existing AMA policy on data transparency is guided by seven main principles that highlight concerns related to privacy, data accuracy, transparency, and physician profiling. These seven principles are summarized below, and all relevant AMA policy is provided in full in the Appendix.

- 1. Patient Privacy Safeguards: All entities involved in the collection, use, and release of claims data must comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules. Disclosures made without patient authorization are generally limited to claims data.
- 2. Data Accuracy and Security Safeguards: Effective safeguards must be established to protect against the dissemination of incomplete, invalid, or inaccurate physician-specific medical practice data and the

unauthorized use or disclosure of patient or physician-specific health care data or physician profiles. Physician-specific medical practice data and quality review activities should not be subject to discovery or admittance into evidence in any judicial or administrative proceeding without the physician's consent.

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- 3. Transparency Requirements: When data are collected and analyzed for the purpose of creating physician profiles, the methodologies and results should be developed in conjunction with relevant physician organizations and practicing physicians. Methodologies and data limitations should be disclosed to allow physicians to re-analyze the validity of the reported results prior to more general disclosure.
- 4. Review and Appeal Requirements: Physicians should be provided with an adequate and timely opportunity to review, respond, and appeal the results derived from the analysis of physician-specific medical practice data prior to their use, publication, or release. When the physician and the rater cannot reach agreement, physician comments should be appended to the report at the physician's request.
- 5. Physician Profiling Requirements: 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, should produce accurate results that reflect the quality and cost of care. Data reporting programs should only use accurate and balanced data sources and not use these profiles to create tiered or narrow networks. Physician-profiling programs may rank individual physicians but do not use rankings for placement in a network or for reimbursement.
- 6. Quality Measurement Requirements: The data are used to profile physicians based on quality of care provided, never on utilization of resources alone. Data are measured against evidence-based quality of care measures endorsed by the National Quality Forum (NQF) or in conjunction with appropriate medical specialty societies and practicing physicians.
- 7. Patient Satisfaction Measurement Requirements: The use of patient satisfaction data is not appropriate for incentive or tiering mechanisms. Programs that publicly rate physicians on patient satisfaction should notify physicians of their rating and provide a chance for the physician to appeal that rating prior to its publication.

The advent of new delivery models, increasing pressure to improve health care quality while reducing costs, new technology, and a vast number of interested stakeholders, have significantly increased interest in health care data over the past year. As a result, this data is now more widely available and accessible to all stakeholders than in the past, and physicians will face new challenges and opportunities in engaging with this information. The existing AMA policy, however, does not recognize these significant changes and could be improved to more clearly address the current data transparency environment.

WORK OF THE AMA'S DATA TRANSPARENCY WORKGROUP

Recognizing the growing interest in health care data transparency and following the recommendation from our Board of Trustees, our AMA convened a Data Transparency Workgroup to provide a concentrated effort devoted to data transparency. The goal of this workgroup was to ensure that our AMA prioritizes the right set of regulatory reforms and highlights innovative uses of health care data that benefit physicians.

Through a number of calls and discussions, the workgroup members identified three components of a data transparency framework: 1) Transparency Objectives and Goals; 2) Data Transparency Resources; and 3) Challenges to Transparency. The first category focuses on the transparency initiatives that should be prioritized to engage and inform physicians, promote new payment and delivery models, and improve care choices for patients and other stakeholders. The second category highlights the resources that physicians need to achieve these transparency objectives and goals—this includes data from a broader range of sources, more timely and accurate information, and data that focuses beyond costs to include quality information. This category also highlights the need for data to be presented in a useful format so that physicians can easily access and engage with different datasets to improve care. Finally, the last category highlights current barriers that hinder physician engagement with data transparency initiatives. These principles outline the administrative burden of reviewing datasets and reports, the lack of standardization across current reporting requirements, and errors in data attribution that lead to inaccurate conclusions about care. The full principles are provided in the Appendix to this report.

Ultimately, these principles are intended to guide and develop AMA advocacy and policy as more and more data are sought by stakeholders and new uses of this information emerge. The principles recognize the new data environment and the need for physicians to engage in this area in order to have an impact on future transparency initiatives. Over time, our AMA will continue to drill-down and refine these principles to provide further guidance for physicians.

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RECOMMENDATION

The Board of Trustees recommends that the following recommendation be adopted in lieu of Resolution 213-A-14 and the remainder of the report be filed:

That our American Medical Association adopt as new policy the following Data Transparency Principles to Promote Improvements in Quality and Care Delivery.

DATA TRANSPARENCY PRINCIPLES TO PROMOTE IMPROVEMENTS IN QUALITY AND CARE DELIVERY

Our AMA seeks to help physicians improve the quality reporting of patient care data and adapt to new payment and delivery models to transform our health care system. One means of accomplishing this goal is to increase the transparency of health care data. The principles outlined below ensure that physicians, practices, care systems, physician-led organizations, patients and other relevant stakeholders can access and proactively use meaningful, actionable health care information to achieve care improvements and innovations. These principles do not replace but build upon existing AMA policies H-406.990, H-406.989, H-406.991, and H-406.996 that address safeguards for the release of physician data and physician profiles, expanding these guidelines to reflect the new opportunities and potential uses of this information.

Transparency Objectives and Goals

Engaging Physicians – Our AMA encourages greater physician engagement in transparency efforts, including the development of physician-led quality measures to ensure that gaps in measures are minimized and that analyses reflect the knowledge and expertise of physicians.

Promoting New Payment and Delivery Models – Our AMA supports appropriate funding and other support to ensure that the data that are used to inform new payment and delivery models are readily available and do not impose a new cost or additional burden on model participants.

Improving Care Choices and Decisions – Our AMA promotes efforts to present data appropriately depending on the objective and the relevant end-user, including transparently identifying what information is being provided, for what purpose, and how the information can or cannot be used to influence care choices.

Informing Physicians – Our AMA encourages the development of user interfaces that allow physicians or their staff to structure simple queries to obtain and track actionable reports related to specific patients, peer comparisons, provider-level resource use, practice patterns, and other relevant information.

Informing Patients – Our AMA encourages patients to consult with physicians to understand and navigate health care transparency and data efforts.

Informing Other Consumers – Our AMA seeks opportunities to engage with other stakeholders to facilitate physician involvement and more proactive use of health care data.

Data Transparency Resources

Data Availability – Our AMA supports removing barriers to accessing additional information from other payers and care settings, focusing on data that is valid, reliable, and complete.

Access to Timely Data – While some datasets will require more frequent updates than others, our AMA encourages use of the most current information and that governmental reports are made available, at a minimum, from the previous quarter.

Accurate Data – Our AMA supports proper oversight of entities accessing and using health care data, and more stringent safeguards for public reporting, so that information is accurate, transparent, and appropriately used.

Use of Quality Data – Our AMA supports definitions of quality based on evidence-based guidelines, measures developed and supported by specialty societies, and physician-developed metrics that focus on patient outcomes and engagement.

Increasing Data Utility – Our AMA promotes efforts by clinical data registries, regional collaborations, Qualified Entities, and specialty societies to develop reliable and valid performance measures, increase data utility and reduce barriers that currently limit access to and use of the health care data.

Challenges to Transparency

Standardization – Our AMA supports improvements in electronic health records (EHRs) and other technology to capture and access data in uniform formats.

Mitigating Administrative Burden – To reduce burdens, data reporting requirements imposed on physicians should be limited to the information proven to improve clinical practice. Collection, reporting, and review of all other data and information should be voluntary.

Data Attribution – Our AMA seeks to ensure that those compiling and using the data avoid attribution errors by working to correctly assign services and patients to the appropriate provider(s) as well as allowing entities to verify who or where procedures, services, and items were performed, ordered, or otherwise provided. Until problems with the current state of episode of care and attribution methodologies are resolved, our AMA encourages public data and analyses primarily focused at the system-level instead of on individual physicians or providers.

APPENDIX - Data Transparency Principles to Promote Improvements in Quality and Care Delivery

Our AMA seeks to improve the quality of patient care and promote new payment and delivery models to transform our health care system. One means of accomplishing this goal is to increase the transparency of health care data. The principles outlined below ensure that physicians, practices, care systems, physician-led organizations, patients and other relevant stakeholders can access and proactively use meaningful, actionable health care information to achieve care improvements and innovations. These principles do not replace but build upon existing AMA policies H-406.990, H-406.991, and H-406.996 that address safeguards for the release of physician data and physician profiles, expanding these guidelines to reflect the new opportunities and potential uses of this information.

Transparency Objectives and Goals

Engaging Physicians – Currently, physician data is publicly available and payers, employers, researchers, and other stakeholders are increasingly using this information to make decisions about health care treatments and services. To ensure credibility, meaningful physician engagement from the beginning of transparency projects is essential, to provide relevant information and input with respect to treatment options and appropriate measures of the quality of care. Physician input is especially needed where entities intend to use data to influence the composition of provider networks or to create public reports that could influence or limit patient choice. Our AMA encourages greater physician engagement in transparency efforts, including the development of physician-led quality measures to ensure that gaps in measures are minimized and that analyses reflect the knowledge and expertise of physicians.

Promoting New Payment and Delivery Models – Physician stakeholders need information that will help them meet reporting goals and verify improvements or challenges created by new care and delivery models. Data should track and assess both care improvements for specific patient populations and individual patients, requiring information that goes beyond price and utilization data. When participating in new models, entities should be provided with the tools and timely data that are necessary to inform their efforts. Our AMA supports appropriate funding and other support to ensure that the data that are used to inform new payment and delivery models are readily available and do not impose a new cost or additional burden on model participants.

Improving Care Choices and Decisions – Our AMA recognizes that information sought by patients, researchers, lawmakers, and other stakeholders may differ, both substantively and in formatting, from the information sought by physicians and other providers. Our AMA promotes efforts to present data appropriately depending on the objective and the relevant end-user, including transparently identifying what information is being provided, for what purpose, and how the information can or cannot be used to influence care choices.

Informing Physicians – Physicians require access to data that are presented in a manner that is relevant to a physician's practice, workflow, and patient population and that can be tied to quality improvement actions to change and improve care practices. This requires the use of data analytics, collection, aggregation, and other techniques rather than only claims or other raw data. Our

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AMA encourages the development of user interfaces that allow physicians or their staff to structure simple queries to obtain and track actionable reports related to specific patients, peer comparisons, provider-level resource use, practice patterns, and other relevant information.

Informing Patients – Because "value" can be subjectively defined, it is imperative that data available to patients include more than utilization and/or cost data, and incorporate clinical quality information. Additionally, patient data should include appropriate safeguards, be easily understood, protect patient privacy, and include educational materials to be appropriately used. Our AMA encourages patients to consult with physicians to understand and navigate health care transparency and data efforts.

Informing Other Consumers – Beyond patients, our AMA recognizes that researchers, employers, consumers, and various other stakeholders will benefit from access to and use of health care data. While beyond the scope of these principles, our AMA seeks opportunities to engage with other stakeholders to facilitate physician involvement and more proactive use of health care data.

Data Transparency Resources

Data Availability – Physicians and other relevant stakeholders must have access to information from different health care payers, including private payers, managed care plans, states, and all parts of Medicare. Access to data from different care settings should also be provided, including hospitals, outpatient departments, skilled nursing facilities, home health facilities, pharmacies, and all other sectors. Availability of data, however, must be weighed against the need for information to be accurate. Physicians should also have the choice to obtain relevant data and analyses generated by patients or being used by other stakeholders. Our AMA supports removing barriers to accessing additional information from other payers and care settings, focusing on data that is valid, reliable, and complete.

Access to Timely Data – Data and reports that lag by several years or months are of minimal value in the clinical setting to inform current care decisions. While some datasets will require more frequent updates than others, our AMA encourages use of the most current information and that governmental reports are made available, at a minimum, from the previous quarter.

Accurate Data – Our AMA supports effective safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate, or misleading health care data. Accuracy of data should be judged by the intended use of the information. In particular, our AMA will seek broader and more definitive safeguards for public data and reports as compared to non-public information. Our AMA will seek the following general safeguards for both public and non-public reporting of information:

Publishing the data sources along with its limitations used to create datasets, reports, and analyses;

Allowing physicians the right and ample time to review, correct, and appeal their individually identifiable data to ensure accuracy and that corrections are appropriately included; and

Publishing, in understandable terms, the methodologies and analytics applied to health care data.

Our AMA supports proper oversight of entities accessing and using health care data, and more stringent safeguards for public reporting, so that information is accurate, transparent, and appropriately used.

Use of Quality Data – Rigorously vetted measures will decrease variation and will help prioritize reporting requirements. In contrast, reporting efforts that have not been proven to improve patient outcomes or the delivery of health care but simply are collecting information that focuses on utilization or financial information should be deterred. As new quality standards/guidelines and payment and delivery models evolve, the data sources, analytics, and analyses used to support this evolution should be flexible to allow new information to be incorporated. Our AMA supports definitions of quality based on evidence-based guidelines, measures developed and supported by specialty societies, and physician-developed metrics that focus on patient outcomes and engagement.

Increasing Data Utility – To improve data utility, efforts should be made to identify relevant benchmarks (e.g., risk adjusted, comparable patient demographics, specialty- and subspecialty- specific) that allow stakeholders to compare treatment patterns, patient outcomes, resource utilization, and to identify areas of success or improvement compared to relevant peer sets. Our AMA recognizes that not all physicians and stakeholders have access to these data resources and that limitations exist with respect to the availability of quality measures. Our AMA promotes efforts by clinical data registries, regional collaborations, Qualified Entities, and specialty societies to develop reliable and valid performance measures, increase data utility and reduce barriers that currently limit access to and use of the health care data.

Challenges to Transparency

Standardization – All data, including patient-generated data, should be collected and reported in a standard, uniform manner. Similarly, clinical data definitions should be consistent to reduce fragmentation. This will avoid conflicting and confusing reports and will ensure that different datasets can be combined and used in innovative ways so that physicians will readily comprehend reports and analyses. To streamline access to this information, data from different payers should be aggregated and provided in a standardized format. Standardization will also require a more robust data infrastructure, including more advanced technology to transport and interpret the data. Our AMA supports improvements in electronic health records (EHRs) and other technology to

capture and access data in uniform formats. New requirements to collect, use, or otherwise report on health care data should include a period of stability to allow physicians to implement such requirements and not be imposed on physicians or other providers unless the necessary technology and tools to collect and present this information are widely available and not overly burdensome. Such technology or tools need to be capable of performing these data tasks and formatting this information without significant personal intervention.

Mitigating Administrative Burden – Our AMA recognizes that the collection, reporting, and review of health care data, reports, and analyses can pose significant administrative burden and financial costs on physicians and other providers that take time and resources away from patient care. To reduce these burdens, data reporting requirements imposed on physicians should be limited to the information proven to improve clinical practice. Collection, reporting, and review of all other data and information should be voluntary. Collection of health care data should also be facilitated by the entity seeking the information and should be coordinated and harmonized so that stakeholders are not inundated with numerous requests, reports, and analyses that will lead to overload when trying to access relevant information.

Data Attribution – Our AMA recognizes that a key barrier to meaningful, actionable health care data is proper attribution. Our AMA seeks to ensure that those compiling and using the data avoid attribution errors by working to correctly assign services and patients to the appropriate provider(s) as well as allowing entities to verify who or where procedures, services, and items were performed, ordered, or otherwise provided. Our AMA encourages efforts to link data together across payers, care settings, and into other logical bundles at the patient level. Episodes of care should also be defined consistently to avoid unnecessary fragmentation in efforts to improve care quality. Attribution methods should be transparent so that physicians and other providers can understand and confirm these techniques, and guarantee that a large number of data points, providers, or episodes of care are not excluded. Until problems with the current state of episode of care and attribution methodologies are resolved, our AMA encourages public data and analyses primarily focused at the system-level instead of on individual physicians or providers.

EXISTING AMA DATA POLICY

Release of Physician Data

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

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physicians across appropriate specialties, such as the AMA-convened Physician Consortium for Performance Improvement. (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 the their use, publication or release. (BOT Rep. 18, A-09)

H-406.989 Work of the Task Force on the Release of Physician Data

1. Our AMA Council on Legislation will use the Release of Claims and Payment Data from Governmental Programs as a basis for draft model legislation. 2. Our AMA will create additional tools to assist physicians in dealing with the release of physician data. 3. Our AMA will continue to monitor the status of, and take appropriate action on, any legislative or regulatory opportunities regarding the appropriate release and use of physician data and its use in physician profiling programs. 4. Our AMA will monitor new and existing Web sites and programs that collect and use data on patient satisfaction and take appropriate action when safeguards are not in place to ensure the validity of the results. 5. Our AMA will continue and intensify its extensive efforts to educate employers, healthcare coalitions and the public about the potential risks and liabilities of pay-for-performance and public reporting programs that are not consistent with AMA policies, principles, and guidelines. 6. Our AMA: A) opposes the public reporting of individual physician performance data collected by certification and licensure boards for purposes of MOC and MOL; B) supports the principle that individual physician performance data collected by certification and licensure boards should only be used for the purposes of helping physicians to improve their practice and patient care, unless specifically approved by the physician; and C) will report how certification and licensure boards are currently using, or may potentially use, individual physician performance data (other than for individual physician performance improvement) that is reported for purposes of Maintenance of Certification (MOC), Osteopathic Continuous Certification (OCC) and Maintenance of Licensure (MOL) and report back to the HOD no later than the 2012 Annual Meeting. (BOT Rep. 18, A-09; Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10; Reaffirmed in lieu of Res. 808, I-10; Appended: Res. 327, A-11)

H-406.991 Work of the Task Force on the Release of Physician Data Principles for the Public Release and Accurate Use of Physician Data

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 when it is used in conjunction with program(s) designed to improve or maintain the quality of, and access to, medical care for all patients and is used to provide accurate physician performance assessments in concert with the following Principles:

1. Patient Privacy Safeguards - All entities involved in the collection, use and release of claims data comply with the HIPAA Privacy and Security Rules (H-315.972, H-315.973, H-315.983, H-315.984, H-315.989, H-450.947). - Disclosures made without patient authorization are generally limited to claims data, as that is generally the only information necessary to accomplish the intended purpose of the task (H-315.973, H-315.975, H-315.983). 2. Data Accuracy and Security Safeguards - Effective safeguards are established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physicianspecific medical practice data (H-406.996, H-450.947, H-450.961). - Reliable administrative, technical, and physical safeguards provide security to prevent the unauthorized use or disclosure of patient or physician-specific health care data and physician profiles (H-406.996, H-450.947, H-450.961). - Physician-specific medical practice data, and all analyses, proceedings, records and minutes from quality review activities are not subject to discovery or admittance into evidence in any judicial or administrative proceeding without the physician's consent (H-406.996, H-450.947, H-450.961). 3. Transparency Requirements -When data are collected and analyzed for the purpose of creating physician profiles, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure (H-315.973, H-406.993, H-406.994, H-406.998, H-450.947, H-450.961). - The limitations of the data sources used to create physician profiles are clearly identified and acknowledged in terms understandable to consumers (H-406.994, H-450.947). - The capabilities and limitations of the methodologies and reporting systems applied to the data to profile and rank physicians are publicly revealed in understandable terms to consumers (H-315.973, H-406.994, H-406.997, H-450.947, H-450.961). - Case-matched, risk-adjusted resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients (H-285.931). 4. Review and Appeal Requirements - Physicians are provided with an adequate and timely opportunity to review, respond and appeal the results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release (H-315.973, H-406.996, H-406.998, H-450.941, H-450.947, H-450.961). - When the physician and the rater cannot reach agreement, physician comments are appended to the report at the physician's request (H-450.947). 5. Physician Profiling Requirements - 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 (H-406.994, H-406.997, H-450.947, H-450.961). - Data reporting programs only use accurate and balanced data sources to create physician profiles and do not use these profiles to create tiered or narrow network programs that are used to steer patients towards certain physicians primarily on cost of care factors (450.951). - When a single set of claims data includes a sample of patients that are skewed or not representative of the physicians' entire patient population, multiple sources of claims data are used (no current policy exists). - Physician efficiency of care ratings use physician

data for services, procedures, tests and prescriptions that are based on physicians' patient utilization of resources so that the focus is on comparative physicians' patient utilization and not on the actual charges for services (no current policy exists). - Physicianprofiling programs may rank individual physician members of a medical group but do not use those individual rankings for placement in a network or for reimbursement purposes (no current policy exists). 6. Quality Measurement Requirements - 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 (H-450.947). - Data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties, such as the Physician Consortium for Performance Improvement. (H-406.994, H-406.998, H-450.947, H-450.961). - These evidence-based measures are endorsed by the National Quality Forum (NQF) and/or the AQA and HQA, when available. When unavailable, scientifically valid measures developed in conjunction with appropriate medical specialty societies and practicing physicians are used to evaluate the data (no current policy exists). 7. Patient Satisfaction Measurement Requirements - Until the relationship between patient satisfaction and other outcomes is better understood, data collected on patient satisfaction is best used by physicians to better meet patient needs particularly as they relate to favorable patient outcomes and other criteria of high quality care (H-450.982). - Because of the difficulty in determining whether responses to patient satisfaction surveys are a result of the performance of a physician or physician office, or the result of the demands or restrictions of health insurers or other factors out of the control of the physician, the use of patient satisfaction data is not appropriate for incentive or tiering mechanisms (no current policy exists). - As in physician profiling programs, it is important that programs that publicly rate physicians on patient satisfaction notify physicians of their rating and provide a chance for the physician to appeal that rating prior to its publication (no current policy exists). (BOT Rep. 18, A-09; Reaffirmation A-10; Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10; Reaffirmation I-10; Reaffirmed in lieu of Res. 808, I-10; Reaffirmed in lieu of Res. 824, I-10; Reaffirmation A-11; Reaffirmed: BOT Rep. 17, A-13; Reaffirmed: Res. 806, I-13)

H-406.996 Use and Release of Physician-Specific Health Care Data

(1) Our AMA advocates that third party payers, government entities and others that use and release physician-specific health care data adhere to the following principles: (a) Physicians under review and relevant physician organizations shall be provided with an adequate opportunity to review and respond to proposed physician-specific health care data interpretations and disclosures prior to their publication or release. (b) Effective safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate or subjective physician-specific health care data shall be established. (c) Reliable administrative, technical, and physical safeguards to prevent the unauthorized use or disclosure of physician-specific health care data shall be developed. (d) Such safeguards shall treat all underlying physician-specific health care data and all analyses, proceedings, records, and minutes from quality review activities on physician-specific health care data as confidential, and provide that none of these documents shall be subject to discovery, or admitted into evidence in any judicial or administrative proceeding. (2) Our AMA supports release of severity-adjusted physician-specific health care data from carefully selected pilot projects where the data may be deemed accurate, reliable, and meaningful to physicians, consumers, and purchaser; (3) Our AMA urges that any published physician-specific health care data be limited to appropriate data concerning the quality of health care, access to health care, and the cost of health care; (4) Our AMA opposes the publication of physician-specific health care data collected outside of carefully selected pilot studies or where the data are not deemed accurate, reliable, or meaningful; (5) Our AMA urges that a copy of the information in any such profile be forwarded to the subject physician, and that the physician be given the right to review and certify adequacy of the information prior to any profile being distributed, including being placed on the Internet; and (6) Our AMA urges that the costs associated with creation of any such profiling system should not be paid for by physicians licensure fees. (BOT Rep. Q, I-92; BOT Rep. W, A-92; Reaffirmed: Res. 719, A-93; CMS Rep. 10, A-96; Appended: Res. 316, I-97; Reaffirmation A-01; Reaffirmation A-02; Reaffirmation A-05; Reaffirmed in lieu of Res. 724, A-05; Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10)

H-406.995 Research Related to the Collection, Use and Release of Physician-Specific Health Care Data

The AMA (1) encourages the collection of accurate information on the impact of the release of physician-specific health care data on the access to, quality of, and cost of health care services; (2) encourages research to develop improved approaches to collect, evaluate and disseminate health care data. (BOT Rep. Q, I-92; BOT Rep. P, A-91; CMS Rep. 10, A-96; Reaffirmed: CMS Rep. 8, A-06)

Privacy and Confidentiality:

H-315.983 Patient Privacy and Confidentiality

(1) Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (a) That there exists a basic right of patients to privacy of their medical information and records, and that this right should be explicitly acknowledged; (b) That patients' privacy should be honored unless waived by the patient in a meaningful way or in rare instances when strong countervailing interests in public health or safety justify invasions of patient privacy or breaches of confidentiality, and then only when such invasions or breaches are subject to stringent safeguards enforced by appropriate standards of accountability; (c) That patients' privacy should be honored in the context of gathering and disclosing information for clinical research and quality improvement activities, and that any necessary departures from the preferred practices of obtaining patients' informed consent and of de-identifying all data be strictly controlled; and (d) That any information disclosed should be limited to that information, portion of the medical record, or abstract necessary to fulfill the immediate and specific purpose of disclosure. (2) Our AMA affirms: (a) that physicians who are patients are entitled to the same right to privacy and confidentiality of personal medical information and medical records as other patients, (b) that when patients exercise their right to keep their personal medical histories confidential, such action should not be

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regarded as fraudulent or inappropriate concealment, and (c) that physicians should not be required to report any aspects of their patients' medical history to governmental agencies or other entities, beyond that which would be required by law. (3) Employers and insurers should be barred from unconsented access to identifiable medical information lest knowledge of sensitive facts form the basis of adverse decisions against individuals. (a) Release forms that authorize access should be explicit about to whom access is being granted and for what purpose, and should be as narrowly tailored as possible. (b) Patients and physicians should be educated about the consequences of signing overly-broad consent forms. (c) Employers and insurers should adopt explicit and public policies to assure the security and confidentiality of patients' medical information. (d) A patient's ability to join or a physician's participation in an insurance plan should not be contingent on signing a broad and indefinite consent for release and disclosure. (4) Whenever possible, medical records should be de-identified for purposes of use in connection with utilization review, panel credentialing, quality assurance, and peer review. (5) The fundamental values and duties that guide the safekeeping of medical information should remain constant in this era of computerization. Whether they are in computerized or paper form, it is critical that medical information be accurate, secure, and free from unauthorized access and improper use. (6) Our AMA recommends that the confidentiality of data collected by race and ethnicity as part of the medical record, be maintained. (7) Genetic information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual. (8) When breaches of confidentiality are compelled by concerns for public health and safety, those breaches must be as narrow in scope and content as possible, must contain the least identifiable and sensitive information possible, and must be disclosed to the fewest possible to achieve the necessary end. (9) Law enforcement agencies requesting private medical information should be given access to such information only through a court order. This court order for disclosure should be granted only if the law enforcement entity has shown, by clear and convincing evidence, that the information sought is necessary to a legitimate law enforcement inquiry; that the needs of the law enforcement authority cannot be satisfied by non-identifiable health information or by any other information; and that the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains. These records should be subject to stringent security measures. (10) Our AMA must guard against the imposition of unduly restrictive barriers to patient records that would impede or prevent access to data needed for medical or public health research or quality improvement and accreditation activities. Whenever possible, de-identified data should be used for these purposes. In those contexts where personal identification is essential for the collation of data, review of identifiable data should not take place without an institutional review board (IRB) approved justification for the retention of identifiers and the consent of the patient. In those cases where obtaining patient consent for disclosure is impracticable, our AMA endorses the oversight and accountability provided by an IRB. (11) Marketing and commercial uses of identifiable patients' medical information may violate principles of informed consent and patient confidentiality. Patients divulge information to their physicians only for purposes of diagnosis and treatment. If other uses are to be made of the information, patients must first give their uncoerced permission after being fully informed about the purpose of such disclosures. (12) Our AMA, in collaboration with other professional organizations, patient advocacy groups and the public health community, should continue its advocacy for privacy and confidentiality regulations, including: (a) The establishment of rules allocating liability for disclosure of identifiable patient medical information between physicians and the health plans of which they are a part, and securing appropriate physicians' control over the disposition of information from their patients' medical records. (b) The establishment of rules to prevent disclosure of identifiable patient medical information for commercial and marketing purposes; and (c) The establishment of penalties for negligent or deliberate breach of confidentiality or violation of patient privacy rights. (13) Our AMA will pursue an aggressive agenda to educate patients, the public, physicians and policymakers at all levels of government about concerns and complexities of patient privacy and confidentiality in the variety of contexts mentioned. (14) Disclosure of personally identifiable patient information to public health physicians and departments is appropriate for the purpose of addressing public health emergencies or to comply with laws regarding public health reporting for the purpose of disease surveillance. (15) In the event of the sale or discontinuation of a medical practice, patients should be notified whenever possible and asked for authorization to transfer the medical record to a new physician or care provider. Only de-identified and/or aggregate data should be used for "business decisions," including sales, mergers, and similar business transactions when ownership or control of medical records changes hands. (16) The most appropriate jurisdiction for considering physician breaches of patient confidentiality is the relevant state medical practice act. Knowing and intentional breaches of patient confidentiality, particularly under false pretenses, for malicious harm, or for monetary gain, represents a violation of the professional practice of medicine. (17) Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of genetic testing. (18) Our AMA supports privacy standards that would require pharmacies to obtain a prior written and signed consent from patients to use their personal data for marketing purposes. (19) Our AMA supports privacy standards that require pharmacies and drug store chains to disclose the source of financial support for drug mailings or phone calls. (20) Our AMA supports privacy standards that would prohibit pharmacies from using prescription refill reminders or disease management programs as an opportunity for marketing purposes. (BOT Rep. 9, A-98; Reaffirmation I-98; Appended: Res. 4, and Reaffirmed: BOT Rep. 36, A-99; Appended: BOT Rep. 16 and Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: Res. 246 and 504 and Appended Res. 504 and 509, A-01; Reaffirmed: BOT Rep. 19, I-01; Appended: Res. 524, A-02; Reaffirmed: Sub. Res. 206, A-04; Reaffirmed: BOT Rep. 24, I-04; Reaffirmed: BOT Rep. 19, I-06; Reaffirmation A-07; Reaffirmed: BOT Rep. 19, A-07; Reaffirmed: CEJA Rep. 6, A-11; Reaffirmed in lieu of Res. 705, A-12; Reaffirmed: BOT Rep. 17, A-13)

E-5.07 Confidentiality: Computers

The utmost effort and care must be taken to protect the confidentiality of all medical records, including computerized medical

The guidelines below are offered to assist physicians and computer service organizations in maintaining the confidentiality of information in medical records when that information is stored in computerized data bases: (1) Confidential medical information

should be entered into the computer-based patient record only by authorized personnel. Additions to the record should be time and date stamped, and the person making the additions should be identified in the record. (2) The patient and physician should be advised about the existence of computerized data bases in which medical information concerning the patient is stored. Such information should be communicated to the physician and patient prior to the physician's release of the medical information to the entity or entities maintaining the computer data bases. All individuals and organizations with some form of access to the computerized data bases, and the level of access permitted, should be specifically identified in advance. Full disclosure of this information to the patient is necessary in obtaining informed consent to treatment. Patient data should be assigned a security level appropriate for the data's degree of sensitivity, which should be used to control who has access to the information. (3) The physician and patient should be notified of the distribution of all reports reflecting identifiable patient data prior to distribution of the reports by the computer facility. There should be approval by the patient and notification of the physician prior to the release of patient-identifiable clinical and administrative data to individuals or organizations external to the medical care environment. Such information should not be released without the express permission of the patient. (4) The dissemination of confidential medical data should be limited to only those individuals or agencies with a bona fide use for the data. Only the data necessary for the bona fide use should be released. Patient identifiers should be omitted when appropriate. Release of confidential medical information from the data base should be confined to the specific purpose for which the information is requested and limited to the specific time frame requested. All such organizations or individuals should be advised that authorized release of data to them does not authorize their further release of the data to additional individuals or organizations, or subsequent use of the data for other purposes. (5) Procedures for adding to or changing data on the computerized data base should indicate individuals authorized to make changes, time periods in which changes take place, and those individuals who will be informed about changes in the data from the medical records. (6) Procedures for purging the computerized data base of archaic or inaccurate data should be established and the patient and physician should be notified before and after the data has been purged. There should be no mixing of a physician's computerized patient records with those of other computer service bureau clients. In addition, procedures should be developed to protect against inadvertent mixing of individual reports or segments thereof. (7) The computerized medical data base should be online to the computer terminal only when authorized computer programs requiring the medical data are being used. Individuals and organizations external to the clinical facility should not be provided online access to a computerized data base containing identifiable data from medical records concerning patients. Access to the computerized data base should be controlled through security measures such as passwords, encryption (encoding) of information, and scannable badges or other user identification. (8) Back-up systems and other mechanisms should be in place to prevent data loss and downtime as a result of hardware or software failure. (9) Security: (a) Stringent security procedures should be in place to prevent unauthorized access to computer-based patient records. Personnel audit procedures should be developed to establish a record in the event of unauthorized disclosure of medical data. Terminated or former employees in the data processing environment should have no access to data from the medical records concerning patients. (b) Upon termination of computer services for a physician, those computer files maintained for the physician should be physically turned over to the physician. They may be destroyed (erased) only if it is established that the physician has another copy (in some form). In the event of file erasure, the computer service bureau should verify in writing to the physician that the erasure has taken place. (IV) Issued prior to April 1977; Updated June 1994 and June 1998.

E-5.08 Confidentiality: Insurance Company Representative

History, diagnosis, prognosis, and the like acquired during the physician-patient relationship may be disclosed to an insurance company representative only if the patient or a lawful representative has consented to the disclosure. A physician's responsibilities to patients are not limited to the actual practice of medicine. They also include the performance of some services ancillary to the practice of medicine. These services might include certification that the patient was under the physician's care and comment on the diagnosis and therapy in the particular case. See also Opinion 2.135, "Insurance Companies and Genetic Information." (IV) Issued prior to April 1977.

Third Party Payers' Requests for Patient Information

Our AMA (1) supports compiling and disseminating information about the extent of the problems (especially those related to breaches of confidentiality) created by insurance company practices relating to requests for patient information; (2) supports expressing to major health insurance companies its objections to insurance company practices which potentially jeopardize a physician's ethical responsibility to protect patient confidentiality; and (3) encourages state and county medical associations to work with local carriers to solve problems created by insurance company requirements which potentially jeopardize a physician's ethical responsibility to protect patient confidentiality. (Res. 75, I-89; Reaffirmation I-99; Reaffirmation A-00; Reaffirmed: CEJA Rep. 6, A-10)

E-7.025 Records of Physicians: Access by Non-Treating Medical Staff

Physicians who use or receive information from medical records share in the responsibility for preserving patient confidentiality and should play an integral role in the designing of confidentiality safeguards in health care institutions. Physicians have a responsibility to be aware of the appropriate guidelines in their health care institution, as well as the applicable federal and state laws. Informal case consultations that involve the disclosure of detailed medical information are appropriate in the absence of consent only if the patient cannot be identified from the information. Only physicians or other health care professionals who are involved in managing the patient, including providing consultative, therapeutic, or diagnostic services, may access the patient's confidential medical information. All others must obtain explicit consent to access the information. Monitoring user access to electronic or written medical information is an appropriate and desirable means for detecting breaches of confidentiality. Physicians should encourage the development and use of such monitoring systems. This opinion focuses on the issue of access to

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medical records by medical staff not involved in the treatment or diagnosis of patients. It does not address the need to access medical records for clinical research, epidemiological research, quality assurance, or administrative purposes. (IV) Issued December 1999 based on the report "Records of Physicians: Access by Non-Treating Medical Staff," adopted June 1999.

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7. REDUCING GUN VIOLENCE (RESOLUTIONS 215-A-14 AND 224-A-14)

Reference committee hearing: see report of Reference Committee B.

HOUSE ACTION: REFERRED

INTRODUCTION

At the 2014 Annual Meeting, the House of Delegates (HOD) referred Substitute Resolution 215, which asked that our American Medical Association (AMA) support congressional passage of legislation requiring licensing and background checks for all buyers of firearms. As originally introduced by the Illinois Delegation, Resolution 215, "Reducing Gun Violence," called on our AMA to support Congressional passage of legislation requiring criminal background checks for all gun sales, public and private. Considered along with Resolution 215-A-14, Resolution 224-A-14, "Firearm Violence," was introduced by the New England Delegation. Resolution 224 asked that our AMA support federal efforts to promote legislation to make licensing and background checks mandatory for all firearm purchases and transfers regardless of seller or individual making a transfer.

During the Reference Committee B hearing, overwhelming testimony was presented in support of the intent of both Resolutions 215 and 224. While the reference committee concluded that the sentiments expressed during the testimony were not only timely but also of great public health importance, the committee thought that a substitute resolution was appropriate in order to fully capture the essence of the testimony heard. Along these lines, the reference committee agreed that the substitute resolution should include a broader definition in terms of background checks, consistent with existing AMA policy. The reference committee was also concerned that there may be circumstances where federal legislation related to background checks for the transfer of all firearms would be unworkable and raised questions as to the feasibility of implementing such a background check system. As a result, the reference committee recommended adoption of Substitute Resolution 215 in lieu of Resolution 224. However, the HOD voted to refer Substitute Resolution 215 for the development of a Board report to the HOD at the 2015 Annual Meeting.

This report provides background on federal law on regulating firearm purchases through background checks and licensing, state firearm background check laws and pending legislation, summarizes existing AMA policy, and recommends adopting new AMA policy in lieu of Substitute Resolution 215 as well as the underlying proposals.

BACKGROUND

Federal Law on Background Checks and Licensing for Firearm Purchases

Under the Brady Handgun Violence Prevention Act of 1993 (Brady Act), federally licensed firearms dealers are required to perform background checks on prospective firearms purchasers to ensure that the firearm transfer would not violate federal, state or local law. As originally enacted, the Brady Act included interim provisions that applied to handgun sales only, which were implemented in 1994. The permanent provisions of the Brady Act went into effect in 1998, establishing the National Instant Criminal Background Check System (NICS) and extending the Brady Act's application to purchasers of long guns and persons who redeem a pawned firearm. Since the background check system began, over 196 million background checks have been performed, and over two million firearms sales to prohibited purchasers have been denied. I

Federal law prohibits felons, those convicted of domestic violence misdemeanors, individuals with certain mental health histories (e.g., commitment to psychiatric facilities), and certain others from acquiring or possessing firearms. Under the federally-regulated system of background checks, individuals who purchase firearms from licensed firearms dealers and pawnbrokers must provide identification and undergo a background check to verify that they are not in one of the prohibited categories. In over 90 percent of cases, the background check is completed within minutes, but in some circumstances, where certain information may be missing, the purchaser may have to wait up to three business days before acquiring the firearm.² A permanent record of the sale is kept by the dealer, in case the firearm is later used in a crime. Federal law does not require licensing of gun owners or purchasers.

Federal law on background checks applies only to firearm purchases from federally licensed firearms dealers and does not apply to sales and transfers of firearms by unlicensed sellers. Under federal law, persons "engaged in the business" of dealing in firearms must be licensed; however, a person is not engaged in the business if he or she only makes "occasional sales, exchanges, or purchases of firearms for the enhancement of a personal collection or for a hobby, or who sells all or part of his personal collection of firearms." The National Institute of Justice estimated, in a 1997 report, that 40 percent of all firearms sold in the US are transferred by unlicensed private parties. These sales occur at gun shows, over the internet, through classified ads, and by word of mouth. With such sales, no identification is required, no background check is required, and no record of the transaction is kept.

Surveys have shown that the majority of Americans (89 percent) and gun owners (84 percent) support expanding background check requirements for gun sales. ⁵ Recent studies suggest that universal background checks and firearm purchasing licensing affect homicide rates by reducing the availability of guns to criminals and other prohibited groups, ⁶ and that identifying prohibited persons through background checks reduces their chances of committing a violent crime by 25 percent. ⁷

In April 2013, during Senate debate on strengthening federal laws on background checks, Senators Joe Manchin (D-WV) and Pat Toomey (R-PA) proposed an amendment to pending legislation that would have extended background checks to any gun transfer at a gun show or event, or through advertisements, the Internet, or in publications. Although 54 members of the Senate voted to proceed to debate on the amendment, 60 votes were required, and the amendment died. This was the last attempt in Congress to expand background checks to private sales; any further attempts would be unsuccessful given the current composition of Congress.

State Laws on Background Checks and Pending Legislation

While 18 states and the District of Columbia (DC) have extended the background check requirement beyond federal law to require background checks to some private sales, the scope of these laws vary. Seven states and DC have enacted comprehensive universal background checks at the point of sale for all transfers of all classes of firearms, including purchases from unlicensed sellers (California, Colorado, Connecticut, Delaware, New York, Rhode Island, and Washington). Maryland and Pennsylvania laws do the same, but are limited to handguns. Two states (Illinois and Oregon) require a background check whenever a firearm is sold at a gun show. Four states (Hawaii, Illinois, Massachusetts, and New Jersey) require any firearm purchaser, including a purchaser from an unlicensed seller, to obtain a permit issued after a background check, and four more states (Iowa, Michigan, Nebraska, and North Carolina) do the same only for handguns.

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Background checks at the point of transfer

The most comprehensive approach to ensuring that guns are not sold to prohibited persons is through a requirement for a background check at the point of transfer of any firearm. Eleven states have this requirement for all guns, and six states require this for handguns. The simplest way to accomplish this is to require private sellers to process gun transfers through licensed gun dealers or law enforcement. California and Rhode Island have had this requirement for over two decades while five states recently adopted this approach (Colorado, Connecticut, Delaware, New York, and Washington). The Bureau of Alcohol, Tobacco, Firearms & Explosives issued a guidance document in 2013 that sets out a streamlined procedure for gun dealers to use to conduct background checks on behalf of unlicensed sellers of firearms. ⁸

California, Colorado, Maryland New York, And Washington Require all firearm transfers to be processed through licensed dealers, who must conduct background checks on prospective firearm purchasers. Rhode Island requires all sellers to obtain a completed application form from the prospective purchaser, and to submit the form to law enforcement for purposes of conducting a background check. Connecticut requires any person transferring a firearm to either submit a form to law enforcement or conduct the transfer through a licensed dealer, so that a background check is conducted for every sale or transfer. In the District of Columbia, firearms may be transferred only by or to a licensed dealer. Maryland And Pennsylvania require a background check on every prospective transferee of a handgun, which may be conducted by a licensed dealer or a designated law enforcement agency. Finally, Illinois, and Oregon of require a background check before the sale or transfer of a firearm at a gun show.

Almost all of the existing state laws that require unlicensed sellers to conduct background checks on firearm purchasers apply this requirement to "transfers," as well as sales. Since guns are often transferred to people who do not pay for them, such as in criminal enterprises or as part of guns-for-drugs trades, state laws include the broader term "transfers" in order to allow prosecutors to bring charges against a person for failing to conduct a background check in these circumstances. However, existing state laws that require a background check for transfers or sales by an unlicensed individual usually include certain exceptions, including gifts or loans among close family members, transfers made from a decedent's estate, transfers to law enforcement officers and members of the military, and limited loans for lawful purposes.

Pending state legislation: Background checks at the point of sale or transfer

In 2015, bills are pending in 15 states that attempt to require some type of background checks on private sales. Eight states (Arizona H.B. 2118, H.B. 2601, Iowa H.F. 77, Missouri H.B. 347, Nevada I.P. 2, New Hampshire H.B. 650, New York S.B. 2445, Vermont S.B. 31 and Virginia H.B. 1923/S.B. 768) would require all firearm transfers to be processed through licensed dealers who must conduct background checks on prospective firearm purchasers. If the person selling the firearm is not a licensed firearms dealer, the seller would be required to transfer the firearm to a licensed firearms dealer until the background check is completed.

Pending state legislation: Background checks at gun shows

Five states have pending legislation requiring background checks to be conducted at gun shows. New Mexico H.B. 44, South Carolina H.B. 3033, Texas S.B. 258, and Virginia H.B. 1604/S.B. 694 would require background checks prior to all purchases at gun shows. Kansas S.B. 25 would require background checks at gun shows and over the Internet. The bill does, however, exclude the requirement for background checks when there is a transfer of an antique firearm, gifts or transfers between family members, or transfers through inheritance. Virginia H.B. 2370 would set up a program with the state police to conduct voluntary criminal background checks at gun shows prior to purchase.

Pending state legislation: Repeal background check requirements

Three states have pending legislation to repeal background check requirements. Colorado H.B. 1050/S.B. 86 would repeal the requirement that before any person who is not a licensed gun dealer transfers possession of a firearm to a transferee, he or she must require that a criminal background check be conducted of the prospective transferee and must obtain approval of the transfer from the Colorado Bureau of Investigation. New York A.B. 3943/S.B. 2445 would repeal background check requirements established under The SAFE Act. Washington H.B. 1245 would repeal background check requirements at gun shows. Washington H.B. 1506/S.B. 5579 would exempt the transfer of a

firearm between a private security guard and his or her private security company employer from background check requirements, if the transfer is in the course or scope of employment or official duties. Finally, Washington H.B. 1886 would repeal Initiative Measure No. 594, which required background checks for all gun sales and transfers.

State legislation: Background checks vis-a-vis permit requirements

Another method to expand background checks is to require a state permit or license in order to purchase a firearm. In four states, the background check is done by requiring a potential purchaser to obtain a license or permit before purchasing any firearm from any seller (Hawaii, ²¹ Illinois, ²² Massachusetts, ²³ and New Jersey ²⁴) and four states require permits solely for handguns (Iowa, ²⁵ Michigan, ²⁶ Nebraska, ²⁷ and North Carolina ²⁸).

Pending state legislation: Licensing

Three states have pending legislation to amend gun licensing laws as they relate to concealed handguns. Colorado H.B. 1138 and Oregon H.B. 2533 would amend the application procedure for concealed handgun permits to satisfy federal criminal background check requirements by obtaining a permit. Thus a seller at a gun show would not need to perform a background check if the purchaser has a valid concealed handgun permit. Illinois H.B. 1405 would amend the Firearm Owners Identification Card Act. The bill would require a seller who is not a federally licensed importer, manufacturer, or dealer and who desires to sell or transfer a firearm that may be concealed to a purchaser who is not a federally licensed importer, manufacturer, or dealer, to do so only through a federally licensed firearm dealer who would be required to conduct a background check on the prospective purchaser.

AMA POLICY

Our AMA has numerous, long-standing policies that support increasing the safety of firearms and their use, and reducing and preventing firearm violence. Our AMA "recognizes that uncontrolled ownership and use of firearms, especially handguns, is a serious threat to the public's health inasmuch as the weapons are one of the main causes of intentional and unintentional injuries and deaths" (H-145.997). Specifically related to background checks, AMA policy supports legislation calling for a waiting period before purchasing any form of firearm in the US (H-145.991, H-145.992, and H-145.996), and supports requiring background checks for all handgun purchasers (H-145.991, H-145.996). Moreover, AMA policy supports stricter enforcement of present federal and state gun control legislation, and the imposition of mandated penalties for crimes committed with the use of a firearm, including the illegal possession of a firearm (Policy H-145.999). All of these policies were originally adopted in the late 1980s, when there was a national focus on handguns in part because access to relatively inexpensive handguns had led to an increase in rates of homicide, especially among young people. These policies have been repeatedly reaffirmed since then by the HOD.

DISCUSSION

Firearm-related mortality and morbidity continue to be major public health problems in the United States. According to the Centers for Disease Control and Prevention, more than 32,000 people die each year from firearm injuries. Every day, 20 children and adolescents are sent to the hospital as a result of firearm injuries, 30 and 88 deaths per day are due to firearm-related suicides, homicides, and accidents. Firearms are the second leading cause of death due to injury for adolescents and adults after motor vehicle crashes. Since the Sandy Hook mass shootings in December 2012, there have been almost 100 more incidents of fire-arm violence on school campuses.

Despite such sobering statistics and the public outcry after Sandy Hook and other recent mass shootings for action by Congress to expand background checks for firearm purchases, there is little chance given the current political environment for any congressional action in the foreseeable future to strengthen background check requirements or require licensing for firearms purchasers. The focus of attention for further legislative initiatives on preventing and reducing firearm violence has been, and will continue to be, at the state and local level. As discussed above, a number of states have extended background checks to all private sales of firearms; in such cases, all firearm sales are processed through licensed dealers who must conduct background checks on prospective firearm purchasers. If the person selling the firearm is not a licensed firearms dealer, the seller would be required to transfer the firearm to a licensed firearms dealer until the background check is completed. While some states do require licensing or permits for buyers in lieu of or in addition to requiring the seller to conduct background checks, the most

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straightforward method to ensure that buyers of firearms undergo universal background checks is to require them at the point of sale.

CONCLUSION

In summary, your Board believes it would be consistent with our AMA's existing policies on background checks, and a logical extension of such policies, to adopt new AMA policy that supports legislation requiring background checks for all purchasers of firearms. Your Board also notes that adopting such policy would be consistent with recent action taken by the American Psychiatric Association, which adopted a new policy statement in December that in part calls for requiring background checks (and waiting periods) on all gun sales or transactions, as well as a call to action recently issued by eight medical organizations and the American Bar Association.³⁴ For this reason, your Board recommends adopting the new policy set forth below.

RECOMMENDATION

The Board of Trustees recommends that the following recommendation be adopted in lieu of Substitute Resolution 215-A-14 and Resolutions 215-A-14 and 224-A-14, and that the remainder of this report be filed.

That our AMA support legislation requiring background checks for all purchasers of firearms.

APPENDIX - CURRENT AMA POLICY

H-145.991 Gun Control

The AMA supports using its influence in matters of health to effect passage of legislation in the Congress of the US mandating a national waiting period that allows for a police background and positive identification check for anyone who wants to purchase a handgun from a gun dealer anywhere in our country. (Sub. Res. 34, I-89; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-07)

H-145.992 Waiting Period Before Gun Purchase

The AMA supports legislation calling for a waiting period of at least one week before purchasing any form of firearm in the US (Res. 171, A-89; Reaffirmed: BOT Rep.50, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmation A-07)

H-145.996 Handgun Availability

The AMA (1) advocates a waiting period and background check for all handgun purchasers; (2) encourages legislation that enforces a waiting period and background check for all handgun purchasers; and (3) urges legislation to prohibit the manufacture, sale or import of lethal and non-lethal guns made of plastic, ceramics, or other non-metallic materials that cannot be detected by airport and weapon detection devices. (Res. 140, I-87; Reaffirmed: BOT Rep. 8, I-93; Reaffirmed: BOT Rep. 50, I-93; Reaffirmed: CSA Rep. 8, A-05)

H-145.997 Firearms as a Public Health Problem in the United States - Injuries and Death

Our AMA recognizes that uncontrolled ownership and use of firearms, especially handguns, is a serious threat to the public's health inasmuch as the weapons are one of the main causes of intentional and unintentional injuries and deaths. Therefore, the AMA: (1) encourages and endorses the development and presentation of safety education programs that will engender more responsible use and storage of firearms; (2) urges that government agencies, the CDC in particular, enlarge their efforts in the study of firearm-related injuries and in the development of ways and means of reducing such injuries and deaths; (3) urges Congress to enact needed legislation to regulate more effectively the importation and interstate traffic of all handguns; (4) urges the Congress to support recent legislative efforts to ban the manufacture and importation of nonmetallic, not readily detectable weapons, which also resemble toy guns; (5) encourages the improvement or modification of firearms so as to make them as safe as humanly possible; (6) encourages nongovernmental organizations to develop and test new, less hazardous designs for firearms; (7) urges that a significant portion of any funds recovered from firearms manufacturers and dealers through legal proceedings be used for gun safety education and gun-violence prevention; and (8) strongly urges US legislators to fund further research into the epidemiology of risks related to gun violence on a national level. (CSA Rep. A, I-87; Reaffirmed: BOT Rep. I-93-50; Appended: Res. 403, I-99; Reaffirmation A-07; Reaffirmation A-13; Appended: Res. 921, I-13)

H-145.999 Gun Regulation

Our AMA supports stricter enforcement of present federal and state gun control legislation and the imposition of mandated penalties by the judiciary for crimes committed with the use of a firearm, including the illegal possession of a firearm. (Sub. Res. 31, I-81; Reaffirmed: CLRPD Rep. F, I-91; Amended: BOT Rep. I-93-50; Reaffirmed: Res. 409, A-00; Reaffirmation A-07).

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- 10 Colo. Rev. Stat. § 18-12-112. 2013 Colo. H.B. 1229. See also Colo. Rev. Stat. §§ 12-26.1-101 12-26.1-108 (pre-existing law requiring a background check before a firearm is sold at a gun show).
- 11 Del. Code tit. 11, § 1448B, tit. 24, § 904A.
- 12 N.Y. Gen. Bus. Law § 898. 2013 NY ALS 1. See also N.Y. Gen. Bus. Law §§ 895-897; N.Y. Penal Law § 400.00 (pre-existing law requiring a background check before sale of a firearm at a gun show).
- 13 Initiative Measure No. 594, available at http://sos.wa.gov/ assets/elections/initiatives/FinalText 483.pdf.
- 14 R.I. Gen. Laws §§ 11-47-35 11-47-35.2.
- 15 Conn. Gen. Stat. §§ 29-33(c), 29-36l(f), 29-37a(e)-(j). 2013 Ct. ALS 3. See also Conn. Gen. Stat. § 29-37g (pre-existing law requiring a background check before a firearm is sold at a gun show).
- 16 D.C. Code Ann. § 7-2505.02.
- 17 Md. Code Ann., Pub. Safety §§ 5-101(t), 5-124. Maryland's requirement applies to "regulated firearms," which is defined to include handguns and assault weapons. However, assault weapons are now generally banned in Maryland.
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- 19 430 Ill. Comp. Stat. 65/3, 65/3.1.
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8. OPPOSITION TO LABORATORY REPORTING PROVISIONS OF H.R. 4302 (RESOLUTION 227-A-14)

Reference committee hearing: see report of <u>Reference Committee B</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED

IN LIEU OF RESOLUTION 227-A-14 AND REMAINDER OF REPORT FILED

See Policy D-260.993

INTRODUCTION

At the 2014 Annual Meeting, Resolution 227-A-14, "Opposition to Laboratory Reporting Provisions of H.R. 4302," was referred to the Board of Trustees (Board) for a report back at the 2015 Annual Meeting. Introduced by the Texas Delegation, Resolution 227-A-14 asks that our American Medical Association (AMA) seek changes in the law to eliminate the private sector laboratory reporting requirement in H.R. 4302, the "Protect Access to Medicare Act of 2014" (PAMA), and prohibit the use of such reporting information for rate setting on the Medicare clinical laboratory fee schedule. This report provides a brief history on the Medicare method of rate setting for services and procedures on the Medicare laboratory fee schedule, the likely factors that contributed to certain stakeholders seeking inclusion of a new Medicare laboratory rate setting method in PAMA, and existing options.

BACKGROUND

Medicare: New Pricing Policy for Clinical Laboratory Fee Schedule

On December 10, 2013, the Centers for Medicare & Medicaid Services (CMS) finalized the 2014 Medicare Physician Fee Schedule Final Rule (PFS), which included a fundamental change to the Medicare Clinical Laboratory Fee Schedule (CLFS). Specifically, CMS indicated that it would reexamine payment amounts under the CLFS to assess if changes in technology for the delivery of the services and procedures would support an adjustment to the payment amount. Up until this announced policy change, pricing on the CLFS has remained relatively stable—but not immune to adjustments such as, for example, those required by sequestration. The implementation of the new policy meant that, starting with the 2015 PFS proposed rule, CMS would identify CLFS codes and include proposed pricing adjustments along with the analysis of cost changes precipitated by technological advancements. CMS stated that it would first review the codes that have been on the CLFS the longest and continue reviewing until all of the codes on the CLFS had been reviewed over an approximate five year period. The agency also stated that the order in which codes would be considered would be influenced by additional factors, including volume, high reimbursement amount, or significant spending growth. The new policy included an opportunity for the public to nominate codes for pricing review, although the agency stated that it would retain the discretion on whether to review such nominated tests.

When the agency issued the proposed change, many stakeholders, including the American Clinical Laboratory Association (ACLA), questioned whether CMS had the legal authority to implement this policy change, but did not dispute that technological advancements could alter costs. Given the complexity, ACLA urged CMS to start with a pilot project involving a select number of codes as CMS was proposing to review approximately 200 codes a year. Many were concerned that this exercise would be a reprise of the deeply flawed methods and process used by CMS for pricing the new molecular pathology codes in 2013 (approximately 100)—which led to widespread disruptions and was marked by black box pricing by the Medicare contractors. Stakeholders also urged CMS to conduct the review over a greater number of years than it had proposed, balance its review of high-volume and low-volume codes, and to cap fee adjustments while phasing the latter in over time. However, CMS finalized the proposed policy change largely unchanged.

The agency's decision created widespread concern among ACLA and other key stakeholders, including the Advanced Medical Technology Association (AdvaMed), that there would be substantial reductions in the pricing of tests on the CLFS and that the agency's process would lead to significant instability and confusion. These stakeholders took their concerns to Congress and acted quickly as they viewed PAMA as a viable legislative vehicle because it was germane. Reportedly, these key stakeholders worked to develop PAMA section 216, Improving Medicare Policies for Clinical Diagnostic Laboratory Tests, in order to avert the sharp reductions they anticipated

under the new CMS policy. This provision was inserted without any debate or input from other key stakeholders in the provider community.

PAMA Section 216, Improving Medicare Policies for Clinical Diagnostic Laboratory Tests

On March 26, 2014, PAMA was introduced by Representative Joe Pitts (R-PA) and quickly passed in the US House of Representatives through a voice vote on March 27, 2014. After passage in the US Senate on March 31, 2014, President Obama signed the bill into law on April 1, 2014. Section 216 of PAMA requires sweeping new approaches to pricing on the CLFS. It is notable that these provisions were not widely evaluated by a broad and diverse set of stakeholders until after the PAMA became law. However, PAMA repealed any CMS authority to make changes to the CLFS based on technological changes widely opposed by prominent stakeholders in the clinical laboratory community.

PAMA replaces the process that CMS had identified in the 2014 Final PFS rule with a method and process to adjust CLFS reimbursement based on market rates. Broadly, the law also provides a per test phase-in of reductions in reimbursement and requires a defined reconsideration process for CLFS rates. Other key provisions of PAMA include:

- Starting January 1, 2016, "applicable" laboratories are required to report the payment rate that was paid by each private payor for the test and the volume of such tests for each such payor to the US Department of Health & Human Services (HHS).
- HHS is authorized to establish a low volume or low expenditure threshold for excluding otherwise applicable laboratories.
- Applicable laboratories are not to report data on a laboratory test for which payment is made on a capitated basis or other similar payment basis.
- The reported data must include the actual amount received and must include "all discounts, rebates, coupons and other price concessions."
- This information will then be used to calculate a "weighted median" price for each test that equals the amount Medicare will pay for that test until the year following the next data collection period.
- This weighted median will be calculated by "arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory."
- The new payment rates will go into effect on January 1, 2017.
- Payment reductions for each test, if any, cannot exceed 10 percent in the years 2017-2019 and 15 percent in the years 2020-2022.
- If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty (CMP) in an amount of up to \$10,000 per day for each failure to report or each such misrepresentation or omission.

The final regulations implementing the above provisions are required by statute to be issued by June 30, 2015, though a proposed rule had not been issued yet in the first quarter of 2015.

DISCUSSION

It is undisputed among all major stakeholders that the private sector payment rate reporting requirements of PAMA section 216 will impose a substantial administrative burden on clinical laboratories that will fall most heavily on smaller laboratories and physician office-based laboratories. While section 216 includes a provision that authorizes HHS to establish a low volume or low expenditure threshold for excluding otherwise applicable laboratories, there remains a possibility that: (1) HHS does not exercise this option; (2) certain small or mid-size laboratories could nonetheless be required to report, if the exclusion is limited in scope; and (3) the exclusion of these laboratories could result in skewed pricing that provides an advantage to high volume, low cost providers. If only high volume, low cost providers are left, it could negatively impact patient access, undermine the public health clinical laboratory sentinel system, and undermine quality and innovation.

There are a number of policy solutions that could be pursued by the AMA in collaboration with a diverse range of stakeholders to mitigate and ameliorate the administrative burden and impact of PAMA section 216 provisions related to reporting and rate setting. For instance, an alternative model of data collection—such as targeted statistical

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sampling—could be as accurate, if not more, and far less administratively burdensome and costly. This is one solution that could be pursued congressionally in coordination with key stakeholders. In addition, there is a need to more thoroughly evaluate and offer alternatives to the weighted median method of calculating CLFS test payment. In addition to congressional options, the AMA is able to advocate in coordination with interested stakeholders to seek regulatory clarification during the rule-making process that CMPs must only be imposed where CMS is able to demonstrate there was intent to withhold or provide incorrect or misleading information.

While there are a number of congressional reforms and regulatory clarifications to PAMA section 216 that would enjoy critical support among key stakeholders, it is improbable that providers and stakeholders in the clinical laboratory community would support a wholesale repeal of PAMA section 216 provisions related to the reporting requirement and the CLFS rate setting method. As detailed in the background section above, such a repeal could lead to the reinstitution of the CMS policies that key industry and provider stakeholders sought to avoid when they advocated for congressional action. Your Board therefore believes a more strategic approach would be for our AMA to work with Federation members and other major stakeholders on strategies to eliminate or substantially reduce the reporting burden associated with Medicare rate setting for laboratory fee schedule services and procedures.

RECOMMENDATION

The Board of Trustees recommends that the following be adopted in lieu of Resolution 227-A-14 and that the remainder of this report be filed:

That our American Medical Association work with Federation members and other major stakeholders, including the clinical laboratory and hospital associations, to identify and pursue viable congressional and regulatory strategies to eliminate or substantially reduce the reporting burden associated with Medicare rate setting for laboratory fee schedule services and procedures while supporting access to clinical laboratory services among the spectrum of providers of these services.

9. UPDATE ON CORPORATE RELATIONSHIPS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

PURPOSE

The purpose of this informational report is to update the House of Delegates (HOD) on the results of the Corporate Review process from January 1 through December 31, 2014. Corporate activities that associate the American Medical Association (AMA) name or logo with a company, non-Federation association or foundation, or include commercial support, currently undergo review and recommendations by the Corporate Review Team (CRT) (Appendix A).

BACKGROUND

At the 2002 Annual Meeting, the HOD approved revised principles to govern the American Medical Association's (AMA) corporate relationships HOD Policy G-630.040. These "Guidelines for American Medical Association Corporate Relationships" were incorporated into the corporate review process, are reviewed regularly and were reaffirmed at the 2012 Annual Meeting. AMA managers are responsible for reviewing AMA projects to ensure they fit within these guidelines.

YEAR 2014 RESULTS

In 2014, 34 new activities were considered and approved through the corporate review process. Of the 34 projects recommended for approval, ten were conferences or events, one was an education or grant program, thirteen were collaborations, and ten were American Medical Association Foundation (AMAF) programs (Appendix B).

CONCLUSION

The BOT continues to evaluate the CRT review process to balance risk assessment with the need for external collaborations that advance the AMA's strategic focus.

APPENDIX A - Corporate Review Process Overview

The Corporate Review Team (CRT) includes senior managers from the following areas: Strategy, Finance, Business, Advocacy, Federation Relations, Office of the General Counsel, Medical Education, Improving Health Outcomes, Ethics, Enterprise Communications and Marketing (ECM) and Membership.

The CRT evaluates each project with the following criteria:

- Type, purpose and duration of the activity;
- Audience:
- Company, association, foundation, or academic institution involved (due diligence reviewed);
- Source of external funding;
- Use of the AMA logo;
- Fit or conflict with AMA Corporate Guidelines;
- Editorial control/copyright;
- Exclusive or non-exclusive nature of the arrangement;
- Status of single and multiple supporters; and
- Risk assessment for AMA.

The CRT reviews and makes recommendations regarding the following types of activities:

- Industry-supported web, print, or conference projects directed to physicians or patients that do not adhere to Accreditation Council for Continuing Medical Education (ACCME) Standards and Essentials.
- Independent and company-sponsored foundation supported projects.
- AMA licensing and publishing programs. (These corporate arrangements involve licensing AMA products or information to
 corporate or non-profit entities in exchange for a royalty and involve the use of AMA's name, logo, and trademarks. This
 does not include database licensing.)
- Member service provider programs such as new affinity or insurance programs and member benefits.
- Third-party relationships such as joint ventures, business partnerships, or co-branding programs directed to members.
- Non-profit association collaborations outside the Federation. The CRT reviews all non-profit association projects (Federation or non-Federation) that involve corporate sponsorship.
- Collaboration with academic institutions only if there is corporate sponsorship.
- Vendor requests for usage of AMA name beyond a client listing.

For the above specified activities, if the CRT recommends approval, the project proceeds. In addition, the Executive Committee of the Board reviews and must approve CRT recommendations for the following AMA activities:

- Any activity directed to the public with external funding.
- Single-sponsor activities that do not meet ACCME Standards and Essentials.
- Activities involving risk of substantial financial penalties for cancellation.
- Upon request of a dissenting member of the CRT.
- Any other activity upon request of the CRT.

All Corporate Review recommendations are summarized annually for information to the Board of Trustees. The BOT informs the HOD of all corporate arrangements at the Annual Meeting.

Individuals should contact the Office of the General Counsel in the event of an AMA logo sighting.

APPENDIX B - Summary of Corporate Review Recommendations for 2014

Project No.	Project Description CONFERENCES/EVENTS	Corporations	Approval Date
1103-0052	Physician ICD-10-CM Coding Summit –AMA co-sponsorship of the Physician ICD-10-CM Coding Summit with DecisionHealth.	DecisionHealth	3/28/2014

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Project No.	Project Description	Corporations	<u>Approval</u> Date
1104-0358	History of Medicine Conference - AMA name and logo use for the History of Medicine conference.	The American Association for the History of Medicine (AAHM)	1/23/2014
2201-0146	Research! America Awards Dinner and Poll Data Summary Publication - AMA logo association for the Research! America awards dinner and poll data summary.	Research!America	1/17/2014
22680	TEDMED Conference Sponsorship – 2014 TedMed Sponsorship and logo use in conjunction with TEDMED 2014 conference.	TEDMED	9/9/2014
22796	Accelerating Change in Medical Education (ACE) Consortium Conference - Josiah Macy Jr. Foundation sponsoring the AMA Accelerating Change in Medical Education Consortium Conference.	The Josiah Macy Jr. Foundation	8/28/2014
22820	International Conference on Physician Health (ICPH) – AMA Sponsors ICPH with British Medical Association (BMA) and Canadian Medical Association (CMA). Seven exhibitors/sponsors were selected by BMA for the ICPH 2014.	Alcoholics Anonymous Medical Council on Alcohol/ Sick Doctors Trust Frontiers CPE Doctors Support Network Canadian Medical Foundation Pine Grove Behavioral Health General Medical Council	9/11/2014
22838	American Health Quality Association - 2014 Annual Meeting - AMA sponsorship and logo use.	The American Health Quality Association (AHQA) The American Geriatrics Society (AGS) The American Health Care Association	9/2/2014
22852	Medical Student Section (MSS) Vendor Fair – MSS vendor fair for the 2014 Interim Meeting.	MDpocket Picmonic, Inc. Tarascon Publishing Wolters Kluwer Elsevier BV National Library of Medicine Lexi-Comp, Inc. Skyscape Medpresso, Inc. Thieme Publishing US Military Medical (Army, Air Force, Marines, National Guard)	9/23/2014
4401-0138	International Medical Graduates Dessert Reception - Sponsored reception held at the AMA Annual Meeting.	American Association of Physicians of Indian Origin Association of Pakistani Physicians of North America Association of Philippine Physicians in American Medical Association American Psychiatric Association of Haitian Physicians Abroad AMHE Korean-American Medical Association of the U.S. National Arab American Medical Association	1/23/2014

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Project No.	Project Description	Corporations	<u>Approval</u> Date
6601-0105	Panasonic Innovation HealthJam - AMA logo use and participation in Panasonic HealthJam.	CITRIS Partners Healthcare Intel Panasonic University California San Francisco	4/22/2014
	EDUCATION/GRANT ACTIVITIES		
1101-0434	AmeriCares Prediabetes Project - AMA name and logo association with project to extend diabetes prevention work to patient populations through free clinics.	AmeriCares GE Foundation	3/28/2014
	COLLABORATIONS/ AFFILIATIONS		
1101-0230	RAND Corporation – Co-branded study on payment models for physician satisfaction focus area.	RAND	11/7/2014
1101-0435	AMA/NACDD collaboration - Co-host and logo association for two regional stakeholder meetings.	The National Association of Chronic Disease Directors (NACDD)	5/28/2014
1101-0436	AMA-CEHCD-CHITREC Patient Data Collection Project - Collaboration with the CEHCD and CHIRTEC to conduct a patient data collection project.	Commission to End Health Care Disparities (CEHCD) Chicago Health Information Technology Regional Extension Center (CHIRTEC)	5/23/2014
2204-0015	AIAMC Partner Program Participation - AMA logo use in the Alliance of Independent Academic Medical Centers (AIAMC) Partner Program.	Alliance of Independent Academic Medical Centers (AIAMC)	2/4/2014
22573	Expanding the Physician-Hospital Relationship – Meeting and co-branding on ensuring guidelines on characteristics for physician-hospital collaboration models.	American Hospital Association	7/3/2014
22579	2015 Survey Research - EHR and Mobile Health - Co-branded the report on EHR and mobile health with KLAS.	KLAS Enterprises, LLC	7/1/2014
22631	Prediabetes Awareness Collaboration – A public awareness campaign on diabetes prevention.	Ad Council American Diabetes Association Centers for Disease Control and Prevention	7/14/2014
22682	Partnership for Promoting Health IT Patient Safety – Collaboration and AMA logo use for Promoting Health IT patient safety with ECRI Institute and other partners.	ECRI Institute American College of Physician Executives American Health Information Management Association Association of Medical Directors of Information Systems American Medical Informatics Association College of Healthcare Information Management Executives Center for Risk Studies and Safety Association for the Advancement of Medical Instrumentation National Patient Safety Foundation Institute for Safe Medications Practices	7/30/2014

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Project No.	Project Description	Corporations	<u>Approval</u> Date
		Physician Insurers Association of America HIMSS other state PSOs	<u></u>
22775	Matter Collaboration - Relationship and logo use in conjunction with Matter and architectural firm HDR for exam room of the future.	Matter HDR Architecture, Inc.	11/20/2014
22974	Credible Labs Inc The AMA name and logo use in association with student loan and origination services (universal form to receive multiple lender quotes) affinity program.	Credible Labs Inc.	11/7/2014
23205	Co-branded Issue Brief on ACOs – Co- sponsored issue brief detailing how ACOs impact physicians.	Leavitt Partners Robert Woods Johnson Foundation (RWJF)	12/19/2014
23272	Co-Sponsorship of eHealth Initiative Annual Meeting - AMA recognized as a co-sponsor for conference.	Mayo Clinic PWC UnitedHealthcare Medicity Chime (College of Healthcare Information Management Executives) Federation of American Hospitals Texas A&M University Analytics Texas A&M University Online Programs CECity,	12/16/2014
5505-0415	New Models of Care - AMA collaboration and logo use on the New Models of Care Findings final report. AMA FOUNDATION PROGRAMS	The Guideline Advantage American Hospital Association (AHA)	4/22/2014
22471	American Medical Association Foundation (AMAF) American Health Lawyers Association (AHLA) Legal Resource Guide for Free Clinics - This toolkit will be a legal resource guide for free clinics and it is a joint project between the AHLA and the National Association of Free & Charitable Clinics (NAFC).	American Health Lawyers Association (AHLA) National Association of Free & Charitable Clinics (NAFC)	8/5/2014
22559	AMAF Healthy Living Grants – Funding for prescription medication safety and abuse program.	Purdue Pharma L.P. Teva Pharmaceutical Industries	7/17/2014
22674	AMAF Corporate Roundtable- New Members – Two new members for the Foundation Corporate Roundtable.	Teva Mallinckrodt Pharmaceutical	8/4/2014
23029	Diabetes Intervention Program for AMAF Free Clinics – Donation of lifestyle coach training software and training on how to use software for diabetes intervention program at AMAF free clinics.	Viridian Health Management	11/18/2014

Project No.	Project Description	Corporations	<u>Approval</u> Date
23212	AMAF Healthy Living Grants – Funding for the AMAF Healthy Living Grants Program on oncology.	Hospira	12/12/2014
6602-0037	AMAF Minority Scholars –Scholarships for award recipients.	Pfizer	3/28/2014
6602-0048	AMAF 2014 Excellence in Medicine Awards - AMA name and logo for the 2014 Excellence in Medicine Awards at the AMA Annual House of Delegates Meeting.	Pfizer Eli Lilly Novo Nordisk PhRMA Boehringer Ingelheim Abbvie	2/25/2014
6602-0402	AMAF Corporate Roundtable – Updated review for previous members of AMA Foundation Roundtable.	BlueCross BlueShield Association Eli Lilly & Co. Pfizer Inc Purdue Pharma AstraZeneca PhRMA Walgreen Co. AbbVie, Inc. Allergan BMO Harris Bank Boehringer Ingelheim Forest Laboratories, Inc. Genentech GlaxoSmithKline Merck Novartis Novo Nordisk Sanofi Takeda Pharmaceuticals US Mentor	3/11/2014
6602-0413	AMAF Free Clinics – Initial funding from Blue Cross Blue Shield for AMA IHO collaboration with AMAF free clinics program focused on hypertension and prediabetes.	Blue Cross Blue Shield	6/2/2014
6602-0414	AMAF Seed Grant Research Program – One year grants to medical students, physician residents and fellows for science and clinical research on neoplastic disease, HIV/AIDS or cardiac pulmonary projects.	Genentech	6/2/2014

10. COUNCIL ON LEGISLATION SUNSET REVIEW OF 2005 HOUSE POLICIES

Reference committee hearing: see report of <u>Reference Committee B</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

The House of Delegates has established a sunset mechanism for House policies (Policy G-600.110). Under which, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to retain it.

The objective of the sunset mechanism is to help ensure that our American Medical Association (AMA) Policy Database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the

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sunset mechanism contributes to the ability of our AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of House of Delegates deliberations.

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The process now includes the following steps:

- In the spring of each year, the House policies that are subject to review under the policy sunset mechanism are identified.
- Using the areas of expertise of the AMA councils as a guide, the staffs of the AMA councils determine which policies should be reviewed by which councils.
- For the Annual Meeting of the House, each council develops a separate policy sunset report that recommends how each policy assigned to it should be handled. For each policy it reviews, a council may recommend one of the following actions: (a) retain the policy; (b) rescind the policy; or (c) retain part of the policy. A justification must be provided for the recommended action on each policy.
- The Speakers assign the policy sunset reports for consideration by the appropriate reference committees.

Although the policy sunset review mechanism may not be used to change the meaning of AMA policies, minor editorial changes can be accomplished through the sunset review process.

In this report, the Board of Trustees presents the Council on Legislation's recommendations on the disposition of the House policies that were assigned to it. The Council on Legislation's recommendations on policies are presented in the Appendix to this report.

RECOMMENDATION

The Board of Trustees recommends that the House of Delegates policies listed in Appendix 1 to this report be acted upon in the manner indicated and the remainder of this report be filed.

APPENDIX 1 - Recommended Actions on 2005 House Policies

Policy Number	Title	Text	Recommendation
H-175.972	Plea Bargaining and	Our AMA opposes the use of harassment and coercive	Retain – This policy remains
	Immunity from	plea bargaining by prosecutors to pressure physicians.	relevant.
	Prosecution	(Res. 205, A-05)	
H-185.957	Coverage for	Our AMA supports legislation that requires all third	Retain – This policy remains
	Strabismus Surgery	party payers that cover surgical benefits to cover all	relevant.
		strabismus surgery where medically indicated. (Res.	
		234, A-01; Renumbered: CMS Rep. 7, I-05)	
H-230.957	Access to Hospital	Our AMA will support legislation guaranteeing that	Retain – This policy remains
	Records	physicians engaged in staff privileges disputes have	relevant.
		free and full access to all medical records related to	
		those disputes so they can adequately defend	
H-230.969	Strengthening	themselves. (Res. 527, A-04; Reaffirmation A-05) The AMA: (1) will study the feasibility of assisting	Retain in part – The Austin
H-230.909	Medical Staff	states in developing legislation to mandate that	v. Mercy case has been
	Bylaws	hospital medical staff bylaws be viewed as contracts;	concluded. The rest of this
	Dylaws	and (2) will study the feasibility of introducing federal	policy remains relevant.
		legislation to mandate that medical staff bylaws be	policy remains relevant.
		viewed as a contract. (Sub. Res. 810, A-95;	
		Reaffirmed: CLRPD Rep. 1, A-05)	
H-265.994	Expert Witness	(1) Regarding expert witnesses in clinical matters, as a	Retain – This policy remains
	Testimony	matter of public interest the AMA encourages its	relevant.
	-	members to serve as impartial expert witnesses. (2)	
		Our AMA is on record that it will not tolerate false	
		testimony by physicians and will assist state, county	
		and specialty medical societies to discipline physicians	
		who testify falsely by reporting its findings to the	
		appropriate licensing authority. (3) Existing policy	
		regarding the competency of expert witnesses and	
		their fee arrangements (BOT Rep. SS, A-89) is	
		reaffirmed, as follows: (a) The AMA believes that the	
1		minimum statutory requirements for qualification as	

Policy Number	Title	Text	Recommendation
		an expert witness in medical liability issues should	
		reflect the following: (i) that the witness be required to have comparable education, training, and occupational	
		experience in the same field as the defendant or	
		specialty expertise in the disease process or procedure	
		performed in the case; (ii) that the occupational	
		experience include active medical practice or teaching	
		experience in the same field as the defendant; (iii) that	
		the active medical practice or teaching experience must have been within five years of the date of the	
		occurrence giving rise to the claim; and (iv) that the	
		witness be certified by a board recognized by the	
		American Board of Medical Specialties or the	
		American Osteopathic Association or by a board with	
		equivalent standards. (b) The AMA opposes payment	
		of contingent fees for all types of medicolegal consultations, including management services	
		provided by firms engaged in locating physician	
		consultants. Where necessary, the AMA supports state	
		legislation making it illegal for medicolegal consulting	
		firms to take a contingent fee in personal injury	
		litigation. Such arrangements threaten the integrity and the compensation goals of the civil justice system.	
		Like the individual expert witness, the role of the	
		medicolegal consulting firm which locates and	
		supplies experts should be one of limited service to the	
		judicial process. Contingent fee arrangements are	
		plainly inconsistent with the scope of this	
		responsibility. (c) The AMA supports the right to cross examine physician expert witnesses on the following	
		issues: (i) the amount of compensation received for the	
		expert's consultation and testimony; (ii) the frequency	
		of the physician's expert witness activities; (iii) the	
		proportion of the physician's professional time	
		devoted to and income derived from such activities;	
		and (iv) the frequency with which he or she testified for either plaintiffs or defendants. The AMA supports	
		laws consistent with its model legislation on expert	
		witness testimony. (Sub. Res. 223, A-92; Appended:	
		Sub. Res. 211, I-97; Reaffirmation A-99; Modified:	
11.077.057	TI 14 C C "	BOT Rep. 8, I-04; Reaffirmed: Res. 2, I-05)	D (' TT' 1' '
H-275.965	Health Care Quality Improvement Act of	The AMA supports modification of the federal Health Care Quality Improvement Act in order to provide	Retain – This policy remains relevant.
	1986 Amendments	immunity from federal antitrust liability to those	relevant.
	1,001 milendine	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. (Res. 203, A-88; Reaffirmed:	
H-340.942	Due Process in PRO	Sunset Report, I-98; Reaffirmation A-05) Our AMA requests CMS to modify its interpretation	Rescind – This policy has
11 5-10.7-2	Quality Review	of confidentiality to allow physician counsel	been superseded by Policy
		representation in Peer Review Organization hearings if	H-340.971—Medicare
		requested by the affected physician. (Res. 209, A-90;	Program Due Process.
11.075.055	D D :	Reaffirmed: Sunset Report, I-00; Reaffirmation A-05)	D ' 1 mi' ' 1
H-375.966	Peer Review Protection Under	Our AMA supports: (1) federal legislation that will	Rescind – This policy has
	Federal Law	enhance protection of peer review information even if such information is shared with governmental	been achieved through enactment of the Patient
	1 cociai Euri	agencies in an effort to better and more	Safety and Quality
		comprehensively analyze the patient safety measures	Improvement Act of 2005,
		and quality of healthcare measures being utilized in	Public Law 109-41.
		clinical settings; and (2) federal legislation to afford	
		peer-review protection to information sharing and reporting in the context of patient safety and quality	
		reporting in the context of patient safety and quanty	

Policy Number	Title	Text	Recommendation
		improvement. (Res. 239, A-01; Appended: BOT Rep. 14, I-02; Reaffirmation A-05)	
H-375.973	Protecting Physicians at the Peer Review Process in the Current Managed Care Environment	Our AMA: (1) will work with the Federation of State Medical Boards to adopt a policy to support state legislative efforts to protect the integrity and effectiveness of the peer review process by prohibiting managed care companies from automatically terminating providers who have been sanctioned by state medical boards or by information being provided by the National Practitioners Data Bank without providing due process to the provider; and (2) espouses as policy the guarantee of due process and civil rights safeguards to physicians in peer review and in credentialing. (Res. 809, I-95; Appended: Res. 723, A-00; Reaffirmation A-05)	Retain – This policy remains relevant.
H-410.959	Criminalization of Physician Departure from Guidelines and Standards	Our AMA condemns the criminalization of medical decisions and actions by physicians and other health care providers who in loyalty to their patients and who in proper exercise of their clinical judgment depart from established medical care and resource allocation guidelines or standards for appropriate reasons, and seeks and/or supports legislation or rules/regulations at federal and state levels preventing such criminalization. (Res. 718, I-04; Modified: BOT Rep. 28, A-05)	Rescind – This policy has been superseded by Policies H-160.946—The Criminalization of Health Care Decision Making, H-160.954—Criminalization of Medical Judgment, and D-160-999—Opposition to Criminalizing Health Care Decisions.
H-435.953	Minor Statute of Repose/ Limitations	Our AMA supports federal legislation that would establish a Minor Statute of Repose/Limitations that includes the following language: An action by a minor upon a medical claim shall be commenced within 3 years from the date of the alleged manifestation of injury, except that actions by a minor under the full age of 6 years shall be commenced within 3 years of manifestation of injury or prior to the minor's 8th birthday, whichever provides the longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care organization have committed fraud or collusion in the failure to bring an action on behalf of the injured minor. (BOT Action in response to referred for decision Res. 230, A-05)	Retain – This policy remains relevant.
H-435.956	Professional Liability Alternative Financing	Our AMA supports legislation that would amend the Internal Revenue Code to allow medical professionals and entities to establish tax-exempt professional liability trusts to pay medical liability claims. (BOT Rep. 16, A-05)	Retain – This policy remains relevant.
H-435.959	Liability Reform	(1) Our AMA states that liability reform is our highest legislative priority; and (2) any federal liability reform legislation advocated by the AMA shall not preempt or supersede any law that imposes greater protections for health care providers and health care organizations from liability, loss, or damages than those provided by this legislation. (Sub. Res. 215, A-02; Reaffirmed: Sub. Res. 910, I-03; Reaffirmed: CME Rep. 2, I-05)	Rescind – Protection against federal medical liability reform legislation preempting state laws is covered in two more recently reaffirmed AMA Policies: H-435.978—Federal Medical Liability Reform; and H-435.967—Report of the Special Task Force and the Advisory Panel on Professional Liability.

Policy Number	Title	Text	Recommendation
D-90.994	Threats Against Physicians Based on Americans With Disabilities Act	Our AMA encourages AMA members who are threatened with non-meritorious lawsuits, supposedly founded on the Americans with Disabilities Act, to contact the AMA's Private Sector Advocacy Group for assistance. The AMA will post a notice on its web site, informing physicians how to report such incidents. (BOT Rep. 6, I-05)	Retain.
D-265.990	Strategic Lawsuits Against Public Participation (SLAPP)	Our AMA will make available, but not as a matter of advocacy priority, model anti-SLAPP legislation protecting physicians' First Amendment rights in the context of proceedings relating to quality of health care. (BOT Action in response to referred for decision Res. 832, I-05)	Retain – This policy remains relevant.
D-270.995	Physician Ownership and Referral for Imaging Services	Our AMA will work collaboratively with state medical societies and specialty societies to actively oppose any and all federal and state legislative and regulatory efforts to repeal the in-office ancillary exception to physician self-referral laws, including as they apply to imaging services. (Res. 235, A-04; Reaffirmed in lieu of Res. 901, I-05)	Retain – This policy remains relevant.
D-435.980	Inclusion of Residents in Medical Liability Reform	Our AMA: (1) officially supports the inclusion of all physicians, including unlicensed residents, in state and federal medical liability caps; (2) will advocate for the inclusion of unlicensed residents in all pending and future federal medical liability reform legislation; and (3) will work with state medical societies to advocate for the inclusion of unlicensed residents in all current, pending, and future state medical liability reform legislation. (Res. 907, I-05)	Retain – This policy remains relevant.
D-435.981	Limits on Non- Economic Damages and Contingency Fees	Our AMA will: (1) support federal legislation that does not preempt state medical tort reform laws that have contingency fee limits that are more restrictive than the MICRA limits on contingency fees; and (2) explore federal legislation that would correct inadequate state medical liability laws, while preserving proven effective state medical liability reforms. (Sub. Res. 214, A-05)	Rescind – Protection against federal medical liability reform legislation preempting state laws is covered in two more recently reaffirmed AMA Policies: H-435.978—Federal Medical Liability Reform; and H-435.967—Report of the Special Task Force and the Advisory Panel on Professional Liability.
D-495.998	Department of Justice Lawsuit Against the Tobacco Industry	Our AMA will: (1) continue to encourage the Department of Justice to seek other remedies in the suit against the tobacco industry including: (a) ending tobacco industry marketing and advertising to children including "point of sale" advertising, promotions and sponsorships and the range of additional marketing activities aimed at youth; (b) halting industry deception and false health claims including the use of misleading terms like "light" and "mild" cigarettes; (c) full disclosure of all tobacco industry documents; and (d) fully funding tobacco cessation that includes a national telephone quitline network, universal access to smoking cessation medication and counseling, an extensive media campaign, research and education of medical providers; and (2) urge the Department of Justice to appeal federal district court decision limiting Racketeer Influenced Corrupt Organization (RICO) Act remedies in the lawsuit against the tobacco industry and not enter into settlement discussions in this case until all appeals are exhausted up to and including appeal to the US Supreme Court. (Res. 446,	Rescind – The lawsuit against the tobacco industry is over. In 2006, US District Court Judge Gladys Kessler issued a final judgment and opinion in the US government's landmark lawsuit against the major tobacco companies, finding that the companies violated civil racketeering laws and defrauded the American people by lying for decades about the health risks of smoking and their marketing to children. This decision was upheld by the US Court of Appeals for the District of Columbia Circuit, and the US Supreme Court declined to hear appeals in the case.

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Policy Number	Title	Text	Recommendation
		A-05)	Other AMA policies cover
			the asks in this directive,
			including H-495.984, which
			addresses tobacco
			advertising and marketing
			toward children; H-495.981,
			which opposes tobacco
			industry advertising using
			the terms "light and low-tar;"
			and H-490.917, H-505.963,
			D-490.976, and D-490.997,
			which support resources for
			tobacco cessation.

APPENDIX 2 - AMA Policies Superseding Policies Recommended for Rescission

H-340.942 Due Process in PRO Quality Review

Our AMA requests CMS to modify its interpretation of confidentiality to allow physician counsel representation in Peer Review Organization hearings if requested by the affected physician. (Res. 209, A-90; Reaffirmed: Sunset Report, I-00; Reaffirmation A-05)

H-340.971 Medicare Program Due Process

The AMA supports legislative and regulatory changes, as necessary, to assure the provision of PRO review with due process protections before any physician is sanctioned under the Medicare Program. Such due process should include at a minimum the following specific protections that would entitle the physician to: (1) a written statement of the charges against him or her; (2) adequate notice of the right to a hearing, his or her rights in the hearing, and a reasonable opportunity to prepare for the hearing; (3) discover the evidence and witnesses against him or her sufficiently in advance of the hearing to enable preparation of the defense; (4) a fair, objective, and independent hearing, with the right to ask questions of the panel members and of any hearing officer designed to reveal bias or prejudice, and the right to challenge the impartiality of any member or hearing officer; (5) be represented by an attorney or other person of the physician's choice; (6) the opportunity to be present at the hearing and hear all of the evidence against him or her; (7) the opportunity to present a defense to the charges, including, but not limited to, the right to call, examine and cross-examine witnesses; (8) a presumption of innocence and assurance that the hearing body shall not render a decision against the physician unless the evidence produced at the hearing clearly supports that adverse determination; (9) a hearing within a reasonable proximity of the location of the physician's practice; and (10) a hearing which protects the interests of the physician, the physician's patients, and the public in quality patient care. (Sub. Res. 107, I-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CMS Rep. 9, A-07)

H-410.959 Criminalization of Physician Departure from Guidelines and Standards

Our AMA condemns the criminalization of medical decisions and actions by physicians and other health care providers who in loyalty to their patients and who in proper exercise of their clinical judgment depart from established medical care and resource allocation guidelines or standards for appropriate reasons, and seeks and/or supports legislation or rules/regulations at federal and state levels preventing such criminalization. (Res. 718, I-04; Modified: BOT Rep. 28, A-05)

H-160.946 The Criminalization of Health Care Decision Making

The AMA opposes the attempted criminalization of health care decision-making especially as represented by the current trend toward criminalization of malpractice; it interferes with appropriate decision making and is a disservice to the American public; and will develop model state legislation properly defining criminal conduct and prohibiting the criminalization of health care decision-making, including cases involving allegations of medical malpractice, and implement an appropriate action plan for all components of the Federation to educate opinion leaders, elected officials and the media regarding the detrimental effects on health care resulting from the criminalization of health care decision-making. (Sub. Res. 202, A-95; Reaffirmed: Res. 227, I-98; Reaffirmed: BOT Rep. 2, A-07; Reaffirmation A-09; Reaffirmation: I-12)

H-160.954 Criminalization of Medical Judgment

(1) Our AMA continues to take all reasonable and necessary steps to insure that errors in medical decision-making and medical records documentation, exercised in good faith, do not become a violation of criminal law. (2) Henceforth our AMA opposes any future legislation which gives the federal government the responsibility to define appropriate medical practice and regulate such practice through the use of criminal penalties. (Sub. Res. 223, I-93; Reaffirmed: Res. 227, I-98; Reaffirmed: Res. 237, A-99; Reaffirmed and Appended: Sub. Res. 215, I-99; Reaffirmation A-09; Reaffirmed: CEJA Rep. 8, A-09; Reaffirmation: I-12; Modified: Sub. Res. 716, A-13; Reaffirmed in lieu of Res. 605, I-13)

D-160.999 Opposition to Criminalizing Health Care Decisions

Our AMA will educate physicians regarding the continuing threat posed by the criminalization of healthcare decision-making and the existence of our model legislation "An Act to Prohibit the Criminalization of Healthcare Decision-Making." (Res. 228, I-98; Reaffirmed: BOT Rep. 5, A-08; Reaffirmation: I-12)

H-435.959 Liability Reform

(1) Our AMA states that liability reform is our highest legislative priority; and (2) any federal liability reform legislation advocated by the AMA shall not preempt or supersede any law that imposes greater protections for health care providers and health care organizations from liability, loss, or damages than those provided by this legislation. (Sub. Res. 215, A-02; Reaffirmed: Sub. Res. 910, I-03; Reaffirmed: CME Rep. 2, I-05)

H-435.978 Federal Medical Liability Reform

Our AMA: (1) supports federal legislative initiatives implementing the following medical liability reforms: (a) limitation of \$250,000 or lower on recovery of non-economic damages; (b) the mandatory offset of collateral sources of plaintiff compensation; (c) decreasing sliding scale regulation of attorney contingency fees; and (d) periodic payment for future awards of damages; (2) reaffirms its support for the additional reforms identified in Report L (A-89) as appropriate for a federal reform vehicle. These are: (a) a certificate of merit requirement as a prelude to filing medical liability cases; and (b) basic medical expert witness criteria; (3) supports for any federal initiative incorporating provisions of this type would be expressly conditional. Under no circumstances would support for federal preemptive legislation be extended or maintained if it would undermine effective tort reform provisions already in place in the states or the ability of the states in the future to enact tort reform tailored to local needs. Federal preemptive legislation that endangers state-based reform will be actively opposed. Federal initiatives incorporating extended or ill-advised regulation of the practice of medicine also will not be supported. Effective medical liability reform, based on the California Medical Injury Compensation Reform Act (MICRA) model, is integral to health system reform. (BOT Rep. S, I-89; BOT Rep. I-93-53; Reaffirmed: BOT Rep. 8, I-98; Reaffirmation A-00; Reaffirmation I-03; Reaffirmed: Sub. Res. 910, I-03; Reaffirmed: Res. 206, I-09; Reaffirmation A-10; Reaffirmed: Sub. Res. 222, I-10; Reaffirmed: Res. 206, A-11; Reaffirmed in lieu of Res. 205, I-11)

H-435.967 Report of the Special Task Force and the Advisory Panel on Professional Liability

(1) It is the policy of the AMA that effective medical liability reform, based on the California Medical Injury Compensation Reform Act (MICRA) model, is integral to health system reform. The AMA's MICRA-based federal tort reform provisions include: (a) a \$250,000 ceiling on non-economic damages, (b) the offset of collateral sources of plaintiff compensation, (c) decreasing incremental or sliding scale attorney contingency fees, (d) periodic payment of future awards of damages, and (e) a limitation on the period for suspending the application of state statutes of limitations for minors to no more than six years after birth. (2) Our AMA also supports federal reform to achieve: (a) a certificate of merit requirement as a prerequisite to filing medical liability cases; (b) statutory criteria that outline expert witness qualifications; and (c) demonstration projects to implement potentially effective alternative dispute resolution (ADR) mechanisms. (3) Our AMA supports medical product liability reform, applicable to the producers of pharmaceuticals and medical devices, as an important state and federal legislative reform objective. (4) Any health system reform proposal that fails to include MICRA type reform, or an alternative model proven to be as effective in a state, will not be successful in containing costs, providing access to health care services, and promoting the quality and safety of health care services. Under no circumstances would support for federal legislation be extended or maintained if it would undermine effective tort reform provisions already in place in the states. Federal preemptive legislation that endangers effective state-based reform will be actively opposed. (BOT Rep. 53, I-93; Reaffirmation A-00; Reaffirmation I-03; Reaffirmed: Sub. Res. 910, I-03; Reaffirmation A-04; Reaffirmed: CCB/CLRPD Rep. 2, A-14)

D-435.981 Limits on Non-Economic Damages and Contingency Fees

Our AMA will: (1) support federal legislation that does not preempt state medical tort reform laws that have contingency fee limits that are more restrictive than the MICRA limits on contingency fees; and (2) explore federal legislation that would correct inadequate state medical liability laws, while preserving proven effective state medical liability reforms. (Sub. Res. 214, A-05)

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D-495.998 Department of Justice Lawsuit Against the Tobacco Industry

Our AMA will: (1) continue to encourage the Department of Justice to seek other remedies in the suit against the tobacco industry including: (a) ending tobacco industry marketing and advertising to children including "point of sale" advertising, promotions and sponsorships and the range of additional marketing activities aimed at youth; (b) halting industry deception and false health claims including the use of misleading terms like "light" and "mild" cigarettes; (c) full disclosure of all tobacco industry documents; and (d) fully funding tobacco cessation that includes a national telephone quitline network, universal access to smoking cessation medication and counseling, an extensive media campaign, research and education of medical providers; and (2) urge the Department of Justice to appeal federal district court decision limiting Racketeer Influenced Corrupt Organization (RICO) Act remedies in the lawsuit against the tobacco industry and not enter into settlement discussions in this case until all appeals are exhausted up to and including appeal to the US Supreme Court. (Res. 446, A-05)

H-495.984 Tobacco Advertising and Media

Our AMA: (1) in keeping with its long-standing objective of protecting the health of the public, strongly supports a statutory ban on all advertising and promotion of tobacco products; (2) as an interim step toward a complete ban on tobacco advertising, supports the restriction of tobacco advertising to a "generic" style, which allows only black-and-white advertisements in a standard typeface without cartoons, logos, illustrations, photographs, graphics or other colors; (3) (a) recognizes and condemns the targeting of advertisements for cigarettes and other tobacco products toward children, minorities, and women as representing a serious health hazard; (b) calls for the curtailment of such marketing tactics; and (c) advocates comprehensive legislation to prevent tobacco companies or other companies promoting look-alike products designed to appeal to children from targeting the youth of America with their strategic marketing programs; (4) supports the concept of free advertising space for anti-tobacco public service advertisements and the use of counter-advertising approved by the health community on government-owned property where tobacco ads are posted; (5) (a) supports petitioning appropriate government agencies to exercise their regulatory authority to prohibit advertising that falsely promotes the alleged benefits and pleasures of smoking as well worth the risks to health and life; and (b) supports restrictions on the format and content of tobacco advertising substantially comparable to those that apply by law to prescription drug advertising; (6) publicly commends those publications that have refused to accept cigarette advertisements and supports publishing annually, via JAMA and other appropriate publications, a list of those magazines that have voluntarily chosen to decline tobacco ads, and circulation of a list of those publications to every AMA member; (7) urges physicians to mark the covers of magazines in the waiting area that contain tobacco advertising with a disclaimer saying that the physician does not support the use of any tobacco products and encourages physicians to substitute magazines without tobacco ads for those with tobacco ads in their office reception areas; (8) urges state, county, and specialty societies to discontinue selling or providing mailing lists of their members to magazine subscription companies that offer magazines containing tobacco advertising; (9) encourages state and county medical societies to recognize and express appreciation to any broadcasting company in their area that voluntarily declines to accept tobacco advertising of any kind; (10) urges the 100 most widely circulating newspapers and the 100 most widely circulating magazines in the country that have not already done so to refuse to accept tobacco product advertisements, and continues to support efforts by physicians and the public, including the use of written correspondence, to persuade those media that accept tobacco product advertising to refuse such advertising; (11) (a) supports efforts to ensure that sports promoters stop accepting tobacco companies as sponsors; (b) opposes the practice of using athletes to endorse tobacco products and encourages voluntary cessation of this practice; and (c) opposes the practice of tobacco companies using the names and distinctive hallmarks of well-known organizations and celebrities, such as fashion designers, in marketing their products; (12) will communicate to the organizations that represent professional and amateur sports figures that the use of all tobacco products while performing or coaching in a public athletic event is unacceptable. Tobacco use by role models sabotages the work of physicians, educators, and public health experts who have striven to control the epidemic of tobaccorelated disease; (13) (a) encourages the entertainment industry, including movies, videos, and professional sporting events, to stop portraying the use of tobacco products as glamorous and sophisticated and to continue to de-emphasize the role of smoking on television and in the movies; (b) will aggressively lobby appropriate entertainment, sports, and fashion industry executives, the media and related trade associations to cease the use of tobacco products, trademarks and logos in their activities, productions, advertisements, and media accessible to minors; and (c) advocates comprehensive legislation to prevent tobacco

companies from targeting the youth of America with their strategic marketing programs; and (14) encourages the motion picture industry to apply an "R" rating to all new films depicting cigarette smoking and other tobacco use. (CSA Rep. 3, A-04; Appended: Res. 427, A-04; Reaffirmation A-05; Reaffirmation A-14)

H-495.981 Light and Low-Tar Cigarettes

Our AMA concurs with the key scientific findings of National Cancer Institute Monograph 13, Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine: (a) Epidemiological and other scientific evidence, including patterns of mortality from smoking-caused diseases, does not indicate a benefit to public health from changes in cigarette design and manufacturing over the last 50 years. (b) For spontaneous brand switchers, there appears to be complete compensation for nicotine delivery, reflecting more intensive smoking of lower-yield cigarettes. (c) Cigarettes with low machine-measured yields by Federal Trade Commission (FTC) methods are designed to allow compensatory smoking behaviors that enable a smoker to derive a wide range of tar and nicotine yields from the same brand. (d) Widespread adoption of lower yield cigarettes in the United States has not prevented the sustained increase in lung cancer among older smokers. (e) Many smokers switch to lower yield cigarettes out of concern for their health, believing these cigarettes to be less risky or to be a step toward quitting; many smokers switch to these products as an alternative to quitting. (f) Advertising and promotion of low tar cigarettes were intended to reassure smokers who were worried about the health risks of smoking, were meant to prevent smokers from quitting based on those same concerns; such advertising was successful in getting smokers to use low-yield brands. (g) Existing disease risk data do not support making a recommendation that smokers switch cigarette brands. The recommendation that individuals who cannot stop smoking should switch to low yield cigarettes can cause harm if it misleads smokers to postpone serious attempts at cessation. (h) Measurements of tar and nicotine yields using the FTC method do not offer smokers meaningful information on the amount of tar and nicotine they will receive from a cigarette. Our AMA seeks legislation or regulation to prohibit cigarette manufacturers from using deceptive terms such as "light," "ultra-light," "mild," and "low-tar" to describe their products. (CSA Rep. 3, A-04; Reaffirmed in lieu of Res. 421, A-12)

H-490.917 Physician Responsibilities for Tobacco Cessation

Cigarette smoking is a major health hazard and a preventable factor in physicians' actions to maintain the health of the public and reduce the high cost of health care. Our AMA takes a strong stand against smoking and favors aggressively pursuing all avenues of educating the general public on the hazards of using tobacco products and the continuing high costs of this serious but preventable problem. Additionally, our AMA supports and advocates for appropriate surveillance approaches to measure changes in tobacco consumption, changes in tobacco-related morbidity and mortality, youth uptake of tobacco use, and use of alternative nicotine delivery systems. In view of the continuing and urgent need to assist individuals in smoking cessation, physicians, through their professional associations, should assume a leadership role in establishing national policy on this topic and assume the primary task of educating the public and their patients about the danger of tobacco use (especially cigarette smoking). Accordingly, our AMA: (1) encourages physicians to refrain from engaging directly in the commercial production or sale of tobacco products; (2) supports (a) development of an anti-smoking package program for medical societies; (b) making patient educational and motivational materials and programs on smoking cessation available to physicians; and (c) development and promotion of a consumer health-awareness smoking cessation kit for all segments of society, but especially for youth; (3) encourages physicians to use practice guidelines for the treatment of patients with nicotine dependence and will cooperate with the Agency for Health Research and Quality (AHRQ) in disseminating and implementing evidence-based clinical practice guidelines on smoking cessation, and on other matters related to tobacco and health; (4) (a) encourages physicians to use smoking cessation activities in their practices including (i) quitting smoking and urging their colleagues to quit; (ii) inquiring of all patients at every visit about their smoking habits (and their use of smokeless tobacco as well); (iii) at every visit, counseling those who smoke to quit smoking and eliminate the use of tobacco in all forms; (iv) prohibiting all smoking in the office by patients, physicians, and office staff; and discouraging smoking in hospitals where they work (v) providing smoking cessation pamphlets in the waiting room; (vi) becoming aware of smoking cessation programs in the community and of their success rates and, where possible, referring patients to those programs; (b) supports the concept of smoking cessation programs for hospital inpatients conducted by appropriately trained personnel under the supervision of a physician; (5) (a) supports efforts to identify gaps, if any, in existing materials and programs designed to train physicians and medical students in the behavior modification skills necessary to successfully counsel patients to stop smoking; (b) supports the production of materials and programs which would fill gaps, if any, in materials and programs to train physicians and medical students in the behavior modification skills necessary to successfully counsel patients to stop smoking; (c) supports national, state, and local efforts to help physicians and medical students develop skills necessary to counsel patients to quit smoking; (d) encourages state and county medical societies to sponsor, support, and promote efforts that will help physicians and medical students more effectively counsel patients to stop smoking; (e) encourages physicians to participate in education programs to enhance their ability to help patients quit smoking; (f) encourages physicians to speak to community groups about tobacco use and its consequences; and (g) supports providing assistance in the promulgation of information on the effectiveness of smoking cessation programs; (6) (a) supports the concept that physician offices, clinics, hospitals, health departments, health plans, and voluntary health associations should become primary sites for education of the public about the harmful effects of tobacco and encourages physicians and other health care workers to introduce and support healthy lifestyle practices as the core of preventive programs in these sites; and (b) encourages the development of smoking cessation programs implemented jointly by the local medical society, health department, and pharmacists; and (7) (a) believes that collaborative approaches to tobacco treatment across all points of contact within the medical system will maximize opportunities to address tobacco use among all of our patients, and the likelihood for successful intervention; and (b) supports efforts by any appropriately licensed health care professional to identify and treat tobacco dependence in any individual, in the various clinical contexts in which they are encountered, recognizing that care provided in

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one context needs to take into account other potential sources of treatment for tobacco use and dependence. (CSA Rep. 3, A-04; Appended: Res. 444, A-05; Reaffirmed: BOT Rep. 8, A-08; Reaffirmed in lieu of Res. 912, I-12)

H-505.963 Federal Efforts Related to Smoking Cessation

Our AMA endorses the use of the federally-funded National Tobacco Quitline network and ongoing media campaigns to help Americans quit using tobacco. (CSA Rep. 3, A-04; Modified: CSAPH Rep. 1, A-14)

D-490.976 Tobacco Settlement Fund

Our AMA supports state and local medical societies in their efforts to formally request that local and state lawmakers allocate at least the Centers for Disease Control and Prevention-recommended minimum amount of the state's Tobacco Settlement Fund award annually to smoking cessation and health care related programs, and encourages society members and the public to demand this of their elected officials. (Res. 431, A-07; Reaffirmation I-11)

D-490.997 Continued Action on States' Allocation of Tobacco Settlement Monies for Smoking Prevention, Cessation and Health Services

Our AMA will: (1) translate that commitment into action through aggressive lobbying activities to encourage and work with state and specialty societies to vigorously lobby state legislatures to: (a) assure that a significant percentage (depending on the objectively determined needs of the state) of the tobacco settlement monies be set aside first for tobacco control, nicotine addiction prevention, cessation and disease treatment for tobacco control and related public health purposes and medical services; (b) assemble an appointed state level task force, when needed, that includes experts in public health, smoking cessation and tobacco prevention programs to ensure that funds are spent on activities supported by the Centers for Disease Control and Prevention guidelines. (Res. 428, A-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmation I-11)

11. ADMINISTRATIVE BURDEN TIME STUDY

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

Administrative tasks place considerable time and resource burdens on physician practices. Many of these administrative activities result from health plan requirements, such as prior authorization, credentialing, formulary compliance, quality reporting, and claims/billing. Regulatory mandates, including the Meaningful Use program and the Physician Quality Reporting System (PQRS), also significantly contribute to practices' administrative workload. These tasks represent uncompensated additional work that an already overtaxed physician must complete to avoid health plan nonpayment or regulatory penalties. The growing volume of nonclinical work is a major contributor to job dissatisfaction and burnout in medicine. Most importantly, time spent on paperwork and regulatory compliance reduces the number of hours available for patient care.

Physicians frequently express concern regarding the effect of these administrative burdens on their practices, but objective data regarding the impact of these nonclinical tasks on practice workload are lacking. Recognizing the important role that such data play in effective advocacy against health plan and regulatory administrative requirements, our American Medical Association (AMA) adopted two resolutions addressing this research need. At the 2014 Annual Meeting, the House of Delegates adopted Policy D-330.909, which calls on our AMA to "perform or commission an analysis of the direct and indirect costs and documented benefits associated with significant administrative and regulatory requirements imposed by the Centers for Medicare and Medicaid Services, including but not limited to face-to-face documentation requirements, the [PQRS], and the Meaningful Use program." Policy D-320.988, which was adopted at the 2014 Interim Meeting, calls for the AMA to "conduct a study to quantify the amount of time physicians and their staff spend on nonclinical administrative tasks, to include (1) authorizations and preauthorizations and (2) denial of authorization appeals."

The AMA Physician Satisfaction and Practice Sustainability and Advocacy groups are jointly managing a research project to address these policies. This report, which is presented for the information of the House, outlines the project's progress to date and details the expected plan and timeline for completing the study.

INITIAL STUDY PREPARATION

Through internal discussions and conversations with researchers experienced in the field of time study, AMA staff developed high-level priorities and parameters for the administrative burden study. Major project specifications include:

- 1. Prospective time measurement: Most of the available data regarding physician practice workload measurements are survey results and therefore reliant on physician and staff recall. In order for the results of the AMA study to be widely accepted and reliable, administrative tasks will be quantified prospectively.
- 2. Inclusion of nonphysician staff: Practice staff often assist physicians with administrative tasks. For example, nurses and/or clerical staff may perform some, and sometimes all, of the work associated with prior authorizations. To ensure that the full-time burdens of nonclinical work are captured, other appropriate practice staff will be included in the study.
- 3. Use of observers: Trained observers will shadow physicians and relevant staff to measure time spent on various tasks. This minimizes the work disruptions and study noncompliance that could be associated with physician/staff self-recording of time measurements.
- 4. Inclusion of medical specialties: To maximize the generalizability of the results, one or two specialties, in addition to primary care, will be included in the study.
- 5. Data granularity: Administrative task categories will be sufficiently granular to ensure that the average amount of time that practices spend on specific tasks (e.g., prior authorization) can be easily ascertained from study results.

Based on these parameters, the AMA drafted a request for proposal (RFP) to solicit potential research partners for the project. In addition to describing the specifications outlined above, the RFP stated the AMA's overall goal of establishing credible time estimates for various administrative tasks in the physician practice and using these data to drive interest in practice re-engineering, inform and support AMA advocacy efforts, and highlight the immutability of time (i.e., time spent on low-value work reduces time available for high-value, patient-focused activities). The RFP also outlined the proposed schedule for the study and indicated that results were expected to be ready for publication/release by the end of 2015.

More than a dozen vendors were invited to respond to the RFP, and the AMA received five high-quality research proposals. After a thorough review and evaluation of all candidates, the AMA selected Dartmouth-Hitchcock (DH) as its research partner for this project. The DH team's previous experience with direct observation studies and time capture technology, thorough understanding of the complexity and challenges involved in this type of research, and commitment to the project make them an excellent partner for the AMA in this endeavor.

STUDY DESIGN

DH will invite 10–15 physician practices to participate in the study. Practices will be diverse in terms of ownership (private vs. employed), practice arrangement, and geography; the AMA will assist with recruitment of practices outside of the DH health system. Institutional ethics approval will be obtained through DH. It is expected that practices outside the DH system will not be affiliated with research institutions and will therefore not require an extensive institutional review process to participate. While not all specialties can be represented in a study of this size, DH will likely include one or two specialties outside of primary care.

The project will require an intensive preparation phase, during which DH, in consultation with the AMA, will develop a list of task categories and subcategories to describe the work activities of physicians and relevant staff. DH will draw on existing literature on practice workflow to develop task categories and will then observe several physicians/staff to continue building the task list and ensure that all practice activities can be captured with the data categories. To record time data on observed work tasks, DH will utilize the Work Observation Method by Activity Timing (WOMBAT), a research technique and technology that has been successfully used in direct observational studies of health professionals. WOMBAT software is loaded on handheld computers (e.g., iPad minis), allowing observers to capture four dimensions of study participants' work activities: what task is underway, with whom the task is being completed, where the task is being performed, and how/what resource is being used (e.g., phone, paper, desk computer). In addition to capturing task time and the four task dimensions, WOMBAT can also record multitasking, further adding to the value of the tool. DH will purchase a WOMBAT license and modify the tool to

accommodate the task categories developed for the AMA study. The task categories and the WOMBAT tool will be further tested and validated during data collection pilots.

Data will be collected through direct observation of physicians and practice staff by trained observers. DH plans to develop a team of trained observers from medical students at the Geisel School of Medicine. Observers will receive training in research ethics and extensive specific instruction on study data collection tools and methods. Observers will be deployed in teams of two to study sites. During each observation, one team member will record data in WOMBAT, while the other will take field notes. Data will be collected in two-three hour shifts to prevent observer fatigue; practices will confirm that planned shifts accurately reflect typical work activities and include sufficient administrative work. It is anticipated that pair teams will complete two observation sessions per day, with 1000 hours of data being captured during the study.

In addition to the time involved in various practice activities, DH will also assess the value of various tasks via Value Stream Mapping, a lean manufacturing technique. Tasks will be categorized by a representative focus group of patients, physicians, and nonphysicians as (1) value (value to patient), (2) nonvalue added (no value to patient), or (3) business nonvalue added (tasks with no value to patient but required for business such as documentation and billing). This value assessment will further support AMA advocacy, as well as practice re-engineering efforts.

STUDY TIMELINE

At the time that this report was written, formal work on the administrative burden time study was expected to begin in late March 2015, following finalization of contract terms between the AMA and DH. The tentative timeline for project completion is shown in the table below. As previously noted, the study will require a substantial preparation phase to develop task categories, adjust the WOMBAT tool for this particular research, and train the observers.

Month	Activity
March – April 2015	Recruit study practices/institutional review
	Recruit observers
	Analyze workflow/develop task list; modify WOMBAT
May 2015	Train observers
	Pilot task list and modified WOMBAT tool; adjust as needed
June – August 2015	Collect data (1000 observation hours)
September – October 2015	Analyze time data
	Define and analyze task value
November – December 2015	Complete study report
	Prepare and submit manuscript

Throughout the course of the study, DH will regularly update the AMA on the progress of the project. In addition, DH will solicit AMA input on practice sites, task categories, and other relevant study elements. The study should be completed by the end of 2015. The Board of Trustees will keep the House of Delegates apprised of the status of the administrative burden time study.

CONCLUSION

The AMA is undertaking a major research project to credibly quantify the time that physician practices spend on various administrative activities. The partnership with a well-qualified academic research partner with significant expertise in observational studies will ensure that the results of this project are widely accepted and suitable for publication in a peer-reviewed journal. The data gathered from this study are expected to be a valuable component of our AMA's advocacy campaign to reduce administrative burdens imposed on physicians by health plans and regulatory requirements. Our AMA will also be recognized as making a major contribution to the field of physician practice workload research.

12. DEVELOPMENT AND PROMOTION OF SINGLE NATIONAL PRESCRIPTION DRUG MONITORING PROGRAM (RESOLUTION 230-A-14)

Reference committee hearing: see report of <u>Reference Committee B.</u>

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

IN LIEU OF RESOLUTION 230-A-14 AND

REMAINDER OF REPORT FILED

See Policies H-95.939, H-95.945, H-95.946, H-95.947 and H-95.990

INTRODUCTION

At the 2014 Annual Meeting, Resolution 230-A-14, Development and Promotion of Use of Single National Prescription Drug Monitoring Program introduced by the Resident and Fellow Section and referred by the House of Delegates (HOD), asked:

That our AMA encourage the creation of one national prescription drug monitoring program (PDMP) database of controlled substances for physicians to detect and monitor prescription drug abuse;

That our AMA oppose requirements that physicians must consult prescription drug monitoring programs before prescribing medications; and

That a national PDMP not add undue burden onto patients who need chronic controlled substance treatments or the physicians who prescribe them.

During reference committee, testimony in support of this resolution highlighted that state-level PDMPs can provide helpful clinical information if the PDMP has reliable information. Several testified as to the need to share information across state lines. Some said that several neighboring states across the country were forming collaboratives and/or pilots with the intent to share such information. These were among the reasons the HOD referred this resolution.

This report reviews the current status of state-based PDMPs, considers the experience of mandates, and discusses the effects on patients with substance use disorders and pain management needs. The report recommends that existing AMA policy be reaffirmed and that new recommendations be adopted.

BACKGROUND

The US Centers for Disease Control and Prevention (CDC) reports that while deaths involving prescription opioids declined for the first time in a decade in 2012, they once again increased in 2013 and remain unacceptably high at more than 16,000 lives lost annually. At the same time, there has been a substantial increase in deaths from heroin, and factors may include individuals not being able to obtain prescription opioids, greater supply of heroin, and heroin being less expensive than prescription opioids. The CDC recently reported that 8,257 people died of heroin-related deaths in 2013 and prescription opioids. Total drug (illicit and prescription) overdose deaths in 2013 rose to 43,982, up 6 percent from 2012.

In response, many states have recently introduced legislation concerning, among other things, ways to enhance state PDMPs. At its core, a PDMP is an electronic database that collects certain information concerning controlled substances prescribed and dispensed. This might include a patient's name, the prescriber's name, the drug prescribed, the quantity, the dosage, whether the prescription was a refill, the method of payment, physician licensing information, and other information as required by state law. As of February 2015, every state and the District of Columbia had enacted legislation to authorize the creation and/or implementation of a PDMP–except Missouri, which was considering legislation at the time of this report's drafting.

CURRENT STATUS OF STATE-BASED EFFORTS ARGUES AGAINST A NATIONAL PDMP

Physicians in states with a modernized, easily accessible PDMP generally express support for using PDMPs when clinically appropriate and where feasible. Generally, PDMPs contain extensive information, including state licensing and other provider-specific data, prescription information, personal identifying information, and more. Most states house the PDMP within a Board of Pharmacy or other agency with a public health focus, but some states, such as California, house the PDMP within a law enforcement agency. Overall, varying levels of PDMP functionality exist, but the general sense is that PDMPs–if they contain relevant clinical data, are seamlessly integrated into a physician's workflow, and provide actionable information— can be useful clinical tools in helping identify potential signs of prescription drug abuse or misuse.

In addition to the different information collected by state PDMPs, there are differences in state laws governing the collection, use, and privacy of PDMP data including but not limited to differences in whether: (1) delegates (e.g., physician assistants, nurses, medical assistants) can access the data on behalf of the prescriber or dispenser; (2) physicians can receive unsolicited reports; and (3) the data must be checked by all prescribers – or whether exceptions might apply. In 2015, more than 115 separate pieces of state-based legislation concerning PDMPs have been proposed. Given the high level of interest and activity in the states, it is reasonable to conclude that states want to take action, they are taking action, and federal intervention via creation of a single, national PDMP seems premature at best.

Furthermore, many states have committed, after years of legislative debate, to authorize and/or modernize their PDMP as well as commit significant state funds. This includes California, the District of Columbia, Kentucky, New York, Ohio, Pennsylvania, Tennessee, and many other states. Anecdotal reports from other states also suggest that PDMPs can be highly useful clinical tools for certain specialties, including pain medicine. This is not to suggest that all physicians in these states fully support the PDMP as it currently exists, but rather that state-based efforts already have taken hold in a significant number of states. Thus, even if a single, national PDMP were feasible, the fact that almost all states already have adopted PDMPs—and are making the effort to upgrade them — arguably makes a single, national PDMP largely duplicative and unnecessary.

States also are taking efforts necessary to enable data sharing among state PDMPs. Thirty-four states, or more than two-thirds of the nation, now participate in the National Association of Boards of Pharmacy (NABP) InterConnect program. This program authorizes PDMP users in a state to view PDMP data in another state that participates in the program. This system proves highly useful in areas of the country where major cities are near borders, yet not all states are members. The Bureau of Justice Assistance (BJA) developed the other main technology platform to share information – the prescription monitoring information exchange (PMIX). The NABP and BJA are working to have the systems be mutually compliant. Current AMA policy supports this interstate sharing as long as there are appropriate privacy and other safeguards. (See Policy H-95.947, "Prescription Drug Monitoring to Prevent Abuse of Controlled Substances.")

DATA INCONCLUSIVE WHETHER PDMPS REDUCE PRESCRIPTION DRUG ABUSE, MISUSE, OVERDOSE OR DEATH

As noted above, states continue to advance legislation to authorize and modernize their PDMPs. The predominant state legislative issue surrounds whether a prescriber should be mandated to check the PDMP before prescribing controlled substances. Many states have made significant strides in developing PDMPs in concert with state and specialty society input. The AMA has supported the efforts of states to enact policies and implement solutions that focus on a voluntary, public health approach to using a PDMP. This is consistent with current AMA policy. (See Policy H-95.990, "Drug Abuse Related to Prescribing Practices," which says, in part, that the AMA "encourages physicians to query a state's controlled substances databases for information on their patients on controlled substances," and that the AMA "opposes any federal legislation that would require physicians to check a prescription drug monitoring program [PDMP] prior to prescribing controlled substances"). The AMA has testified before Congress and worked with the National Governors Association, National Conference of Insurance Legislators, and others in support of this approach.

Proponents of mandatory checks of PDMPs point to recent data, for example, in Kentucky, New York, Ohio, and Tennessee to suggest that mandating use of PDMPs reduces prescription drug abuse and diversion. For example, the PDMP Center of Excellence at Brandeis University⁸ makes the correlation between reductions of "multiple provider

episodes" (also referred to as "doctor shopping"), and decreases in amount of opioids prescribed with an increase in "medically warranted prescribing and dispensing." While the former can be objectively documented, the latter is largely subjective and does not have data to support the conclusion.

Data correlating a PDMP with objective measures of prescription drug abuse are elusive at best. The CDC has highlighted the great, regional variation in prescribing rates and mortality death rates. In its July 2014 publication, "Where You Live Makes a Difference," data were presented to show states with the highest rates of prescribing opioids and states with the lowest rates. Of the five states with the lowest rates of prescribing, only two, New York and Minnesota, mandate the use of a PDMP. Yet, consider that New York's law contains several exceptions for when a prescriber must check, and Minnesota only requires a check by the medical director (or his/her delegate) of a methadone clinic prior to prescribing a controlled substance. At the high end of prescribing rates, three states that continue to struggle with high death rates due to opioids all mandate a PDMP check are: Kentucky, Tennessee, and West Virginia. Similarly, the National Survey on Drug Use and Health shows that four of the top 10 states with the highest incidence of nonmedical use of prescription pain relievers have no mandate to check a PDMP, and of the other six, there are many exceptions to when a check must be performed.

There is preliminary research from New York, moreover, that expresses concern that the mandatory check required by New York's PDMP may be having an unintended effect of increasing that state's heroin problem. ¹³ This is due to prescribers discharging patients who have a questionable PDMP report, including discontinuing patients on long-term opioid therapy, or refusing to accept new patients if the PDMP report shows potentially aberrant behavior related to opioids. It is not clear what happens when a prescriber receives a PDMP report that indicates a patient may have received controlled substances from multiple providers or multiple pharmacies in a short time frame. Does the prescriber have the requisite clinical education and experience to effectively assess the patient for a potential substance use disorder? Does the prescriber have a referral network if the patient does present with a high risk for substance use disorder? Or does the prescriber, as in the case of the New York research, fire the patient? The data simply do not exist to say what is happening to the patients.

Moreover, the requirement for all physicians to check the PDMP glosses over the fact that physicians prescribe controlled substances in vastly different settings to vastly different patient populations. For example, a surgeon performing a relatively minor procedure may determine, based on the patient's history and complexity of the procedure, that a five-day prescription of an opioid is appropriate. Should that necessitate a PDMP check? Or the pediatrician who prescribes a controlled substance for attention deficit hyperactivity disorder? Should the pediatrician first check the PDMP? What about the emergency physician who prescribes a muscle relaxant to a patient who presents with muscle spasms? Or the hospice physician who wants to provide relief to his dying patient?

Some proponents of mandatory checks of a PDMP would answer affirmatively to all of the above questions. Their theory is that because the opioid crisis is so widespread, significant measures must be taken. To be clear, the AMA "encourages physicians to query a state's controlled substances databases for information on their patients on controlled substances." (See Policy H-95.990, "Drug Abuse Related to Prescribing Practices"). Yet, the AMA believes that the decision on when to consult a PDMP should remain with a physician, who is in the best position to determine what information he or she requires when determining a course of therapy, which may include opioids. The AMA also notes that physicians in many states, while acknowledging the potential benefits that a PDMP may have in providing clinical information, also indicate that PDMPs may not contain relevant clinical information, be integrated into a prescriber's workflow, or have other barriers that raise challenges to using the databases.

As such, the AMA believes that it is premature to support a mandated PDMP consultation for every clinical encounter. While some data positively suggest that physicians in selected states with mandatory PDMP consultations have changed their prescribing behavior, a more predominant viewpoint is that "attributing significant changes in total opioid prescribing or health outcomes to PDMPs [is] a challenge." Therefore, while there may be some promising opportunities for further research, it is premature to suggest that a proven model exists on which to support mandates on PDMP consultations for all physicians. Accordingly, the Board recommends reaffirming Policy H-95.990.

PDMPS AND PATIENTS WITH CHRONIC PAIN OR SUBSTANCE USE DISORDER

While the bulk of current PDMP policy debates focus on monitoring patient and prescriber prescribing patterns, there is little activity surrounding how PDMPs might help physicians enhance overdose prevention and treatment

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efforts as well as ensuring care for patients with pain. As noted above, one of the most common statewide findings of the effects of PDMPs is a reduction in doctor- or pharmacy-shopping. Yet, it is not clear what happens to the patient in those situations; whether the patient's care is uncoordinated; whether the patient needs treatment; or whether the patient simply is seeking out controlled substances for illegal purposes.

An Oklahoma survey of PDMP users found that 21 percent of prescribers made a patient referral for treatment, including a mental health professional; and that 64 percent of PDMP users referred a patient to a pain management specialist. ¹⁵ (Note: Oklahoma's new mandate does not go into effect until Nov. 1, 2015.) Other data exist suggesting that when a PDMP report provides reliable, relevant data, physicians generally prescribe fewer opioid analgesics and can more easily identify potentially harmful drug interactions. Data from multiple sources suggest that PDMP information has the potential to alter a physician's prescribing habits. ¹⁶

It is beyond the scope of this report to detail how a PDMP can be useful for physicians and other prescribers who provide treatment for substance use disorder as well as for chronic or any other type of pain. The key for this report is to underscore that a PDMP not add undue burdens onto patients who need chronic controlled substance treatments or the physicians who prescribe them. Furthermore, a PDMP should be able to aid physicians in helping recognize signs of abuse and provide the data and other information necessary to support appropriate referral and/or treatment. This is in line with AMA policy that PDMPs be used as a public health tool. (See, generally, Policy H-95.945, "Prescription Drug Diversion, Misuse and Addiction"; Policy H-95.946, "Prescription Drug Monitoring Program Confidentiality"; Policy H-95.947, "Prescription Drug Monitoring to Prevent Abuse of Controlled Substances"; and Policy H-95.990, "Drug Abuse Related to Prescribing Practices.")

RECOMMENDATIONS

The Board recommends that the following be adopted in lieu of Resolution 230-A-14, and that the remainder of the report be filed.

- That our AMA reaffirm Policy H-95.945, "Prescription Drug Diversion, Misuse and Addiction," Policy H-95.946, "Prescription Drug Monitoring Program Confidentiality," Policy H-95.947, "Prescription Drug Monitoring to Prevent Abuse of Controlled Substances," and Policy H-95.990, "Drug Abuse Related to Prescribing Practices."
- 2. That our AMA support the voluntary use of state-based prescription drug monitoring programs (PDMP) when clinically appropriate;
- 3. That our AMA encourage states to implement modernized PDMPs that are seamlessly integrated into the physician's normal workflow, and provide clinically relevant, reliable information at the point of care;
- 4. That our AMA support the ability of physicians to designate a delegate to perform a check of the PDMP, where allowed by state law;
- 5. That our AMA encourage states to foster increased PDMP use through a seamless registration process;
- 6. That our AMA encourage all states to determine how to use a PDMP to enhance treatment for substance use disorder and pain management;
- 7. That our AMA encourage states to share access to PDMP data across state lines, within the safeguards applicable to protected health information; and
- 8. That our AMA encourage state PDMPs to adopt uniform data standards to facilitate the sharing of information across state lines.

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13. METHODS TO INCREASE THE US ORGAN DONOR POOL (RESOLUTION 001-A-14)

Reference committee hearing: see report of <u>Reference Committee on Amendments to Constitution and Bylaws</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED

IN LIEU OF RESOLUTION 1-A-14 AND REMAINDER OF REPORT FILED

See Policy H-370.959

At the 2014 Annual Meeting, the American Medical Association (AMA) House of Delegates referred to the Board of Trustees Resolution 001-A-14, "Opt-Out Organ Donation," which was introduced by the Medical Student Section, Resolution 001-A-14 asked:

That our American Medical Association study potential models for increasing the United States organ donor pool.

BACKGROUND

The most significant obstacle facing organ transplantation in the United States is the shortage of transplantable organs compared to the number of patients who need them. This disparity is due to the increasing need for organs

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versus insufficient donor rate [1]. Organ donation in the United States is voluntary, in which individuals "opt in" by documenting before death their desire to donate organs. When the patient's preferences are not documented or known, the next of kin may decide to allow organs to be harvested for transplantation.

However, opt in is only one model for organ donation. Other models include mandated choice and presumed consent for donation of cadaver organs as well as novel models for living donation, such as kidney registries.

CURRENT AMA POLICY

Several policies of the AMA House of Delegates seek to encourage voluntary organ donation:

- H-370.996, "Organ Donor Recruitment," urges Americans to sign donor cards, encourages state governments to undertake pilot studies on stimulating adults to sign donor cards, and supports the exploration of methods to greatly increase organ donation [2].
- H-370.998, "Organ Donation and Honoring Donor Wishes," similarly urges citizens to sign donor cards and supports continued efforts to educate the public on organ donation [3].
- H-370.995 "Organ Donor Recruitment" supports the development of "state of the art" educational materials for both the medical community and the public at large about the need for organ donors and various aspects of organ recruitment [4].

Additional policies address specific concerns with respect to organ donation:

- H-370.964, "Surrogate Consent for Living Organ Donation," opposes surrogate consent for living organ donation from patients in a persistent vegetative state [5].
- E-2.151, "Cadaveric Organ Donation: Encouraging the Study of Motivation," urges physicians to support innovative approaches to encourage organ donation and outlines key considerations for ethical study of the use of financial incentives for donation [6].
- E-2.155 "Presumed Consent and Mandated Choice for Organs from Deceased Donors," describes the ethical challenges of presumed consent and mandated choice models and emphasizes the need for education about organ donation [7].

ALTERNATIVES TO VOLUNTARY, ALTRUISTIC ORGAN DONATION

All models for organ donation seek to balance the rights and well-being of prospective donors (and their families) with the benefits of increasing the supply of transplantable organs; different models have struck that balance differently. Questions about the role—and quality—of informed consent have been central.

Mandated choice models for donation require individuals "to express their preferences regarding organ donation at the time of performing a state-regulated task," [7] for example, getting a driver's license. In this model, individuals are asked to decide whether to opt in or opt out of being a donor [8]. To be ethically appropriate, mandated choice requires that the individual be well informed and base the decision whether to become an organ donor on a "meaningful exchange of information" [7]. It also requires that organ retrieval take place only after physicians have verified that the individual's consent to donate was documented.

Presumed consent models, in contrast, *presume* that deceased individuals are organ donors unless they have explicitly refused to donate. In this model, organs could ethically be retrieved "only if it could be determined that individuals were well aware of the presumption" [7]. To be ethically appropriate, presumed consent further requires that there be effective, readily accessible mechanisms for documenting and honoring refusals.

Incentivized choice models offer defined incentives, such as monetary payments or health services, in exchange for an individual's consent to donate.

To be ethically supportable, alternatives to voluntary, altruistic donation must be able to demonstrate that they have a positive effect on donation. Absent such evidence, alternative models should not be widely implemented [6,7].

EFFECTIVENESS OF ALTERNATIVE MODELS

There is limited empirical evidence about the effectiveness of different models for increasing the number of organs available for transplant, and that evidence is mixed.

In the United States, Texas and Virginia experimented unsuccessfully with mandated choice programs. In 1991, Texas implemented a mandated choice program that required individuals to indicate their preference with respect to organ donation when receiving a driver's license. The program was repealed in 1997, having had a negative overall effect, with the number of individuals *declining* to donate rising to 80 percent [9]. Virginia's program, inaugurated in 1989 had similar results. Where Texas offered only a "yes" or "no" option, the Virginia program also allowed individuals to choose "undecided"; "undecided" responses were then categorized with "no" responses [9]. In both states, those who declined to donate were placed on the state's "non-donor" list.

In 2006, Illinois implemented its legally binding First-Person Consent Act (FPCA) requiring "all citizens over age eighteen to inform the state, when acquiring or renewing their driver's licenses, whether they consent to being an organ donor after death" [9]. Unlike Texas and Virginia, Illinois does not place individuals who decline to donate on a non-donor list, which allows for next of kin to permit organ donation at the time of death. (Next of kin may not override an individual's prior decision to donate.) Since 2006, the number of individuals who choose to donate has risen to 60 percent [9]. However, it is not clear whether the increase can be attributed to the mandated choice model as such or whether other factors have also played a role.

Studies regarding the efficacy of presumed consent have been conducted in countries outside of the United States. In general, these studies have produced conflicting evidence regarding the effectiveness of presumed consent in increasing organ donation. In 2010, Chile replaced its voluntary consent system with a presumed consent model. Based on a review of data from January 2000 to December 2011, the presumed consent program not only did not have a positive effect, but rather had a damaging effect on organ donation [10].

In Singapore, two studies have found that the presumed consent Human Organ Transplant Act (HOTA) of 1987 has resulted in a greater number of potential donors, but has not yielded the expected increase in the number of transplantable organs available [11,12]. However, this could be in part because potential donors in that country are identified only from brain death, whereas in the United States potential donors may be identified from brain death or cardiac death. The specifics of how donors are identified therefore important and should not be underemphasized in evaluating models for organ donation.

An analysis of data from 27 countries within the European Union from 2000-2010 suggests that those with presumed consent models had higher cadaveric donation and kidney transplant rates, once other variables were accounted for [13]. A similar study looking at 22 countries over ten years concluded that "When other determinants of donation rates are accounted for, presumed consent countries have roughly 25%–30% higher donation rates than informed consent countries" [14]. However, critics of these studies argue that the statistics produced by cross-country studies are biased or cannot be generalized. The authors of the study last mentioned above state themselves that "Additional research is necessary for practical application of findings. Generalizing these findings beyond Europe may be problematic because of external validity constraints" [15].

In order for any model to be ethically sound, there must be demonstrated effective informed consent, which would require a "meaningful exchange of information" [7]. It must also be clear that individuals were aware of the donation model, for example, that a presumed consent system was in effect. None of the published studies found to date have examined the success of efforts to inform the public of the chosen donation system, or have analyzed the effectiveness of informed consent procedures. An analysis of these essential parts of the system is necessary before any new method can be implemented.

OTHER WAYS TO ENHANCE ORGAN TRANSPLANTATION

The goal of efforts to increase the donor pool is ultimately to match more organs with individuals on transplant waiting lists. Increasing the number of potential donors by means of different consent models is not the only way to achieve that. Expanding criteria for who may become a donor [16] and improving the efficiency of organ retrieval and transplantation are important as well [17,18].

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The use of "extended criteria donors," that is, use of organs from donors who fail to meet previously established criteria offers some promise of reducing the number of patients awaiting transplant without undue risk. For example, in 2014, the Canadian Society of Transplantation, in coordination with the Canadian National Transplant Research Program published guidelines for the use of "increased infectious risk donors," based on available data about risks and outcomes for transplant recipients [19]. As the CST/CNTRP observed, transplantation involving increased risk donors carries implications for informed consent on the part of transplant recipients and the need for post-transplant screening.

In the United States, a 2006 study from the University of Indiana School of Medicine found that outcomes for liver grafts from extended criteria donors were "comparable to those for [standard donors] without resorting to living donor liver transplantation" [20]. In December 2014, new kidney allocation criteria from the Organ Procurement and Transplantation Network went into effect [21]. The changes affect both clinical criteria for matching and the operations of the national allocation system.

CONCLUSION

Evidence is inconclusive with respect to the effectiveness of alternative consent models for organ donation. At the same time, other avenues show promise for increasing the availability of organs and tissues for transplantation and reducing candidates' time on waiting lists.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendation be adopted in lieu of Resolution 001-A-14 and the remainder of this report be filed:

In order to encourage increased levels of organ donation in the United States, our American Medical Association: (1) supports studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation; (2) urges development of effective methods for meaningful exchange of information to educate the public and support well-informed consent about donating organs; and (3) encourages continued study of ways to enhance the allocation of donated organs and tissues.

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14. RISK EVALUATION AND MITIGATION STRATEGIES FOR METHADONE (RESOLUTION 512-A-14)

Reference committee hearing: see report of <u>Reference Committee E.</u>

HOUSE ACTION: RECOMMENDATION ADOPTED

IN LIEU OF RESOLUTION 512-A-14 AND REMAINDER OF REPORT FILED

See Policy D-120.985

Resolution 512-A-14, "Risk Evaluation and Mitigation Strategies (REMS) for Methadone," introduced by the American Academy of Pain Medicine and referred by the House of Delegates, asked:

That our American Medical Association urge the US Food and Drug Administration to require an "individual" Risk Evaluation and Mitigation Strategy (REMS) for the clinical use of methadone in pain management.

That our AMA advocate that the manufacturer deemed responsible for developing a methadone-specific REMS consult experts in pain medicine in designing the program.

This report provides a brief historical perspective on the risk evaluation and mitigation strategy (REMS) for extended release and long-acting opioids, and evaluates whether an individual REMS for methadone is advisable.

RISK EVALUATION AND MITIGATION STRATEGIES

With the passage of the 2007 Food and Drug Administration (FDA) Amendments, the FDA was granted new authorities to mandate post-marketing studies for drugs, require changes in prescription drug labeling, and establish REMS for certain new drugs and biologics as well as already marketed products if new safety information becomes available. A REMS can include a communication plan for health care practitioners and elements to assure safe use. As designed, REMS also include an implementation system, a sponsor's plan to assess the performance of the REMS, and a timetable for assessment. Manufacturers are accountable for development of the REMS program, certification and education of physicians, collection of performance and outcomes data, and surveillance/assessment of program effectiveness.

REMS for Extended-Release and Long-Acting Opioid Medications

In July 2012, FDA approved a REMS for extended release (ER) and long-acting (LA) opioid medications. ER/LA opioids include all opioid products that are long acting by virtue of an extended release oral formulation, transdermal fentanyl products, and methadone, which is long-acting based on its disposition kinetics.²

Approximately 320,000 prescribers registered with the Drug Enforcement Administration at the time the opioid REMS was announced had written at least one prescription for these drugs in the previous year.

The ER/LA opioid REMS is part of a broader federal multi-agency effort to address the misuse and abuse of prescription opioids. This program was created with the intention of reducing risks and improving the safe use of ER/LA opioids, while preserving access to these medications for patients suffering from pain.

The opioid REMS affected more than 20 companies that are required to make voluntary education programs available to prescribers based on an FDA blueprint and delivered via certified continuing medical education providers.³ The blueprint contains general as well as specific drug information, key messages and information on weighing the risks and benefits of opioid therapy, choosing patients appropriately, managing and monitoring patients, counseling patients on the safe use of ER/LA opioids, and evaluating the potential for, and monitor the signals of, opioid misuse, abuse and addiction. Other components of the opioid REMS are an updated medication guide and patient counseling document. The counseling document provides information on safe use, storage and disposal of ER/LA opioid products, signs of potential overdose and emergency contact advice, and instructions for patients to contact their prescriber before changing doses.

Labeling Changes for ER/LA Opioids

New safety measures for the clinical use of ER/LA opioids were announced by the FDA in September 2013 including safety-related labeling changes and post market requirements. These changes became effective in April 2014 with FDA approval of a class labeling supplement for ER/LA opioid analgesics. Such drugs are now indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Because of the risks of addiction, abuse, and misuse with ER/LA opioids, and the greater risks of overdose and death with such products, their use should be reserved for patients for whom alternative treatment options are ineffective, not tolerated, or would otherwise be inadequate to provide sufficient management of pain. ER/LA opioids are not indicated as an as-needed (prn) analgesic. Additionally, companies were directed to conduct several new post-marketing studies designed to: (1) gain better information on the risks of misuse, abuse, overdose, addiction, and death associated with long term use of opioid analgesics for persistent pain; (2) validate coded medical terminologies used to identify certain opioid-related adverse events; (3) define and validate "doctor/pharmacy shopping" as outcomes suggestive of misuse, abuse and/or addiction; and, (4) estimate the risk for developing hyperalgesia following use of ER/LA opioid analgesics for at least one year to treat persistent pain.

Clinicians can consult the FDA supplemental document or the product labeling of specific ER/LA products for further information on: (1) dosage and administration; (2) rotation from other oral opioid products; (3) warnings and precautions, including the risk of addiction, abuse, and misuse and the potential for life-threatening respiratory depression; and (4) recommendations for patient counseling.

METHADONE

Methadone is a long-acting opioid analgesic based on its pharmacokinetic properties, including a highly variable elimination half-life ranging from 8-59 hours (or longer based on some studies); dosage adjustments must be done cautiously using a minimum 1 to 2 day interval. Methadone is primarily metabolized in the liver to inactive metabolites. Various cytochrome P450 (CYP450) enzymes, primarily CYP3A4, CYP2B6, and CYP2C19 and to a lesser extent CYP2C9 and CYP2D6, are responsible for conversion of methadone to inactive metabolites, which are excreted mainly in the urine. Many of these CYP450s are subject to pharmacogenetic variation, introducing another variable into the individual disposition of methadone. Pharmacokinetic drug-drug interactions with methadone also are complex, with some CYP450 inducers decreasing methadone levels, and some CYP450 inhibitors increasing methadone levels. Methadone is a basic compound and the pH of the urinary tract also can alter its disposition. Also, since methadone is lipophilic, it may accumulate and persist in body tissues. Slow release from the liver and other tissues may prolong the duration of methadone action.

The analgesic properties of methadone are shorter than its elimination half-life would predict. Additionally, peak respiratory depression occurs later and persists longer than the analgesic effect; benzodiazepines may increase respiratory depression. Methadone also has the potential to cause QTc prolongation and torsade de pointe. When used for pain management, methadone must be administered in divided doses.

Methadone also has some unique pharmacodynamic properties; in addition to activating the opioid *mu* receptor, methadone may act as an antagonist at the N-methyl-D-aspartate (NMDA) receptor. The contribution of NMDA receptor antagonism to methadone's efficacy is unknown. Converting patients from another opioid analgesic to methadone using equianalgesic tables is difficult to predict; prescribers should consult the product labeling for methadone for specific advice on this practice. Only clinicians who are familiar with the unique properties of methadone should use it for pain management or palliative care.

Should an Individual REMS for Methadone be Created?

Methadone has been safely used to treat heroin and opioid addiction for decades. However, from 1999-2009, deaths from methadone overdoses increased 6-fold, peaking in 2007 and then slowly decreasing. It is the most common single opioid associated with overdose deaths. During this time period, methadone's low acquisition cost and status as a preferred drug in state Medicaid programs prompted an increasing pattern of use for pain management in Medicaid populations and in palliative care. Although the number of prescriptions increased, the number of unintentional overdoses and fatalities attributed to methadone exceed its prescribing rate in a disproportionate manner. The majority of such deaths were attributable to the use of methadone for pain management and methadone diverted and/or used for a nonmedical purpose, and not in patients receiving methadone as part of medication-assisted therapy in opioid treatment programs.

In recognition of methadone's potential for harm, the FDA revised the product labeling to encourage more cautious dosing, including a black box warning in 2006, and the Drug Enforcement Administration directed manufacturers to limit supply of higher dosage forms (40 mg) to opioid treatment programs and hospitals. A voluntary state-based initiative in Utah, the Prescription Pain Medication Program, was successful in reducing unintentional methadone overdoses and deaths between 2007 and 2010.⁸ The American Academy of Pain Medicine adopted a policy statement in 2013 opposing the use of methadone as a preferred analgesic, a policy position also endorsed by the AMA (Policy H-120.937).⁹

DISCUSSION

Risks are associated with the use of all opioid analgesics, especially ER/LA opioid products, and particularly with methadone because of substantial variability in patient disposition, respiratory depressant effects which persist longer than the analgesic effects, the potential for cardiac rhythm disturbances and multiple drug-drug interactions. Methadone does have certain unique attributes and is a viable alternative for pain management in patients who have not responded to other opioid analgesics.

Methadone is already included in the current ER/LA opioid REMS. Only two generic manufacturers are supplying the dosage forms of methadone indicated for pain management. The cost of any decision by the FDA to require a specific REMS for methadone would have to be borne by these manufacturers, who are already participating in the ER/LA opioid REMS. A requirement to create a singular REMS for methadone could lead to a decision to discontinue the production and marketing of methadone given the very low acquisition cost of this drug. Rather than require the development of an entirely new program, it is reasonable to wait and evaluate the success of the current ER/LA opioid REMS as it pertains to methadone. In the meantime, it is appropriate to focus on the training and education of prescribers, and foster the view that an individualized approach to prescribing and a need for close monitoring exists whenever methadone is used for pain management.

RECOMMENDATION

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

That Policy D-120.985, "Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone," be reaffirmed in lieu of Resolution 512-A-14.

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15. OVER THE COUNTER (OTC) INSULIN (RESOLUTION 507-A-14)

Reference committee hearing: see report of <u>Reference Committee B</u>.

HOUSE ACTION: RECOMMENDATION ADOPTED

 $(RESOLUTION\,507\text{-A-14 NOT ADOPTED})\,AND$

REMAINDER OF REPORT FILED

Resolution 507-A-14, "Over the Counter (OTC) Insulin," introduced by the Indiana Delegation and referred by the House of Delegates, asks:

That our American Medical Association seek federal regulation or legislation requiring insulin be available by prescription and to encourage individual states to seek regulations or legislation requiring prescriptions for insulin.

Concerns raised in the preamble to Resolution 507-A-14 include the availability of insulin and insulin syringes without a prescription, the need for medical supervision of patients with diabetes mellitus, the possibility that commercial truck drivers and pilots with diabetes may self-treat and falsify applications for certification, and the potential for over-the-counter (OTC) availability of syringes to fuel illicit drug use.

REGULATION OF INSULIN PRODUCTS

In the United States, the US Food and Drug Administration (FDA) has authority to approve drugs before they are marketed. The United States uses a two-class drug system—prescription and nonprescription—established by the 1951 Durham-Humphrey Amendments to the Federal Food, Drug, and Cosmetic Act.¹ Prescription drugs can be dispensed only with written or oral orders (i.e., a prescription) from a licensed prescriber—such as a doctor, nurse practitioner, or physician's assistant—to a pharmacist or other licensed dispenser, while nonprescription drugs do not require a prescription. When the current two-class drug system was codified, medications that required administration by injection (or that were sufficiently toxic that patients could not self-treat), were made prescription-only, except for insulin. Legislators apparently wanted to ensure that patients requiring insulin would have easy access to this necessary, life-saving medication, in part because patients with insulin-dependent diabetes had an enduring condition for life.

Although most nonprescription drugs in the United States are publicly available without any restrictions, insulins that are available OTC in the United States are stored behind the counter due to refrigeration requirements; other products also may be restricted to pharmacy sale in order to monitor quantity of purchase (e.g., pseudoephedrine), or to monitor consumer age (e.g., levonorgestrel). According to the Orange Book, insulin products that can be sold OTC in the United States include human recombinant formulations of regular insulin, isophane insulin suspension (also referred to as NPH), and a 30/70 combination of the two.² Although these insulin products are available OTC, insurance plans may require a prescription for reimbursement purposes. According to information derived from the IMS Health *Xponent* database, prescriptions for these formulations comprise approximately 15% of the market for

insulin products (Robert Hunkler, personal communication, March 3, 2015). All other newer modified-release insulin formulations require a prescription.

DIABETES MELLITUS AND COMMERCIAL MOTOR VEHICLES

The Council on Science and Pubic Health previously examined the issue of commercial transportation drivers with diabetes mellitus.³ Insulin-treated patients with diabetes are prohibited from driving commercial motor vehicles in interstate commerce, but can apply for a medical exemption (49 CFR 391.41).³ The current standard for such individuals was established in 1970, based on studies revealing that diabetic drivers experienced a higher rate of accidents. The standards do not distinguish between insulin-dependent (type 1) and noninsulin dependent (type 2) subjects with diabetes mellitus who take insulin to control blood glucose concentrations. For 2015, 66 drivers met the exemption qualifications and were granted waivers.⁴ Therefore, it seems clear that it is in the best interests of such drivers to seek medical exemptions. Those who would attempt to hide a diabetic condition via self-treatment would be exposed to substantially increased liability. No data are available to support the premise that individuals with diabetes who are being treated with insulin are attempting to falsify applications in order to acquire commercial driving licenses.

PILOTS

A history of diabetes mellitus requiring hypoglycemic medication is a disqualifying condition for a pilot's license in the United States.⁵ Exemption protocols differ depending on whether the applicant is insulin-dependent or not. Insulin-dependent individuals are limited to a 3rd class certificate which covers students, recreational, and private pilots.⁶ No data are available indicating prospective pilots are falsifying medical records in an attempt to garner a commercial pilot certificate.

SYRINGES

Access to syringes needed for injecting insulin and other prescription drugs is regulated by state law. Such regulations vary but generally fall under three categories: (1) syringe laws and regulations; (2) pharmacy regulation/miscellaneous statutes that impose various restrictions on the sale of syringes by pharmacists or others; and (3) drug paraphernalia laws prohibiting the sale or possession of items intended for the administration of illegal drugs. In many states and localities, laws that prohibited acquiring or possessing syringes without a prescription have been repealed or amended over the years to allow syringe/needle exchange programs to operate and/or provide pharmacists the authority to sell syringes over-the-counter.

Accordingly, the vast majority of states (46 out of 50) currently do not require a prescription in order to purchase needles and syringes. Quantities over a certain limit trigger a prescription requirement in some states, and some also exempt diabetic patients from prescription requirements. However, as a business practice, some pharmacies may not sell syringes/needles without a prescription; and those that do so may be geographically dispersed. In some states or counties, only small quantities are allowed to be sold at one time, or the pharmacist must have personal knowledge of the buyer or otherwise exercise discretion in syringe sale decisions. A counter prevailing factor is that some states retain drug paraphernalia laws that make it illegal for injection drug users to possess syringes. These circumstances and concerns about deception, disease transmission and improperly discarded syringes have led to wide variations in syringe sales by individual pharmacists and the possibility of "discrimination based on sex, age, race, ethnicity, or socioeconomic status."

Injection Drug Use and Infectious Disease

In response to the public health imperative of reducing the spread of human immunodeficiency virus (HIV) and hepatitis C infection, syringe and needle exchange programs were developed for injection drug users. Syringe exchange programs provide free sterile syringes and collect used syringes from injection drug users. A substantial body of evidence supports the view that such exchange programs reduce transmission of bloodborne pathogens, including human immunodeficiency virus, hepatitis B virus and hepatitis C virus, without either encouraging drug use or increasing drug related crime. ¹²⁻¹⁴ Sterile needle and syringe access may include needle and syringe exchange, or the legal, accessible, and economical sale of needles and syringes through pharmacies, voucher schemes, and physician prescription programs. Many syringe exchange programs also offer preventive health and clinical services, screenings, and referral to treatment for substance use disorders. Such findings support the view that syringe

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prescription and drug paraphernalia laws should be modified to allow injection drug users to purchase, possess, and exchange sterile syringes, a view consistent with AMA policy. 11

DISCUSSION

Resolution 507-A-14 raises several concerns based on the fact that some older insulin products and equipment needed to administer these products (i.e., syringes/needles) are available without a prescription in most states. Overthe-counter availability may be an important factor for patient access to certain older insulin preparations. It is unknown how making these formulations prescription only would affect patient access and costs. In the absence of data indicating that this practice creates an individual or public health hazard, support is lacking for this type of mandate.

Linked with the OTC availability of insulin is the OTC availability of syringes and needles.

However, nonprescription pharmacy sales of syringes are also intricately linked with efforts to reduce the spread of bloodborne pathogens among injection drug users. In states and cities that permit syringe acquisition and possession without a prescription, pharmacies are a major source of sterile syringes for local injectors. Available evidence suggests that access to clean needles and syringes has been an important determinant in the substantial decrease in HIV transmission (and other bloodborne pathogens) among injection drug users over the last 25 years.

RECOMMENDATION

The Board of Trustees recommends that Resolution 507-A-14 not be adopted and the remainder of the report be filed.

REFERENCES

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16. PROGRESS REPORT FOR THE PRIVATE PRACTICE OF MEDICINE

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

Policy D-405.988, The Preservation of the Private Practice of Medicine, asks that our American Medical Association (AMA):

- Create, maintain and make accessible to medical students, residents and fellows, and physicians, resources to
 enhance satisfaction and practice sustainability for physicians in private practice, with a progress report at the
 2015 Annual Meeting.
- Create and maintain a reference document establishing principles for entering into and sustaining a private practice, and encourage medical schools and residency programs to present physicians in training with information regarding private practice as a viable option.

The AMA has invested considerable resources to define a pathway and, through educational means and several tangible resources and tools, assist practicing physicians in creating professional satisfaction in sustainable practices. Tools currently accessible to medical students, residents and fellows, and physicians include the *Introduction to the Practice of Medicine (IPM), STEPS Forward*TM, and *Succeeding from Medical School to Practice*.

While the STEPS ForwardTM product specifically targets the physician currently in private practice, the IPM program and the Succeeding from Medical School to Practice program are specifically designed for medical students, residents, fellows and young physicians and include several private practice modules. Through the IPM program the AMA works with 96 residency programs/institutions to promote private practice as a viable option through educational training. The Succeeding from Medical School to Practice program was specifically designed for medical students, residents, fellows and young physicians. STEPS ForwardTM is a new and evolving program in 2015. Both the IPM program and the Succeeding from Medical School to Practice are in a process of strategic review and revision to increase their overall functionality, relevance and appeal for their target audience. This review will continue through 2015.

These continuously evolving tools are online educational interfaces with some providing educational credit for practice-based learning. The AMA is constantly adding new content and new functionality to support private practice sustainability with these programs.

Finally, the AMA is currently reorganizing and repositioning its current resources to reflect support for all modes of practice including private practice. This work will include the release of a product that lists the advantages and disadvantages of each practice mode and highlights AMA products and offerings which support each. This product and associated reference documents, which will include *principles for entering into and sustaining a private practice*, will be launched and released by the end of 2015.

CURRENT AND EVOLVING AMA PRIVATE PRACTICE PROGRAMS

Introduction to the Practice of Medicine (IPM)

IPM is an interactive, web-based and tablet-compatible educational series that helps residents and their institutions meet the competencies of the Accreditation Council for Graduate Medical Education. IPM is a collaboration between AMA, The Ohio State University Medical Center, and Ohio State Medical Association. Currently, there are more than 30 modules in the IPM library including such topics as Choosing the Practice that's Right for You, Financing a Practice Start-Up and others. Each module includes a formal lecture or interactive lesson, post-assessment and evaluation and offers a certificate of completion. In 2014, IPM learners successfully completed 49,731 modules. Courses with practice focused topics such as Choosing the Practice That's Right for You, and Financing and Practice Start Up were taken by 900, and 500 medical residents respectively in 2014.

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Approximately 96 residency programs/institutions and 19,800 residents participate in the IPM program.

Some prominent subscribers include:

- The Ohio State University Medical Center
- Yale New Haven Hospital/Yale School of Medicine
- David Geffen School of Medicine at UCLA
- Medical College of Wisconsin
- University of California San Diego Health Systems
- Indiana University

There are also subscribers from small, community-based programs such as:

- Carolinas Medical Center–Family Medicine
- Ellis Hospital
- Long Beach Memorial Hospital
- Providence St. Peter Hospital
- Multicare Health System, East Pierce Family Medicine
- York Hospital-Wellspan Health

The AMA plans to continue to offer *IPM* to sponsoring residency institutions and is actively seeking to expand the program's audience of resident and fellow physicians. The *IPM* library continues to be supplemented with current, engaging content on topics that will aid young physicians as they transition into practice (especially private practice).

STEPS ForwardTM

Goals of the AMA's Physician Satisfaction and Practice Sustainability focus area include creating tools to enable physicians to adopt proven health care delivery strategies that fit with their specific practice setting, including private practice.

In October 2014, AMA launched STEPS ForwardTM, an interactive online learning platform for physicians and their care teams. The educational content—referred to as the Practice Transformation Series—offers innovative strategies and interventions to help practices:

- Reduce or eliminate barriers to providing quality care;
- Help physicians reach their highest aspirations of becoming a "good doctor" (e.g., preserving time for a meaningful physician-patient relationship); and
- Strengthen the power of teamwork in the practice.

The STEPS ForwardTM platform is not just a repository of educational content. The website provides a list of live events that learners can attend. It also offers implementation support to practices that need help executing the strategies presented in each module.

During four months of beta testing, the website has been accessed by hundreds of users. Ninety percent of respondents rated the content as relevant to their practice, and 97 percent indicated that they will continue to engage with the learning opportunities offered via the website.

The full launch for the website, www.stepsforward.com, is scheduled for June 2015. At this time, the site will have significantly enhanced content and functionality with at least 12 new modules added. A module titled *Succeeding in Private Practice* is currently in development which will specifically address principles for *entering into and sustaining a private practice*. This module is planned to be released in late 2015. The AMA will continue to develop relevant content and enhancements to this growing tool to assist physicians in practice sustainability.

Succeeding from Medical School to Practice

This comprehensive, easy-to-navigate resource includes a wealth of valuable information as well as streaming video to help medical students, residents, fellows and young physicians confront the nonclinical demands of training and

today's practice environment. Developed by AMA physician members, this guide offers physicians the tools needed to succeed at every stage of their career. Topics are divided into the two sections below.

Medical school and residency, contains information on topics such as:

- Board certification process and requirements
- Personal financial management

Preparing for practice, contains information on topics such as:

- Assessing practice options
- Medical practice valuation
- Medical professional liability insurance

AMA continues to add and update content to *Succeeding from Medical School to Practice* in order to maintain relevancy for physicians to use throughout their professional journey. This resource also presents physicians in training with tangible tools regarding private practice.

MEDICAL SCHOOL AND RESIDENCY PROGRAM COMMUNICATION

The February 2015 issue of AMA MedEd Update included an article with advice for resident/fellow physicians considering their practice options. AMA MedEd Update is a monthly email newsletter that is distributed to nearly 30,000 individuals, including medical school faculty and administrators and residency program directors. The article, "Things to consider before you choose a practice setting," profiled five different potential options: solo practice, group practice, hospitalist practice, academic medical practice, and employment (within a managed care organization, hospital-based specialty, corporate health department, public service or similar setting). The article is available online at ama-assn.org/ama/pub/ama-wire/ama-wire/post/things-consider-before-choose-practice-setting.

SUMMARY

Across the organization, the AMA is continuously developing and expanding educational resources and tools to assist practicing physicians to increase their professional satisfaction in sustainable private practices. As *IPM*, *STEPS Forward*TM, and *Succeeding from Medical School to Practice* grow, the AMA will continue to encourage young physicians to consider private practice as a viable option and to assist currently practicing physicians in attaining greater satisfaction and sustainability in their practices. News and updates on these activities will be disseminated through the appropriate AMA communications media, including *AMA MedEd Update*.

17. INCREASING PHYSICIAN EFFICIENCY (RESOLUTION 717-A-14)

Reference committee hearing: see report of <u>Reference Committee G</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED

IN LIEU OF RESOLUTION 717-A-14 AND REMAINDER OF REPORT FILED

See Policies H-480.971, D-478.976 and D-478.995

INTRODUCTION

At the 2014 Annual Meeting, the House of Delegates (HOD) referred Resolution 717-A-14, "Increasing Physician Efficiency," which was introduced by the Illinois Delegation. The resolution asked that our American Medical Association (AMA) adopt policy encouraging the integration of dictation systems into present and all future electronic health records (EHRs) and encourage the business and technical communities to integrate dictation systems into present and all future EHRs.

BACKGROUND

Since the inception of the meaningful use (MU) program in 2009, adoption and use of EHRs by eligible professionals and eligible hospitals has risen dramatically. Unfortunately, so has the level of dissatisfaction with the usability of this technology.

The AMA-sponsored RAND study, "Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems and Health Policy," highlights the many challenges that physicians face today in delivering high-quality patient care, including the use of cumbersome EHRs. The report, a qualitative and quantitative study of physician practices from six states in 2013, identified a number of issues related to EHRs. Physicians noted that EHRs had the potential to improve some aspects of patient care and professional satisfaction. However, for many physicians, current EHR functionalities have led to professional dissatisfaction. Issues that many EHRs have today include "poor usability, time-consuming data entry, and interference with face-to-face patient care, regulatory requirements, insufficient health information exchange and degradation of clinical documentation quality." The AMA-RAND study was followed by the 2014 AMA publication "Improving Care: Priorities to Improve EHR Usability," developed in conjunction with an expert advisory panel that identified eight priorities to improve overall usability of EHRs in an effort to improve patient care and physician efficiency while strengthening the patient-physician relationship. These priorities are informing the AMA's efforts to engage EHR vendors, other health IT developers, physicians and policymakers to improve overall EHR usability.

The focus of much of the dissatisfaction with clinical documentation quality is the so-called note bloat that results from the use of both structured data entry forms and copy and paste edits in which key findings and actions can often be obscured, making the patient narrative difficult and time consuming to read.²

Some have suggested that the solution to this problem is a return to the use of dictation, which was widely utilized before the emergence of the EHR and the MU program. However, as technology has evolved so have dictation strategies. Today, the following four EHR documentation modalities are recognized:³

- Manually driven—Physicians point and click in templates/structured forms and/or type to enter patient information (this is referred to as team documentation, also known as scribing);
- Traditional dictation—Notes are dictated by phone or recording device and transcribed by a medical transcriptionist;
- Speech-assisted transcription—Post-processed speech recognition (so-called back-end speech recognition) edited by a medical transcriptionist, then released to the physician for approval; and
- Speech-driven—Physicians drive EHR documentation using speech recognition (so-called front-end speech recognition), then edit and complete the note themselves.

Today, most EHR vendors support all four modalities⁴ with obvious trade-offs between acquisition costs (other than manually driven documentation), implementation costs, and time spent by the physician vs. time spent by a transcriptionist (and corresponding cost), with the indirect cost to physicians (i.e., time spent in the manually driven option) cited as the highest among these methods.⁵ A white paper authored by a voice recognition vendor cites a study of radiologists⁶ comparing traditional dictation and voice recognition (speech-driven). Voice recognition took fifty percent (50%) longer to dictate notes despite notes that were twenty-four percent (24%) shorter than those traditionally transcribed. Based on average radiologist and transcription salaries, the additional time spent dictating with voice recognition cost an additional \$6.10 per case or \$76,000 annually.

While most vendors build into the cost of their EHR the ability to create a placeholder for a dictated note to subsequently be added to the record, all charge extra for integrating speech-assisted and speech-driven documentation. In addition, both speech-assisted and speech-driven documentation have the added cost of specialized hardware (e.g., microphones and processors).

Finally, physician preferences regarding the method of documentation are not consistent. In one study⁷, 7,000 coronary artery disease and diabetes patients made 18,569 visits to 234 primary care physicians. Of these, nine percent (9%) predominately dictated their notes, twenty-nine percent (29%) predominately used structured documentation and sixty-two percent (62%) predominately typed free text notes. In general, physicians who predominantly used dictation were older, had more patient visits and were attending physicians when compared to physicians who used other methods. In another study,⁸ 293 faculty physicians completed a survey showing that

ninety-four respondents (32.6%) use dictation or speech recognition, primarily in the outpatient setting. Overall, 128 respondents (44.9%) rated having either dictation or speech recognition to document inpatient notes as critical or important to them.

DISCUSSION

While the intent of Resolution 717-A-14 is to increase physician efficiency, the case is far from clear. Indeed, in the reference committee, the testimony was mixed; while some speakers agreed that the ability to integrate dictation systems into EHRs would be helpful, others indicated that dictation systems are not always the most effective or efficient way to maximize the value of EHRs. The potential to increase cost was also noted.

In addition to the cost associated with the different methods of documentation and varying physician and organizational preferences, questions have been raised about the impact of different documentation methods on quality. The primary objective of the previously cited study regarding documentation methods for primary care visits was to evaluate the impact on fifteen (15) measures of quality. The authors found that overall quality of care was worse for physicians who used dictation than those who used either structured or free text methods. Those dictating notes came out below the others on three (3) of the fifteen (15) measures, while those employing structured data entry surpassed the other groups on three (3) measures. The authors explanation for these findings were that those using structured data entry were less likely to miss necessary steps in patient care than those dictating a note that would be added later. Direct interaction with the EHR has the added benefit of embedded clinical-decision support. Unfortunately, a previous study in the same health care system of self-reported satisfaction with documentation method found that the least satisfied physicians were those who used structured documentation. 10

The previously cited study¹¹ of radiologists, examining the time taken using voice dictation and the additional cost of this approach, also noted that ninety percent (90%) of all voice recognition reports contained errors prior to sign off and thirty-five percent (35%) still had errors after sign off. Error rates for conventionally transcribed reports were ten percent (10%) and three percent (3%) for pre- and post-sign off, respectively.

So, what are physicians and physician organizations to do? Clearly one size does not fit all. In a 2010 report of the American Health Information Management Association, 12 the authors noted the challenges faced by health information management professionals and chief information officers in balancing physician productivity, satisfaction and preferences with the need for discrete data in the EHR. The authors go on to cite a survey of the Healthcare Information and Management Systems Society Analytics stage six hospitals—defined as institutions that are completely automated and using paperless medical records—which found that, on average, there was a thirty-five percent (35%) use of structured templates, sixty-two percent (62%) use of dictation and transcription and four percent (4%) use of voice recognition. At the Mayo Clinic in Jacksonville, Florida, seventy percent (70%) of physicians create notes using dictation and transcription while twenty-five percent (25%) use structured templates. The authors conclude that a blended approach to physician documentation appears to be the norm.

With the blended approach, different modalities are used depending on physician preference, practice patterns, document type and organizational imperatives for measuring performance and quality. The latter is of particular importance as the market shifts to value-based payment arrangements. Physicians use templates when appropriate and retain the option to dictate when desired. This is least disruptive to physician workflow, achieving higher levels of adoption. The experience of the Rockwood Clinic in Spokane, Washington is instructive. Lyn Willett, Director of Health Information Management, endorses the use of dictation and transcription alongside structured templates for certain specialties and physicians. "Implementing an EHR sounds easy, but before you leap into implementation you have to take a serious look at workflows within your organization and assess the various documentation needs and styles of your providers." Using a blended approach, the clinic's physicians and staff give their EHR high marks for readability, accessibility and data analysis.

Finally, some observers point to natural language processing (NLP)—the ability to extract highly granular data from ordinary speech or free text—to enable pre- and post-care analytics that can drive clinical decision making at the point of care and support the transition to value-based payment methods. Unfortunately, this technology has not reached a level of maturity where it can be relied on to meet these needs. It is also very expensive, making it almost unattainable for most organizations and especially for individual or small physician practices.

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CONCLUSION

In spite of the challenges posed by many EHRs today, physicians recognize the potential of this technology. Creating efficiency in the use of EHR technology should be considered in the context of overall usability that can improve patient care, strengthen the patient-physician relationship and increase professional satisfaction. The method of documentation in the EHR has been a particular source of frustration. In response, some have advocated the use of dictation. In fact, most EHRs being used today support various forms of documentation including structured and free text entry, conventional dictation and transcription as well as speech-assisted and speech-driven modalities. No one method appears to be preferred by a majority of physicians and concerns have been raised about the quality of care with both speech-assisted and speech-driven approaches.

Although some observers point to the advent of natural language processing, which holds out the prospect of extracting highly granular data from ordinary speech or text entry, as a future solution to the problem of balancing structured and unstructured documentation, it has not reached an acceptable level of maturity.

The AMA continues to engage technology developers and EHR vendors to identify workable solutions for physician practices. At this time, it is best to adopt a blended approach that recognizes physician preference, practice patterns, document type and organizational imperatives for measuring performance and quality as well as enabling pre- and post-care analytics that can drive clinical decision-making at the point of care and support the transition to value-based payment methods.

RECOMMENDATION

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 717-A-14, and the remainder of the report be filed.

That the following American Medical Association policies be reaffirmed:

- 1. H-480.971, "The Computer-Based Patient Record"
- 2. D-478.995, "National Health Information Technology"
- 3. D-478.976, "Innovation to Improve Usability and Decrease Costs of Electronic Health Record Systems for Physicians"

APPENDIX A - Current AMA Policy

H-480.971 The Computer-Based Patient Record (CPR)

The following steps will allow the AMA to act as a source of physician input to the revolutionary developments in computer-based medical information applications, as a coordinator, and as an educational resource for physicians. The AMA will: (1) Provide leadership on these absolutely critical and rapidly accelerating issues and activities. (2) Work, in cooperation with state and specialty associations, to bring computer education and information to physicians. (3) Work to define the characteristics of an optimal medical record system; the goal being to define the content, format and functionality of medical record systems, and aid physicians in evaluating systems for office practice computerization. (4) Focus on the CPR aspect of human-computer interaction (the physician data input step) and work with software venders on the design of facile interfaces. (5) Provide guidance on the use of computer diagnosis and therapeutic support systems. (6) Continue to be involved in national forums on issues of electronic medical data control, access, security, and confidentiality. (7) Continue to work to ensure that issues of patient confidentiality and security of data are continually addressed with implementation resolved prior to the implementation and use of a computer-based patient record. (BOT Rep. 29, A-96; Reaffirmation A-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 724, A-13)

D-478.995 National Health Information Technology

1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden to the physician and maintaining the art of medicine without compromising patient care. 2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C) advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care.; and (D) advocates for more research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems. 3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent

evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians' practices; and (B) develop minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs. 4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery. 5. Our AMA will seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology's (ONC) certification process. 6. Our AMA will collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability. 7. Our AMA will directly engage the EHR vendor community to promote improvements in EHR usability. (Res. 730, I-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation A-10; Reaffirmed: BOT Rep. 16, A-11; Modified: BOT Rep. 16, A-11; Modified: BOT Rep. 17, A-12; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed: BOT Rep. 24, A-13; Reaffirmed in lieu of Res. 724, A-13; Appended: Res. 720, A-13; Appended: Sub. Res. 721, A-13; Reaffirmed: CMS Rep. 4, I-13; Reaffirmation I-13; Appended: BOT Rep. 18, A-14; Appended: BOT Rep. 20, A-14; Reaffirmation A-14)

D-478.976 Innovation to Improve Usability and Decrease Costs of Electronic Health Record Systems for Physicians

1. Our AMA will: (A) advocate for CMS and the Office of the National Coordinator (ONC) to support collaboration between and among proprietary and open-source EHR developers to help drive innovation in the marketplace; (B) continue to advocate for research and physician education on EHR adoption and design best practices specifically concerning key features that can improve the quality, safety, and efficiency of health care regardless of proprietary or open-source status; and (C) through its partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs--open source and proprietary--to create more transparency and support more informed decision making in the selection of EHRs. 2. Our AMA will, through partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs--open source and proprietary--to create more transparency and formulate more formal decision-making in the selection of EHRs. 3. Our AMA will work with AmericanEHR Partners to modify the current survey to better address the economics of EHR use by physicians including the impact of scribes. 4. Our AMA will make available the findings of the AmericanEHR Partners' survey and report back to the House of Delegates. (BOT Rep. 23, A-13; BOT Rep. 24, A-13)

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18. CREATION OF THE AMA SUPER PAC (RESOLUTION 606-I-14)

Reference committee hearing: see report of Reference Committee F.

HOUSE ACTION: REFERRED

Resolution 606-I-14, "Creation of the AMA Super PAC", introduced by the Georgia Delegation, called upon our AMA to create and provide significant initial and ongoing funding for an AMA Super PAC (political action committee) to participate in independent expenditures for or against candidates for federal office based on recommendations from state medical society PACs and support from the American Medical Association Political Action Committee (AMPAC). The resolution called for the AMA Board of Trustees to determine an organizational structure for an AMA Super PAC Board and for the AMA Board of Trustees to determine an annual contribution to the Super PAC. The resolution identified AMA reserve funds as a potential source of funding for this effort. In addition, the AMA Super PAC Board would be required to develop a plan for soliciting contributions from outside entities eligible to contribute under federal election regulations.

The reference committee received testimony indicating that the issue of creating a Super PAC was complicated and warranted thorough analysis. Issues identified for study included federal disclosure and reporting requirements, prudent use of AMA financial resources including reserves, the possibility of significant tax implications for the AMA, ability to have a meaningful impact on election outcomes in highly competitive races, and potential impact on AMPAC fundraising. The resolution was referred to the Board with instructions to report back at the 2015 Annual Meeting.

DISCUSSION

Direct and Indirect Funding Sources for Federal Campaigns

Super PACs are an outgrowth of two federal court decisions in early 2010. In *Citizens United v. Federal Election Commission*, the United States Supreme Court held that the government could not prohibit corporations and unions from making independent expenditures for political purposes. In *Speechnow.org v. Federal Election Commission*, the US District Court for the District of Columbia held that contributions to groups that only make independent expenditures could not be limited in either size or source. Super PACs are best known as "independent expenditure-only committees" that can raise unlimited funds from individuals, corporations, unions, and other groups. A Super PAC may not coordinate its communications with federal candidates or political party committees and may not make direct contributions to federal candidates, PACs, or political party committees. Super PACs are required to file regular reports of receipts and disbursements with the Federal Election Commission (FEC).

Super PACs are normally financed by multi-million dollar contributions from wealthy individuals who normally exercise tight control over where and how those Super PAC funds are spent. The non-partisan Brennan Center for Justice reported that in the three federal elections held since *Citizens United*, just 195 individuals and their spouses donated nearly 60 percent of Super PAC funding. Super PACs are generally highly partisan and focused on single or narrow issues. They are best known for employing negative ads to attack their opponents rather than airing positive ads on behalf of favored candidates. A large number of Super PACs are candidate-specific and have limited lifespans.

The term "Super PAC" has become a generic term for outside money groups seeking to influence federal campaigns, but there are several distinctly different direct and indirect sources for funding of US House, Senate and Presidential races. Traditional funding sources, such as personal contributors, connected PACs, non-connected PACs, leadership PACs, and political party committees, have long been involved, but they vary in terms of contribution limits, donor bases, and reporting requirements.

There are two other major players in federal campaign finance similar to Super PACs that fall into the category of "outside money." Section 501(c)(4) organizations are defined by the Internal Revenue Service as "social welfare" organizations that, unlike 501(c)(3) charitable organizations, may participate in political campaigns and elections as long as the organization's "primary purpose" is the promotion of social welfare and not political advocacy. Section

501(c)(4) organizations are required to report only their spending on political activity, but they are not required to disclose their donors publicly except in limited cases.

Section 527 groups are organized under Section 527 of the Internal Revenue Code and, technically, almost all political committees, including candidate committees, traditional PACs, political parties and Super PACs are "527s." However, in common practice the term is usually applied only to such organizations that are not regulated under state or federal campaign finance laws because they do not "expressly advocate" for the election or defeat of a candidate.

In the 2014 election cycle, nearly \$4 billion was spent on US House and Senate elections. Candidates spent \$1.576 billion and political parties spent \$1.136 billion. Outside money totaled nearly \$770 million, while PAC administrative overhead accounted for \$290 million. In the 2016 presidential election cycle, outside spending is expected to increase dramatically and even perhaps double in size.

Benefits and Risks of a Super PAC

Super PACs are expected to continue to prosper—at least in the near future. For example, the Koch brothers with their network of wealthy conservative donors have already announced plans to double their spending in the next cycle to over \$900 million. Many new Super PACs devoted specifically to the presidential election are being created. Even with all this anticipated growth in outside spending, the ability of Super PACs to determine the outcome of most races is not universally accepted. The highly-regarded University of Virginia Center for Politics recently concluded that the heavy involvement of liberal and conservative outside groups in competitive races offset each other and the sheer volume of spending has probably exceeded the point of diminishing returns.

There are very few examples of Super PACs created by associations like our AMA. We have identified only one association that raises a substantial amount of money for its Super PAC. The association itself does not contribute any funds to the PAC, thus avoiding a 35 percent excise tax.

Nor has it sought funding through large personal and corporate contributions. It has instead chosen to increase general membership dues and designated the new money for the Super PAC. This allows the association to claim that "third parties" (i.e., members) are the source of Super PAC funding and not the association.

A number of persuasive arguments can be made on either side of this issue. For every perceived benefit, however, there are often risks that should be carefully considered. A few of the pros and cons that have been considered are listed below and are worthy of further debate.

Arguments in Favor

- Unlimited personal and corporate contributions could provide the AMA with new outside funding sources for use as independent expenditures in federal campaigns.
- Prominent campaign ads would increase awareness of AMA involvement in congressional elections and potentially sway public opinion in highly competitive races.
- The AMA has a very high favorable image with most voters which enhances its ability to positively influence election outcomes.
- Organized medicine needs more champions in Congress and a Super PAC would be an extra advocacy tool to help elect our preferred candidates.

Arguments in Opposition

- Special interest mega-donors are viewed negatively by a substantial percentage of voters.
- The use of AMA corporate funds for political campaign activities could alienate some AMA members who might object from a partisan or ethical perspective.
- High visibility involvement in some races risks having a negative impact that harms rather than benefits supported candidates and/or the AMA's advocacy efforts.
- Creation of an AMA Super PAC could negatively impact AMPAC hard dollar fundraising efforts and diminish its ability to continue to make appropriate direct contributions and interact with elected officials.

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Funding a Super PAC

There are three possible funding sources for an AMA Super PAC. First, the use of AMA corporate funds is allowable under federal law; however, any funds contributed to a Super PAC would be subject to a prohibitive 35 percent excise tax. In addition, all administrative costs provided by the AMA for the operation of a Super PAC would potentially also be subject to the 35 percent excise tax. A second option is for the AMA to attempt to find personal and corporate mega-donors willing to finance this effort on a continuing basis. A third, and far less effective means of funding a Super PAC, is by attempting to attract large numbers of low dollar contributors through expensive direct mail and telemarketing efforts.

Effect on AMPAC Fundraising and Current Activities

Perhaps the most important assessment that must be made in determining if the AMA should create a Super PAC is the potential impact it might have on AMPAC fundraising and existing programs. Our first priority should be to strengthen AMPAC which has served for more than 50 years as a key component of the AMA's overall advocacy efforts.

AMPAC makes direct contributions to candidates for the US Senate and House of Representatives in consultation with state medical society PACs. AMPAC also has a 30-year history of making independent expenditures when there have been promising opportunities to make a difference in key competitive races of importance to medicine. AMPAC has spent in excess of \$1 million in independent expenditures in four separate election cycles since 2004. In the 2010 and 2014 cycles it was determined that engaging in independent expenditures would not be a prudent use of AMPAC resources.

As the AMA's "connected PAC," AMPAC's administrative costs are funded by the AMA without any tax liabilities. AMPAC raises funds from its "restricted class" made up of members of the AMA, state and county medical societies, their family members, and medical society staff. Most AMPAC funds are raised through its direct membership efforts and a lesser amount is raised jointly with partner state medical societies who have agreed to comply with collecting agent requirements determined by the FEC. Contributions to AMPAC must be made using personal funds and the maximum contribution limit is \$5,000 per year.

AMPAC also maintains the AMA Political Education Fund (PEF) which is made up of individual contributions to AMPAC made with corporate funds. PEF funds are not eligible for contributions to federal candidates but do benefit other AMPAC campaign related activities such as AMPAC's political education programs, partisan communications, and political research.

We have not yet been able to predict with confidence what effect a new Super PAC might have on AMPAC's future fundraising. From a professional/trade association perspective there are no similar predictive models currently available so further effort must be made to assure AMPAC is not negatively affected by the addition of a Super PAC.

RECOMMENDATIONS

The Board of Trustees recommends that the following be adopted in lieu of Resolution 606-I-14 and that the remainder of the report be filed:

- 1. That AMA policy be that the use of AMA corporate funds, including reserves, is not a fiscally responsible option for funding a Super PAC given the 35 percent excise tax imposed on the use of such funds and should not be pursued.
- 2. That our AMA continue to monitor and implement innovative advocacy efforts that maximize our ability to advance our public policy agenda.

19. LIABILITY RELATED TO REFERRALS FROM FREE CLINICS (RESOLUTION 217-A-14)

Reference committee hearing: see report of <u>Reference Committee B</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

IN LIEU OF RESOLUTION 217-A-14 AND

REMAINDER OF REPORT FILED

See Policy D-435.969

At the 2014 Annual Meeting, the House of Delegates (HOD) referred Resolution 217-A-14, "Liability Related to Referrals from Free Clinics," for report back at the 2015 Annual Meeting. This resolution was introduced by the Michigan Delegation and asked that:

Our American Medical Association (AMA) work to enact regulations to provide immunity from medical malpractice lawsuits to physicians who provide charity care at their offices or clinics to patients referred from free clinics similar to the immunity that would have been granted to those physicians had they performed those services within the scope of their work at the free clinic per the Free Clinic Federal Tort Claims Act (FTCA) Medical Malpractice Program at both the state and federal levels.

This report provides background on FTCA medical liability protections, highlights state efforts to expand these provisions, and outlines relevant AMA policy focused on this issue.

THE FEDERAL TORT CLAIMS ACT

Congress originally enacted the FTCA in 1946 to provide immunity to federal government employees from tort liability when acting within the scope of their work. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) extended FTCA protection to certain health professionals at qualifying free clinics, recognizing that these centers rely on volunteers to provide health services to poor and underserved patients.² Funds to support this program were appropriated in 2004, and the first free clinic volunteers were deemed in 2005.

The liability protections provided by the FTCA are strong and have ensured that physicians and other practitioners are not deterred from volunteering their services at free clinics. Under the FTCA, a patient who alleges acts of medical liability cannot sue the center or the provider directly, but must instead file the claim against the United States government. The Federal government acts as the primary insurer and then reviews and/or litigates claims via the US Department of Health and Human Services (HHS) or the Department of Justice. Not only does this mitigate frivolous claims against health care providers, it also results in significant cost savings for free clinics since they do not need the protection of expensive liability insurance policies.

Initially, this liability protection was only offered to the center's health care professionals, leaving a loophole that allowed individuals to file claims against the clinic's other employees. In 2010, with the passage of the Affordable Care Act, FTCA liability coverage was expanded to the clinic's board members, officers, paid health professional staff, and certain health professional contract employees. With this extension, FTCA immunity now broadly covers clinic staff and allows these centers to direct their limited funding toward patient care or other needed services.

To be eligible for this comprehensive protection, the clinic and its health care professionals must comply with explicit statutory requirements. Specifically, the clinic must be operated by a nonprofit entity, not accept reimbursement for providing health care services from any third-party payor (but may accept voluntary donations), and only impose charges on patients according to their ability to pay. 6 Similarly, the professional must be appropriately licensed or certified, may not receive compensation from the patients directly or from any third-party payor (but may receive reimbursement from the clinic for reasonable expenses), and must provide patients with written notification of the limited liability prior to providing services. Free clinics must also submit an annual FTCA deeming application on behalf of their eligible individuals to the Health Resources Services Administration (HRSA), which administers the free clinics FTCA Program.⁸ This process requires a free clinic to provide information as evidence that it has fulfilled statutory and program requirements, including:

Description of the free clinic's credentialing and privileging systems;

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- Description of the free clinic's risk management systems;
- Disclosure of medical liability claims and disciplinary actions;
- Evidence that each licensed or certified individual was credentialed and privileged by the sponsoring free clinic within the last two years; and
- Evidence of a Quality Improvement/Quality Assurance plan. 9

STATE EXPANSION OF FTCA PROTECTIONS

While the FTCA provides liability protections for those working within the free clinics, it does not extend these protections for referrals to other care settings. Oftentimes physicians working at free clinics need to refer the charity care patient for more specialized care or treatment at a hospital or physician practice. Physicians working outside of the free clinic generally agree to provide their services to these patients at no cost. Yet, those working outside of the free clinic walls will not be covered by the FTCA liability protections. This lack of coverage may ultimately discourage physicians and other care workers from volunteering their services since they would be exposed to potential liability claims.

States have recognized this significant barrier to providing charity care and sought expansion of the FTCA liability protection. In particular, Michigan, in 2011, enacted a broader version of the FTCA law that affords immunity to professionals providing uncompensated care as a result of a referral from a free clinic. ¹⁰ This extension of the law ensures that physicians volunteering nonemergency services in hospitals, physician offices, or other care settings receive the same liability protections as those working at free clinics. To protect patients, the law requires that the patient must sign a written disclosure informing them of this immunity. In addition, the law's protections are not absolute but will not apply for gross negligence or willful and wanton misconduct by the physician.

AMA POLICY

AMA policy explicitly supports broader liability protections than those currently offered under the FTCA. In particular, AMA policy is not limited to protecting services that are provided at free clinics but include liability protection for whenever free care is offered to indigent patients. This policy urges states to adopt legislation that would provide liability relief for all physicians that deliver pro bono care or volunteer services.

DISCUSSION

While consistent with AMA policy, extending FTCA protections through federal regulations would require Congress to make an amendment to the FTCA statute or pass a new law. The current political environment, however, is unlikely to lead to such a change in the near future. In the last few years, Congress has been unable to garner enough bi-partisan support to pass medical liability reform legislation, even when the issue is essentially only a technical clarification.

In contrast, states continue to be more proactive in adopting medical liability reform. Legislative and ballot initiatives at the state level have enacted significant tort reform measures, including innovative approaches to protect volunteer physicians. Given the greater potential of a successful advocacy campaign at the state level, the AMA should focus its efforts on introducing and passing state FTCA expansion laws. Specifically, the AMA is developing draft model state legislation to facilitate the passage of these laws that are consistent with existing AMA policy regarding physicians who volunteer their services. The AMA will work with interested medical associations to advance this legislation at the state level. This approach is not only more likely to garner success but can also build off of Michigan's approach as an example for other states to follow.

RECOMMENDATION

The Board of Trustees recommends that the following be adopted in lieu of Resolution 217-A-14 and the remainder of the report be filed.

That our American Medical Association will work with interested medical associations to enact state legislation that provides medical liability immunity, similar to the protections granted under the Federal Tort Claims Act (FTCA), to physicians who provide charity care in hospitals, offices, clinics or other health care settings to patients referred from free clinics.

APPENDIX - Current AMA Policy

H-160.953 Free Clinics

The AMA: (1) encourages the establishment of free clinics as an immediate partial solution to providing access to health care for indigent and underserved populations; (2) will explore the potential for a partnership with state and county medical societies to establish a jointly-sponsored free clinic pilot program to provide health services and information to indigent and underserved populations; and (3) will develop strategies that will allow the AMA, along with one or more state or county medical societies, to join in partnership with private sector liability insurers and government - especially at the state, county, and local levels - to establish programs that will have appropriate levels of government pay professional liability premiums or indemnify physicians who deliver free services in free clinics or otherwise provide free care to the indigent. (BOT Rep. 27-A-94; Reaffirmed: BOT 17, A-04; Reaffirmed: CME Rep. 6, A-12)

H-160.940 Free Clinic Support

Our AMA supports: (1) organized efforts to involve volunteer physicians, nurses and other appropriate providers in programs for the delivery of health care to the indigent and uninsured and underinsured through free clinics; and (2) efforts to reduce the barriers faced by physicians volunteering in free clinics, including medical liability coverage under the Federal Tort Claims Act, liability protection under state and federal law, and state licensure provisions for retired physicians and physicians licensed in other United States jurisdictions. (Sub. Res. 113, I-96; Reaffirmed: BOT 17, A-04; CMS Rep. 1, A-09; Reaffirmed in lieu of Res. 105, A-12; Appended: CME Rep. 6, A-12)

D-375.998 Peer Review Protection for Physicians Covered by the Federal Tort Claims Act

Our AMA will work with the Indian Health Service headquarters, Public Health Service, and the Department of Health and Human Services Office of the General Counsel to enact federal legislation protecting the confidentiality of peer review/clinical quality assurance information done by physicians and organizations covered by the Federal Tort Claims Act. (Res. 230, A-01; Reaffirmed: BOT Rep. 22, A-11)

D-130.971 The Future of Emergency and Trauma Care

Our AMA will: (1) expand the dialogue among relevant specialty societies to gather data and identify best practices for the staffing, delivery, and financing of emergency/trauma services, including mechanisms for the effective regionalization of care and use of information technology, teleradiology and other advanced technologies to improve the efficiency of care; (2) with the advice of specific specialty societies, advocate for the creation and funding of additional residency training positions in specialties that provide emergency and trauma care and for financial incentive programs, such as loan repayment programs, to attract physicians to these specialties; (3) continue to advocate for the following: a. Insurer payment to physicians who have delivered EMTALA-mandated, emergency care, regardless of in-network or out-of-network patient status, b. Financial support for providing EMTALA-mandated care to uninsured patients, c. Bonus payments to physicians who provide emergency/trauma services to patients from physician shortage areas, regardless of the site of service, d. Federal and state liability protections for physicians providing EMTALA-mandated care; (4) report on progress in addressing these issues to the AMA House of Delegates at the 2007 Interim Meeting; (5) disseminate these recommendations immediately to all stakeholders including but not limited to Graduate Medical Education Program Directors for appropriate action/implementation; (6) support demonstration programs to evaluate the expansion of liability protections under the Federal Tort Claims Act for EMTALA-related care; (7) support the extension of the Federal Tort Claims Act (FTCA) to all Emergency Medical Treatment and Labor Act (EMTALA) mandated care if an evaluation of a demonstration program, as called for in AMA Policy D-130.971(6), shows evidence that physicians would benefit by such extension; and (8) if an evaluation of a demonstration program, as called for in AMA Policy D-130.971(6), shows evidence that physicians would benefit by extension of the FTCA, our AMA will conduct a legislative campaign, coordinated with national specialty societies, targeted toward extending FTCA protections to all EMTALA-mandated care, and the AMA will assign high priority to this effort. (BOT Rep. 14, I-06; Reaffirmation A-07; Reaffirmation A-08; BOT action in response to referred for decision Res. 204, A-11; Appended: Res. 221, I-11)

H-435.949 Liability Relief for Physicians Who Volunteer at Free Clinics

Our AMA urges states to adopt legislation that provides for liability relief for volunteer physicians who serve at free clinics, deliver pro bono care, or volunteer in times of disaster. (Res. 929, I-07)

H-435.976 Liability Protection for Medical Volunteers

It is the policy of the AMA to endorse the concept of liability protection for medical volunteer services and to promote legislative efforts to achieve that goal. (Res. 86, A-90; Reaffirmed: BOT Rep. M, I-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmation A-06; Reaffirmed in lieu of Res. 223, A-06)

D-190.990 Federal Funding for Liability for Physicians Working in Free Clinics

Our AMA shall implement a plan to have regulations and funding for Section 194 of the HIPAA bill approved, which states that liability coverage for physicians volunteering in free clinics will be provided through the US Public Health Service, and will continue to monitor the implementation of Section 194 of HIPAA. (Res. 226, A-02; Appended: BOT Rep. 17, A-04)

Board of Trustees - 19 June 2015

REFERENCES

- 1 42 U.S.C. § 233.
- 2 42 U.S.C. § 233(o).
- 3 Health Resources and Services Administration (HRSA) Free Clinics. Available at http://bphc.hrsa.gov/ftca/freeclinics/ Accessed February 12, 2015.
- 4 42 U.S.C. § 233(o)(1).
- 5 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10608 (2010).
- 6 42 U.S.C. § 233(o)(3)(A).
- 7 42 U.S.C. § 233(o)(5)(C).
- 8 HRSA. Free Clinics. Available at http://bphc.hrsa.gov/ftca/freeclinics/Accessed February 12, 2015.
- 9 HRSA. Calendar Year 2015 FTCA Deeming Application for Free Clinics http://bphc.hrsa.gov/policiesregulations/policies/pdfs/pal201404.pdf Accessed February 12, 2015.
- Mich. Health Code § 333.16277. Nonemergency health care; limitation on liability; additional restrictions; exceptions; definitions. Available at http://www.legislature.mi.gov/(S(lt3pzy3mfwlurmeh02fj0033))/ mileg.aspx?page=getObject&objectName=mcl-333-16277 Accessed February 12, 2015.

20. REVIEW OF STRADDLE DRUG PRICING RULES FOR MEDICARE PART D PARTICIPANTS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

Policy D-120.943, "Review of Straddle Drug Pricing for Medicare Part D Participants," was adopted at the 2014 Interim Meeting. This report is in response to the second clause, which asks that our AMA prepare a report explaining the straddle drug pricing rules and their potential impact on patients, incorporating information that is available from CMS regarding implementation by Medicare Part D benefit plan sponsors (which may offer standalone prescription drug plans (PDP) or Medicare Advantage (MA) plans that include the Part D benefit (MA-PD plans)).

BACKGROUND

Under Medicare Part D, each time a beneficiary purchases a prescription drug, the beneficiary is responsible for paying either a fixed-dollar amount (copayment) or a percentage of the cost (coinsurance). The amount of the beneficiary's payment depends on which of four coverage phases the beneficiary is in. The Medicare prescription drug plan coverage phases generally include the following:

- <u>Initial Deductible phase</u>, where the beneficiary is responsible for 100 percent of the prescription drug purchase cost (though not all Medicare Part D plans include a deductible).
- <u>Initial Coverage phase</u>, where the beneficiary shares the negotiated retail cost of the prescription purchase with the Part D plan either as a co-insurance percentage or as a fixed co-payment.
- <u>Coverage Gap phase</u> (which is often referred to as the donut hole), where the beneficiary is 100 percent responsible for the purchase price of the prescription drug minus a percentage discount (though it is important to note that certain Part D plans do offer some coverage in this "gap").
- <u>Catastrophic Coverage phase</u>, where beneficiaries, after spending a certain amount on their prescription drugs, pay a maximum of five percent of the negotiated retail drug prices.

The ACA altered the above framework so that current beneficiaries in the Coverage Gap phase will pay less than 100 percent of their costs. It closes the Coverage Gap phase altogether as of 2020 so that enrollees will pay 25 percent of their costs (or the actuarial equivalent of an average expected payment of 25 percent) until they enter the Catastrophic Coverage phase. This will be achieved by offering percentage discounts that are gradually increased for brand name and generic drugs in the Coverage Gap.

It is important to note that Medicare Part D prescription drug plan benefit designs vary considerably and may or may not include an initial deductible and may include some coverage in the Coverage Gap phase (beyond the ACA statutorily mandated discounts to close the Coverage Gap). Part D prescription drug plans must have a "standard

benefit" package or an actuarially equivalent benefit design. Part D plan sponsors may also offer "enhanced" plans that provide benefits in addition to the standard benefit, which typically includes some coverage during the Coverage Gap phase. Therefore, calculating a beneficiary's share of the negotiated purchase price will vary depending on the benefit design of the Part D plan.

What Are Straddle Claims?

Straddle claims are prescription drug claims that cross phases of a beneficiary's Medicare Part D prescription drug plan benefit. Generally, a straddle claim usually occurs in three instances when the cost of the prescription drug purchase crosses the following phases:

- From the Initial Deductible phase into the Initial Coverage phase where coinsurance or copayment applies.
- From the Initial Coverage phase where copayment or coinsurance applies into the Coverage Gap phase where discounts apply (and where some plans offer coverage).
- From the Coverage Gap phase into the Catastrophic Coverage phase where co-payment or coinsurance may apply, but only up to a maximum of five percent of the negotiated retail price.

The following example shows how a beneficiary's share of the negotiated price could be calculated when a claim straddles the Deductible and Initial Coverage phases. Mr. Smith, a Medicare beneficiary, is enrolled in a Medicare Part D plan with an initial deductible of \$250. Mr. Smith's total cumulative covered retail drug purchases to date is \$200, and now Mr. Smith just purchased a covered prescription drug with a negotiated retail price of \$100.

- Of the \$100 purchase, \$50 is under the \$250 Initial Deductible limit. Mr. Smith is responsible for 100 percent of this \$50 of prescription costs.
- The remaining \$50 is a claim that moves Mr. Smith into the Initial Coverage phase. Mr. Smith's Part D plan includes a 25 percent coinsurance (or \$12.50) and his Medicare Part D prescription drug plan pays 75 percent.
- Therefore, Mr. Smith pays \$50 (from the Initial Deductible phase) plus \$12.50 (from the Initial Coverage phase) for a total of \$62.50.
- Mr. Smith is not responsible for the full negotiated retail price of \$100.

CMS Policy: The Co-Pay First Approach

CMS has not enforced a consistent method to determine a beneficiary's portion of the negotiated price when a claim straddles the Initial Coverage phase and the Coverage Gap phase. At least three methods have been identified and CMS has permitted Part D plans to use the approach that is the least favorable to beneficiaries, dubbed the "Co-Pay First" approach. In August 2014, a Federal District Court in *Stanley H. Epstein v. U.S. Department of Health & Human Services (HHS)* dismissed a beneficiary lawsuit brought against HHS in order to challenge the "Copay-First Approach" to handling of Medicare Part D claims that straddle the gap between the Initial Coverage phase and Coverage Gap phase. The Copay-First Approach allows health plans to resolve straddle claims by counting a beneficiary's copay toward the initial coverage limit before determining the Part D plan's share of the prescription drug negotiated retail rate.

In 2010, the plaintiff, Mr. Epstein, was enrolled in a Part D plan and he purchased a covered prescription drug called Actonel. Reportedly, at the time of this purchase, he had incurred \$2,746.67 in prescription drug costs and he was \$83.33 below his plan's Initial Coverage phase limit. Because the Actonel cost \$334.92, his purchase pushed him into the Coverage Gap phase. During the Initial Coverage phase, Mr. Epstein's copay for the Actonel was \$187.50. If his entire Actonel purchase had been made during the Initial Coverage phase, the Part D plan's share of the costs would have been \$147.42 (\$334.92 – \$187.50 = \$147.42).

There are three possible approaches to calculate Mr. Epstein's cost of the straddle claim in the above scenario including:

- <u>Initial Coverage phase approach</u>. The Part D plan should pay the \$147.42 share for Mr. Epstein's straddle claim because he was still in the Initial Coverage phase when he made the purchase.
- Pro Rata approach. The Part D plans must at least pay its pro rata share of all costs beneath the initial coverage limit. Under this approach, the Part D plan would pay its 44 percent share of the \$83.33 he paid for the Actonel, \$36.66, before he reached the \$2,830 initial coverage limit.

• <u>Copay-First approach</u>. Because Mr. Epstein's \$187.50 copay for the Actonel pushes him into the Coverage Gap

phase, the Part D plan concluded that Mr. Epstein was not entitled to any benefits. The Part D plan had counted Mr. Epstein's copay towards the initial coverage limit before determining its share of the cost. This is the "Copay-First approach" to straddle claims.

The Court held that CMS has the discretion to allow Part D plans to decide the method by which the beneficiary share of straddle claims are calculated because the statute (42 U.S.C. § 1395w-102(b)(3)(A)) sets the Initial Coverage phase limit, but is silent as to how to process claims against the limit. The Copay-First approach results in beneficiaries paying more out-of-pocket where there are at least two alternative methods for calculating respective costs that are more equitable.

Impact of Part D Plan Formulary Tiers

The above policy considerations are further complicated by the inclusion of formulary tiers that include variable coinsurance or co-pays—which all Part D plans (PDPs and MA-PDs) include as part of their benefit structure. The calculation of a beneficiary's cost for a drug that is on a tier involves use of an additional rule when the claim is straddling coverage phases. As background, Part D plans have the discretion to offer a benefit with tiered cost sharing in order to offer different levels of cost sharing for generic, preferred, and non-preferred drugs, for example. Part D plans may also designate a specialty tier for high cost drugs that include a variable co-insurance (a percentage of the cost of the prescription drug) and this tier is exempt from cost-sharing exceptions.

There are several methods for calculating the beneficiary's cost when a claim is straddling a coverage phase and the prescription drug has been placed on a cost-sharing tier. One method could, perversely, result in the beneficiary's share of the cost exceeding the gross drug cost. To avoid this outcome, Part D plans should apply the "lesser of" logic when determining the straddle claims that have beneficiary cost sharing amounts. The beneficiary pays the lesser of (a) 100 percent of the gross drug cost or (b) the sum of the co-insurance and co-pay (which may include deductible) amounts.

While CMS has stated that the use of formulary tiers ensures stability for Part D plans, it is widely recognized that the use of tiers has increasingly shifted costs to beneficiaries. This is particularly concerning where drugs are placed on specialty tiers which are not subject to exceptions. In addition, the complicated calculations of cost sharing for straddle claims, which are further complicated when the prescription drugs are on tiers with variable co-insurance, prevents beneficiaries from readily and easily identifying when Part D plans are improperly calculating beneficiary cost sharing. In addition to AMA advocating for increased scrutiny of Part D plan practices, during Open Enrollment beneficiaries should annually review the Part D formulary coverage of various plans based on their existing and expected medication. Beneficiaries are able to obtain this information from the Medicare toll free number and by utilizing tools such as the CMS *Medicare Plan Finder* online.

AMA ADVOCACY

Since Policy D-120.943 was adopted, our AMA has urged CMS to examine how Medicare Part D plans are applying the straddle drug pricing rules and to determine whether costs are being inappropriately shifted to beneficiaries whose drug spending totals span multiple coverage phases. As provided in the policy, this report explains the straddle drug pricing rules and their potential impact on patients, incorporating information that is available from CMS regarding implementation by Part D plans. In addition to the foregoing, our AMA has urged CMS to issue guidance directing Part D plan sponsors (and Medicare Advantage plan sponsors with Part D benefits) to adopt either a Pro Rata or Initial Coverage phase approach as the appropriate method for Part D plans to use for straddle claims between the Initial Coverage and Coverage Gap phases. Our comments were included in the March 6, 2015, comments to CMS in response to the CMS 2016 Call Letter, which addresses Medicare Advantage and Part D policy implementation.

21. AMA-PROVIDED INNOVATION GRANTS TO SUPPORT NEW PHYSICIAN MODELS TO IMPROVE QUALITY, EFFICIENCY AND REDUCE COST (RESOLUTION 604-I-14)

Reference committee hearing: see report of <u>Reference Committee F</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED

IN LIEU OF RESOLUTION 604-I-14 AND REMAINDER OF REPORT FILED

See Policy H-390.843

INTRODUCTION

Resolution 604-I-14, "AMA-Provided Innovation Grants to Support New Physician Models to Improve Quality, Efficiency and Reduce Cost," introduced by the Maryland Delegation and referred to the Board of Trustees, asked:

That the AMA develop innovation grants to explore new ways to improve quality and efficiency and reduce cost in all medical practice settings, including independent private practice.

At the 2014 Interim Meeting, the reference committee received testimony indicating that the American Medical Association (AMA) is actively addressing the actions requested in this resolution through various initiatives, including application for participation in the Centers for Medicare and Medicaid Services (CMS) Transforming Clinical Practice Initiative (TCPI) and our AMA's STEPS ForwardTM program.

This report describes AMA's proposed role in TCPI and presents additional information about the STEPS ForwardTM program. In addition, this report highlights grants from CMS to promote innovative change throughout the health care system, as well as other activities currently taking place throughout the AMA.

CMS' TRANSFORMING CLINICAL PRACTICE INITIATIVE

In 2014, the Center for Medicare & Medicaid Innovation (CMMI) announced the TCPI—a funding opportunity designed to help 150,000 clinician practices achieve large-scale health care transformation through nationwide, collaborative and peer-based learning networks over the next four years. The AMA was instrumental in bringing this initiative to physicians and other providers by urging that CMS do more to assist physicians with the adoption of new payment and care delivery models.

There are six overarching goals of the TCPI:

- Supporting clinicians in their practice transformation initiatives;
- Improving health outcomes for those enrolled in Medicare, Medicaid, Children's Health Insurance Program (CHIP) and other patients;
- A reduction in unnecessary hospitalizations;
- Generating \$1-4 billion in savings to both public and private payers;
- A reduction in unnecessary services (such as tests and procedures) to sustain efficient care delivery; and
- Building the evidence base for practice transformation so that effective solutions can be scaled.

The TCPI model will test a three-pronged approach to national technical assistance, which includes:

- 1. Aligning federal and state programs and resources moving toward common transformation goals;
- 2. Establishing Practice Transformation Networks (PTN) formed by group practices, health care systems and others that join together to serve as trusted partners to provide clinician practices with quality improvement expertise, best practices, coaching and help as they prepare and conduct clinical and operational practice transformation; and
- 3. Establishing Support Alignment Networks (SANs) formed by professional associations and others that align their memberships, communication channels, continuing medical education credits and other work to support the PTNs and clinician practices.

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Utilizing this three-pronged approach, the transformation of clinician practices will occur through five phases of transformation: setting objectives for practices, using data to drive care, achieving progress on the outlined objectives, achieving benchmark status and finally flourishing as a business through value-based payment approaches.

While practices who participate in the TCPI as part of a PTN will be asked to do a fair amount of work to attain such transformations, they will also achieve a number of benefits. With the support and resources offered by the SANs, physicians and their practices can optimize health outcomes and promote connectedness of care for their patients. In addition, physicians can learn from high performers on how to effectively engage patients and families in care planning, and have a stronger alignment with new and emerging federal policies. In the end, all of these benefits and opportunities will help physicians spend more time delivering high-quality care for their patients.

In February 2015, the AMA applied for SAN status and proposed three related work streams to advance the objectives of the TCPI:

- 1. Engaging the national physician community in the objectives of the TCPI

 To support the PTNs and clinician practices, the AMA will align memberships, communication channels, continuing medical education (CME) programming and more. The AMA will also address broad awareness and adoption of TCPI goals, as well as clinician-directed education and transformation enablement.
- Accelerating the maturation of clinical data registries to meet TCPI-related requirements
 The AMA intends to provide coordination, resources and tools needed by registries to mature in the direction and at a pace consistent with the goals of the TCPI. By 2020, the AMA also aims to increase clinician access to and participation in qualified clinical data registries (QCDRs), even as the criteria for QCDR status become more stringent.
- 3. Elevating the collective capability and capacity of PTNs and SANs

 As part of a high-functioning national collaborative, the AMA intends to develop relationships with experts and bring them together to increase the ability, readiness and effectiveness of all participating PTNs and SANs. The AMA also intends to provide nationally recognized adjunct faculty to lead 16 virtual collaboration events for PTNs and other SANs.

SAN cooperative agreement awardees will receive \$1 to \$3 million in funding over four years to disseminate practice transformation learnings to primary care physicians and specialists. The AMA will be notified sometime in mid-to late spring if the application is approved.

Aside from its SAN application, our AMA is committed to helping physicians transform their practices into entities that will thrive in the nation's evolving health care environment. The AMA has built a multi-year strategy around three mission focus areas with relevance to the TCPI, and has deep expertise and bench strength in these domains. These focus areas of Improving Health Outcomes, Accelerating Change in Medical Education and Professional Satisfaction and Practice Sustainability also create an extensive network of external relationships that the AMA can tap in an advisory capacity to assist the TCPI in achieving its goals.

Other CMS and CMMI Initiatives

In addition to the TCPI, AMA advocacy efforts have sought additional funding opportunities for physician-led initiatives from the CMMI. The opportunities offered by CMMI to date include:

- Bundled Payments Initiative;
- Comprehensive Primary Care Initiative; and
- Healthcare Innovation Challenge.

The AMA has also done considerable work to improve the Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) so that physicians can successfully participate in them. Most recently, this work included joining with 18 other health care organizations representing most of current MSSP ACOs to respond to an MSSP proposed rule from CMS. These recommendations, sent in a joint comment letter to CMS on February 6 of this year, were drafted with the intent of ensuring the sustainability of the MSSP so that it could achieve necessary

cost reductions and quality improvements in the Medicare program. Recommendations included allowing flexibility in ACO approaches to improving care coordination, including how they use health information technology (HIT) and increased access to capital by providing alternative payment methods with more money up front.

Furthermore, our AMA has been working for a number of years advocating for the development and implementation of Accountable Payment Models (APMs) that would give physicians opportunities for greater flexibility and responsibility for improving patient care and controlling health care spending. To help in this effort, our AMA has been working closely with medical specialty societies to develop APMs for the conditions they typically manage, and ultimately to get CMS approval on a series of APMs, having at least one APM where physicians from each specialty could participate.

STEPS FORWARD™ PROGRAM

In October 2014, our AMA launched the beta website of STEPS ForwardTM with the mission of providing quality care to patients and improving professional satisfaction and practice sustainability.

STEPS ForwardTM is an interactive online learning platform for physicians and their care teams. The educational content—referred to as the Practice Transformation Series—offers innovative strategies and interventions that will allow practices to:

- Reduce or eliminate barriers to providing quality care
- Help physicians establish a more meaningful physician-patient relationship
- Strengthen the power of teamwork in the practice

Four modules were made available on the STEPS ForwardTM beta program: pre-visit planning and preparing for patient visits, instituting a collaborative documentation process, managing prescription renewals, and implementing efficient rooming and discharge protocols. Each module gives physicians the opportunity to earn CME credits by offering AMA PRA Category I CreditsTM. Other members of the care team can earn a certificate of completion.

The STEPS ForwardTM platform is not just a repository of educational content. The site includes active learning modules, video testimonials, and downloadable resources. The platform also provides a list of live events that learners can attend. It also offers implementation support to practices that need help executing the strategies presented in each module.

During the STEPS ForwardTM beta period, hundreds of users have viewed the website and completed modules. Ninety percent of respondents rated the content as relevant to their practice and 97 percent indicated that they will continue to engage with the learning opportunities offered in the website.

The official launch of STEPS ForwardTM will take place in June 2015 in conjunction with AMA's 2015 Annual Meeting. The website will have more than a dozen modules, as well as a number of site improvements based on the beta phase evaluation.

The AMA is committed to getting the best ideas from today's physicians and practices. Along with the launch, our AMA will announce a competition for physician- and practice-sourced content to develop the next set of practice transformation modules to be included in the STEPS ForwardTM program. Practices will be asked to submit innovative solutions addressing methods to reduce administrative burdens within the practice and to improve the experience of patients and physicians alike.

As AMA learns more about STEPS ForwardTM users and audiences, it will remain steadfast in improving the platform to meet the evolving needs of physicians and their care. The AMA will also continue to encourage physicians to consider private practice as a viable option and assist physicians in achieving greater professional satisfaction and creating sustainable practices.

OTHER AMA ACTIVITIES

There are many other activities currently underway at the AMA that support the exploration of new and innovative ways to help physicians improve quality, efficiency and reduce costs in their practices, regardless of the setting. The Board of Trustees - 21 June 2015

following summaries outline related programs currently underway and other activities that support Triple Aim outcomes.

The AMA's Accelerating Change in Medical Education (ACE) Initiative

The AMA's "Accelerating Change in Medical Education" initiative and participating institutions are creating the medical school of the future by launching innovative projects and sharing them with each other and the wider academic community.

In 2013, our AMA launched the "Accelerating Change in Medical Education" (ACE) initiative, a competitive grant program designed to stimulate innovation in undergraduate medical education and change the way physicians are trained in the United States. More than 84 percent of accredited US MD-granting medical schools filed letters of intent outlining potential projects. A national advisory panel comprised of leading medical educators selected 31 applicants who were then invited to submit expanded proposals. The AMA awarded 11 medical schools approximately \$1 million each over a five-year period to jumpstart the complex process of transforming medical education and the way future physicians are trained. Project descriptions for all 11 schools can be found in Appendix A.

At the end of the five-year grant period, our AMA envisions that participating institutions will do more than just graduate medical students prepared for the next stage of physician training. They will graduate physicians ready to care for patients in the modern health system, and the tested innovations will spread to other educational environments. The AMA ACE initiative will be the catalyst to create a medical education system that trains physicians who:

- Master a core education in basic, clinical and health care delivery sciences
- Customize their learning experience through technology, moving to advanced training based on the achievement of competencies rather than time spent learning
- Understand and affect positive change in our rapidly changing health care systems
- Embrace the physician's new roles in the health care system.
- Responsibly steward health care resources
- Participate as leaders and members of health care delivery teams
- Provide leadership for ongoing improvements in health care delivery to optimize health outcomes for patients, families and communities

Since funding began in September 2013, the 11 grant recipient schools have demonstrated an affinity for working together through the AMA ACE Consortium by sharing their innovations and methods within a formalized agreement on intellectual property protection that enhances collaborative work. The schools come together regularly to share progress and identify additional consortium-wide programs that can be developed as a team. Consortium activities have included national organizations with an important stake in the future of medical education (e.g., Association of American Medical Colleges, Accreditation Council for Graduate Medical Education, National Board of Medical Examiners) that have contributed to creative thinking, collaboration and, ultimately, provided important input and perspective on how best to design for sustainable transformation.

The AMA ACE Consortium established interest groups for grant recipients working in similar areas. These topic-based groups cut across Consortium member schools in the areas of technology, competency-based assessment and milestones development, systems-based practice, master adaptive learning, organizational change and faculty development.

These interest groups are:

- Investigating the tools necessary to create a robust virtual health care learning system with authentic deidentified clinical data sets, teaching EMRs and interactive ePortfolios.
- Developing a systems-based practice model focused on the components of the science of health care delivery in undergraduate medical education.
- Creating a faculty development needs assessment survey to help the Consortium address this critical component of all the grant projects.

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Drafting a conceptual model of the master adaptive learner—the Consortium term for an expert, self-directed, self-regulated and lifelong workplace learner—to serve as a roadmap for medical students and schools.

Establishing a collaborative evaluation and learner assessment approach including the development of knowledge-based tests and the collection of objective structured clinical exams/simulation cases that focus on the Consortium priority areas of inter-professional education, quality improvement/safety and evidence-based practice.

As Consortium members continue to implement solutions, schools will share materials, tools and ideas with one another. Once refined as best practices, the Consortium will disseminate these solutions to medical schools across the country.

AMA-convened Physician Consortium for Performance Improvement[®] (PCPI[®])

Another way that the AMA is improving quality and efficiency and helping to reduce cost in medical practice settings is through the PCPI. Established fourteen years ago, the PCPI is the developer of more than 350 evidencebased performance measures and a major contributor of measures for use in federal accountability programs. The PCPI was one of the first entities to work with HIT and practice sites to incorporate performance measures into electronic health records (EHRs). This work supports the PCPI multilevel model which includes developing both human and machine readable e-specifications, and real-world testing of these specifications in EHRs. Finally, the PCPI is now offering measure development services to specialty societies and others who are interested in becoming measure developers and stewards.

More recently, the AMA sponsored and provided leadership to the National Quality Registry Network (NQRN®), a voluntary multi-stakeholder network that aims to promote the use and utility of clinical registries. The NQRN is a leader in supporting the efforts of registry stewards to be designated as Qualified Clinical Data Registries (OCDRs) for reporting to the Physician Quality Reporting System (PQRS). Many PCPI-developed measures are reported via OCDRs.

In addition, the PCPI is implementing a Quality Improvement (QI) Program comprised of two key components. The first component is a learning network to support specialty and state societies in developing their performance improvement activities. The learning network will build upon the science of large scale improvement spread and adoption, increase access to evidence-based knowledge on performance improvement and share real-life learnings from performance improvement projects. The second component is to develop cross cutting improvement projects. The first project is focused on improving physician and patient satisfaction, as well as timeliness of the ambulatory referral process called "Closing the Referral Loop."

Through these efforts, and adherence to evidence-based PCPI measures, the AMA is once again working to help physicians meet the Triple Aim goals of better health for populations, improved patient experience and lower cost in all medical practice settings, from large health systems to the independent private practice.

Supporting Physician Practice Innovation: MATTER

On February 4, 2015, our AMA announced its partnership with MATTER, a health care technology incubator in Chicago. This partnership will drive innovation and create an adaptable space that allows physicians, entrepreneurs and other health care stakeholders to come together and learn from each other to develop tools and resources that meet the demands and challenges of the ever-changing health care environment.

This partnership created an AMA Interaction Studio at MATTER, a physical and virtual environment that brings entrepreneurs into the physician office to help in the development of innovative technologies, products and services. The AMA Interaction Studio will allow all stakeholders to work directly with physicians to develop and test new models for health care delivery. It brings entrepreneurs into the physician office to help in the development of innovative technologies, products and services and fosters collaboration to create solutions to health care issues.

The AMA Interaction Studio is designed to help developers better understand physician practice workflow and key challenges, and how potential solutions fit into the care delivery environments so they can develop solutions that meet these key challenges and have a real impact.

The AMA Interaction Studio will also host educational workshops, interactive simulations and collaborative events focused on optimizing health care, with a particular focus on the physician-patient interaction.

Professional Satisfaction and Practice Sustainability Group Focus Area

After releasing the AMA-RAND study entitled "Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy" in October 2013, the AMA set forth a multi-year plan to identify effective care delivery and payment models that can improve the quality of patient care, reduce health care costs, increase professional satisfaction and ensure practice sustainability.

To support physicians and their practices to implement solutions and strategies that can improve practice efficiency and achieve the Triple Aim outcomes of improving the patient experience, improving the health of the nation and reducing the per capita cost of health care, our AMA launched its STEPS Forward TM platform (described above).

To address one of the single largest drivers of professional dissatisfaction among physicians—the poor usability of EHRs—our AMA created an external expert advisory committee on EHR usability. This committee identified and released a framework, "Improving Care: Eight Priorities to Improve the Usability of EHRs," which set forth a set of goals for America's EHRs. The AMA is utilizing these priorities to work with EHR and HIT vendors, physicians, policymakers and health care systems to advance its action plan to improve EHR usability and interoperability so these important tools enhance, not detract from, physicians' ability to efficiently provide high quality care to their patients.

Recognizing the importance of care coordination across the health care delivery system to improve the value of health care to patients, our AMA continues to drive discussions with leaders of our nation's largest integrated health care systems and hospitals to strengthen the role of physicians as leaders in new integrated delivery system models of care. Further, our AMA is researching the effects of alternative health care payment models on physicians and physician practices to help guide efforts by our AMA and other stakeholders to make improvements to current and future alternative payment models and help physician practices, regardless of their mode of practice, succeed in these new payment models.

This work supports our AMA's ongoing federal and state legislative activities to shape better payment and care delivery models, which will create a more sustainable environment that better serves physicians and patients under their care. By identifying and supporting current and emerging payment and care delivery models that work best for physicians across a variety of practice settings, our AMA is playing a vital role in helping them provide high-quality care and achieve professional satisfaction.

CONCLUSION

As the nation's health care system continues to evolve, our AMA stands ready to help physicians navigate the environment successfully by promoting sustainable practices that can result in improved health outcomes for patients and greater professional satisfaction. The AMA, alone and in partnerships, has been actively working toward developing innovative resources that span the lifecycle of the individual physician in all medical practice settings, including independent private practice. These initiatives will aid physicians in achieving the Triple Aim outcomes of better health for populations, improved patient experience and lower cost.

RECOMMENDATION

Therefore, it is the recommendation of the Board of Trustees that in lieu of Resolution 604-I-14, our AMA continue its involvement in activities that support physicians in all practice settings to implement solutions and strategies that can improve practice efficiency, helping them achieve improved quality at an affordable cost and the remainder of this report be filed.

APPENDIX - AMA "Accelerating Change in Medical Education" Institutions and Their Educational Innovations

Visit the <u>AMA website</u> for more information on each school's innovative program.

Institution	Educational Innovations
Indiana University School of Medicine	Technology to enhance learning: Creating teaching EMR (tEMR) populated with deidentified patient data. Faculty development of Quality Systems Coaches in Systems-based
Mayo Medical School	Practice and tEMR. Science of Health Care Delivery: Interaction of Inter-professional teams, patients, communities, public health resources and healthcare systems on outcomes and cost, incorporated into all years of medical schools. Developing milestones that will form the basis to assess competencies in the science of health care delivery. Resiliency (wellness) toolbox for students.
NYU School of Medicine	Technology to enhance learning: Creation of a large clinical data set – <u>available online</u> : medical students analyze patients' health through the lens of big data, looking at cost, patient outcomes, disparities, etc. Includes an ePortfolio that allows students to track their own activities for quality improvement, safety and value-added care.
Oregon Health & Science University School of Medicine	Competency-based re-design of the curriculum: Enables students to advance through individualized learning plans as they achieve key milestones tracked by a portfolio. Faculty serve as student coaches and mentors, teaching and assessing skills related to informatics, quality science and inter-professional teamwork. Creating master adaptive learners who can self-assess and adapt to change.
Penn State College of Medicine	Integration of medical education and the healthcare delivery system: Students embedded early in the clinical system as Patient Navigators and experience curriculum in the core systems sciences such as health policy, high-value care, and population and public health, evidence-based medicine, teamwork and leadership training. System leaders involved in curriculum development and implementation. Faculty triads – basic & clinical science and HC delivery faculty.
The Brody School of Medicine at East Carolina University	Emphasis on quality and safety: Comprehensive longitudinal curriculum focusing on quality improvement, safety, inter-professional skills, team-based care and leadership. Teachers of Quality Academy – model for faculty development in these competencies.
The Warren Alpert Medical School of Brown University	Underserved, Workforce Focus: Educate medical students to become physician leaders equipped to promote the health of the population they serve. Created an MD/ScM degree program in primary care and population medicine. All MD students at Brown will experience two of the Master Degree courses in health disparities and epidemiology/biostatistics.
University of California – Davis School of Medicine	Underserved Workforce Focus & competency-based re-design of curriculum: Establishes a three-year, competency-based medical school pathway linked to residency programs run by Kaiser Permanente Northern California and UC Davis for a total of six years of training (UME and GME combined). Emphasis on integration of medical education and the health care delivery system & work within ethnically diverse communities.
University of California – San Francisco School of Medicine	Integration of medical education and the healthcare delivery system: Students embedded early in the clinical system in inter-professional teams from first day of medical school. Integrates the basic sciences throughout medical school. Design and implement a Systems Improvement Immersion School to prepare students from all health professions schools to be contributing members of student improvement teams.
University of Michigan Medical School	Competency-based re-design of the curriculum: Foundational 'trunk' or core curriculum followed by flexible, differentiated 'branches.' Pace based on milestones achievement. Emphasis on leadership and change-management. Will graduate physician leaders and change agents who will improve health care at a system and patient level.
Vanderbilt University School of Medicine	Technology to enhance learning & Competency-based re-design of the curriculum: Comprehensive electronic portfolio linked to learning management system. Students use competency-based assessment evidence collected to carry out self-assessments, helping to form master adaptive learners who can self-assess and adapt to change. Creating curriculum to move at an individualized pace, based on competency attainment.

22. REDEFINING THE AMA'S POSITION ON ACA AND HEALTH CARE REFORM – UPDATE

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

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

REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR

On April 16, 2015, the President signed into law the "Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)." MACRA repeals the SGR, ending the annual threat of significant across the board reductions in Medicare physician reimbursements. The legislation, representing more than two years of bipartisan and bicameral work, passed the House on March 26, 2015, by a vote of 392-37 and was adopted by the Senate on April 14 by a vote of 92-8. The bill also had the overwhelming backing of medicine.

MACRA provides for modest positive updates for a period of five years and again in 2026 and beyond. The law consolidates multiple current incentive programs into one single Merit-based Incentive Payment System (MIPS), providing greater alignment and flexibility and the potential for significant new performance bonuses. Penalties are also reduced. Physicians who participate in alternative payment models will be exempt from MIPS and benefit from five percent payment bonuses for five years to aide transition to two-sided risk models. Primary Care Medical Home models will also benefit from the bonuses but do not require two-sided risk. Technical support for small practices, transition payments for new models, funding for measure development, and timelier physician access to data are also included.

Beyond SGR repeal, the bill also included the "Standard of Care Protection Act" to prevent quality improvement programs from being twisted into new causes of action against participants, ends the necessity for renewing opt-out status for physicians who chose to privately contract with patients, extends the Children's Health Insurance Program for an additional two-years and provides significant new resources for Community Health Centers.

PAY-FOR-PERFORMANCE

As discussed above, the new MIPS program consolidates the current Physician Quality Reporting System, Meaningful Use, and Value Based Modifier. Prior to enactment of MACRA, combined penalties for these programs in 2019 were scheduled to be at least 11 percent with a very limited potential for bonuses under the VBM only. Under MIPS, the total penalty risk in 2019 is limited to four percent with a bonus potential of four percent plus up to 10 percent for very high results. Total potential penalties under MIPS are limited to nine percent in 2020 and beyond while bonus potential also grows to nine percent over the same time period.

Implementation of MACRA will be a difficult undertaking. While it is certainly not the model physicians would have created, it is in every major aspect superior to prior law – providing greater coordination and flexibility, limiting penalties to levels below current law, and introducing potentially substantial bonuses not previously available. Furthermore, as mentioned above, physicians who engage in alternative payment models are exempt from MIPS altogether.

The AMA will closely monitor MACRA implementation while continuing to seek further reductions in regulatory burdens for Meaningful Use and quality reporting.

In addition to Congressional activity on pay-for-performance, several key improvements were included in the 2015 Medicare Physician Fee Schedule rule as a direct result of AMA advocacy. Among them:

• Value-Based Payment Modifier (VBM): Centers for Medicare & Medicaid Services (CMS) is scaling back its plan to increase the potential VBM penalties for all physicians to four percent in 2017. Instead, the final rule limits the four percent penalty to groups of 10 or more, and limits the penalty for groups of less than 10 to two percent. CMS will continue to exempt unassigned claims from the VBM. The VBM will apply to Accountable Care Organizations (ACOs) and Center for Medicare and Medicaid Innovation (CMMI) models, but CMMI may provide a waiver.

- Physician Quality Reporting System (PQRS): CMS will require just one new "cross cutting" measure; it slightly altered the Qualified Clinical Data Registry (QCDR) requirements; and CMS withdrew its proposal to shorten the time physicians have to review their feedback reports so they will still have 60 days for this review. PQRS becomes a penalty-only program in 2015. All physicians must report successfully in 2015 to avoid PQRS (and VBM) penalties in 2017, on at least nine quality measures covering three "domains."
- Physician Compare: CMS plans to better prevent and correct errors; will notify physicians when they can
 preview their reports; and withdrew its plan to post benchmarks. The public website continues to expand,
 however, showing performance under PQRS, the EHR Incentive Program, and for ACOs, despite concerns with
 the information posted.
- ACO Quality Measures: CMS is dropping several obsolete measures and retaining several measures that have
 had good results, keeping the total number of measures constant, maintaining measure stability for two years,
 reducing the reporting burden, and increasing rewards for quality improvement. However, CMS adopted several
 new measures that the AMA had opposed.

The AMA will continue to seek improvements in pay-for-performance programs consistent with HOD policy.

REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

While the 113th Congress failed to repeal the Independent Payment Advisory Board (IPAB), legislation to accomplish that goal has been reintroduced in the 114th Congress with the backing of the AMA. Senator John Cornyn (R-TX) introduced S.141, the "Protecting Seniors' Access to Medicare Act of 2015" on January 8, 2015. At this time, the legislation has 37 cosponsors. The legislation was introduced in the House by Representative Phil Roe, MD, (R-TN) and Representative Linda Sanchez (D-CA) on March 2, 2015 and currently has 215 cosponsors. Though similar legislation has stalled in previous Congresses, hopes remain high that the 114th Congress will finally enact IPAB repeal. The AMA will continue to work with the bill sponsors to build additional support for this proposal.

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

Several proposals have been introduced in the 114th Congress to increase the availability of health savings accounts, including one by Representative Michael Burgess, MD (R-TX). AMA is reviewing these proposals and will continue to seek opportunities to advance AMA policy in this area.

The "Restoring Access to Medication Act" has been reintroduced in the Senate by Sen. Pat Roberts (R-KS) and in the House by Rep. Lynn Jenkins (R-KS). This bipartisan, bicameral legislation, supported by the AMA, would repeal ACA imposed restrictions on the use of FSA and HSA funds to purchase over-the-counter medication without a prescription. The AMA has supported this bill for several years and will continue to work with bill sponsors to advance it during the 114th Congress.

The Medicare Patient Empowerment Act was reintroduced by Rep. Tom Price, MD (R-GA) on March 26, 2015. The AMA has communicated our support of the legislation to Dr. Price and will continue to work with his office to seek opportunities to improve Medicare through lifting restrictions on private contracting and creating opportunities for Medicare beneficiaries to enter into agreements with their physicians without penalty to either party.

Board of Trustees - 22 June 2015

STEPS TO LOWER HEALTH CARE COSTS

The AMA continues to review opportunities to advance legislation to lower health care costs, including the expansion of new models of care delivery.

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

At this time, Representative Andy Harris, MD (R-MD) has not reintroduced the "Protect Patient Access to Quality Health Professionals Act" which would repeal the non-physician provider non-discrimination provisions of the ACA. The AMA will continue to work with Representative Harris and other interested parties, however, to accomplish this goal.

23. A VIRTUAL MEDICAL ASSOCIATION (RESOLUTION 601-A-14)

Reference committee hearing: see report of Reference Committee F.

HOUSE ACTION: RECOMMENDATION ADOPTED

(RESOLUTION 601-A-14 NOT ADOPTED) AND

REMAINDER OF REPORT FILED

Resolution 601-A-14, A Virtual Medical Association, was introduced by the Indiana Delegation. Resolution 601 asked that our American Medical Association:

Allow future virtual live attendance of our House of Delegates meetings, with virtual attendees having the full ability to vote and communicate with the House leadership and the delegates;

Allow live virtual attendance of reference committees with full ability to communicate with the committee members and the attendees of the reference committees; and

Determine when virtual live attendance of association meetings would begin with the goal that the House of Delegates sessions be virtually available by 2016 and that all reference committees would be virtually available by 2020.

The resolution was referred. Your Board of Trustees has examined the feasibility of the proposal and offers this report. Based on our analysis, the implementation is both a very complex and costly undertaking, due to three principle reasons.

LOGISTICAL COMPLEXITY

AMA House of Delegates meetings are complex in both the pace and fluidity of the topics of business covered. To that end:

- Supporting real time interactions (enabling synchronous exchanges) among live and virtual participants would be very difficult. For example, this year, there are 538 delegate slots and a like number of alternate delegates. Typically, not all alternate delegate slots are filled, so it is likely there would be 900-950 delegates and alternate delegates. However, only delegates may vote on items of business. So a virtual meeting during the HOD meeting would have to permit only eligible voters at any given time, but also allow for handoffs to alternates (and hand backs to the delegate).
- Currently the Speakers track who approaches the microphones, trying to call on people in the order they
 approach a mic. So managing online comments and live comments would be another hurdle to manage
 effectively, as virtual participants would need to be able to raise a point, without waiting for their turn to come
 around.
- In addition to delegates and alternate delegates, medical society staff members would need to connect to the meeting and to their society's delegate(s) separately to communicate regarding issues as they arise. There are approximately 175 societies in the HOD (not including the AMA sections).

• The reference committees are (and presumably would continue to be) concurrent, with up to 5 going on at any one time. Those are open to any AMA member, and in a truly virtual meeting, some means of allowing any member to participate in the reference committee process would be required.

• Given the logistical complexity, and the need to manage multiple types of interactions, and the requirement that both a live and virtual meeting take place simultaneously, the cost of supporting this change would be significant.

TECHNOLOGICAL COMPLEXITY

There is no single program/ platform today that supports all the functional and logistical requirements needed to manage a meeting that is run concurrently virtually and in-person. To custom develop such a system would be exceptionally costly. Specific technical challenges include:

- Redundant high speed on-site Internet service would be required to support synchronous communications at both Annual and Interim Meeting locations which would require hiring outside professional services to boost networking speed and power.
- Development/ integration with existing HOD on-site voting tools; there is no way to do so now, with our current system – and either a new system would need to be built, or another solution would need to be customized.
- Support streaming audio/ video of all sessions, to inform virtual voters on what is being said during each item of
 business. Given the fluid nature of the meetings virtual participants would need to see and hear what's going
 on in each session which would require hiring multiple camera crews and supporting broadcast quality
 streaming from all meeting sessions and locations.
- A system would need to be developed to archive all votes, and maintain the voting record tally, to ensure if the system fails, it could be restored.

CULTURAL READINESS

The AMA has made a significant effort to improve meetings through digital technology, but has found significant challenges in terms of adoption due to cultural readiness of the HOD.

- The HOD has voted to limit the use of virtual reference committees to collect input, but not guide additional activities (e.g., preliminary reports).
- Participation in virtual reference committees has been modest, and declining steadily over the past few years by members of the HOD.

RECOMMENDATION

In light of the foregoing issues, implementation of a virtual House of Delegates is not feasible at this time. The Board of Trustees recommends that Resolution 601-A-14 not be adopted, and the remainder of this report be filed.

24. AMA PERFORMANCE, ACTIVITIES AND STATUS IN 2014

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Policy G-605.050 calls for the Board of Trustees to submit a report at the American Medical Association (AMA) Annual Meeting each year summarizing AMA performance, activities and status for the prior year.

INTRODUCTION

The AMA's mission is to promote the art and science of medicine and the betterment of public health. As the physician organization whose reach and depth extends across all physicians, as well as policymakers, thought leaders and medical schools, the AMA is uniquely positioned to deliver results-focused initiatives that enable physicians to answer a national imperative to measurably improve the health of the nation.

Board of Trustees - 24 June 2015

STRATEGIC FOCUS AREAS

Improving Health Outcomes

IHO's long-term goals are to increase physician screening of adults for pre-diabetes, since 86 million people have the condition but 90% of them don't know it, and referral of those patients at risk to an evidence-based diabetes prevention program; and, to prevent cardiovascular disease by focusing on the 30 million people who have high blood pressure and a source of care, yet their high blood pressure remains uncontrolled.

Preventing Diabetes

We started our work by collaborating with the YMCA of the USA to increase physician referrals of eligible Medicare patients to the YMCA's evidence-based Diabetes Prevention Program, under a federal Health Care Innovation Award that covers the cost of the program for those patients.

We conducted our community-level work in the state of Delaware, and the cities of Indianapolis, Minneapolis/St. Paul, and Venice and St. Petersburg, FL., where we engaged 11 physician practices to test our diabetes prevention program referral models and feedback loop.

We have now refined our tools and are expanding to more cities and physician practices, creating more clinical-community linkages, in Texas, Arizona, New York, Ohio, and Michigan. This year we'll be spreading this work to include more states and patients ages 18 and up.

Controlling Blood Pressure

We continue our collaboration with two research centers within Johns Hopkins University: the Armstrong Institute for Patient Safety and Quality and the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities.

At 10 clinical sites in Illinois and Maryland, physicians and care teams have helped us develop and test a set of evidence-based recommendations focusing on three main steps, which we call the "M.A.P. for blood pressure control."

- Measuring blood pressure accurately, every time it's measured
- Acting rapidly to address high blood pressure readings, and
- Partnering with patients, families and communities to promote self-management

A subset of these practices is continuing to work with us into 2015, focusing additional attention and efforts on our tools regarding clinical-community resources and partnering with patients.

We have also begun working with the Quality Innovative Network National Coordinating Center and the 14 different QIN-QIOs across the US-to spread our M.A.P. framework. We estimate that if each QIN-QIO were to recruit an average of 50 practices, our framework and tools could potentially reach 7,000 physicians and 7 million patients in their care.

And we have formed one of the first-ever Patient and Family Advisory Groups at the AMA. This group is charged with advising on how to best meet patient and family needs for IHO: BP. The patient and family advisors suggest new ideas, share their stories, review tools and help prioritize tool development.

Accelerating Change in Medical Education (ACE)

The ACE initiative has exceeded expectations in leading the partnerships that will transform medical education to produce the physicians that 21st century patients need.

2014 was the second year of the ACE initiative and the first full year of the five-year \$1 million ACE grants that were awarded to 11 medical schools. Innovative programs funded by ACE grants and launched by grant recipients include those that base student advancement on the demonstration of competencies rather than time spent in a classroom, integrate clinical experiences in all aspects of medical school coursework, train students to become

physician leaders and prepare students to lead inter-professional teams. Some grant recipients are emphasizing new curricular content areas such as health care delivery science, population health and quality improvement and developing new educational tools such as teaching EMRs, virtual health systems and e-portfolios.

Additionally, grant recipients are working together within the ACE Consortium on evaluation and rapid dissemination of best practices to other medical and health professions schools.

Learning Environment Study (LES)

The longitudinal and multi-institutional design of the LES is yielding data on the student experience throughout the four years of medical school and allowing for comparison of educational outcomes across varying medical education learning environments. Three papers identifying the factors in the learning environment that either inhibit or promote the acquisition of professional values and the demonstration of professional behaviors were submitted to peer-reviewed journals. One LES abstract was presented at the Association of American Medical Colleges meeting in Chicago in November.

Liaison Committee on Medical Education (LCME)

LCME approved a revision to accreditation standards. The 132 standards were consolidated into 12 standards with 95 elements. The new standards go into effect July 1, 2015. Schools and survey teams are being oriented to the new standards. The revision was completed to eliminate duplication in the information that schools need to supply during a review.

Professional Satisfaction and Practice Sustainability

After releasing the AMA-Rand study, entitled "Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy" in October 2013, the Professional Satisfaction and Practice Sustainability Unit set forth a multi-year plan to identify effective care delivery and payment models that can improve the quality of patient care, reduce health care costs, increase professional satisfaction and ensure practice sustainability. The AMA is committed to establishing this empirical evidence and developing resources that will allow physicians to succeed in the evolving health care environment.

To support physicians and their practices to implement solutions and strategies that can improve practice efficiency and achieve the Triple Aim outcomes of improving the patient experience, improving the health of the nation and reducing the per capita cost of health care, the AMA launched its *STEPS Forward*TM beta platform in October 2014 (full launch in June 2015). The AMA developed this practice transformation platform to offer innovative strategies that will allow physicians in all practice sizes to thrive now and well into the future. This includes interventions that will reduce or eliminate barriers to providing quality care, which can lead to greater professional satisfaction. The site includes active learning modules, video testimonials, downloadable materials and implementation support.

To address one of the single largest drivers of professional dissatisfaction among physicians—the poor usability of electronic health records (EHRs)—the AMA created an external expert advisory committee on EHR usability. This group identified and released a framework, "Improving Care: Eight Priorities to Improve the Usability of EHRs" which set forth goals for America's EHRs. The AMA is using this highly publicized effort to work with EHR and HIT vendors, physicians, policymakers and health care systems to advance its action plan to improve EHR usability and interoperability so these important tools enhance, not detract from, physicians' ability to provide high quality care.

Recognizing the importance of care coordination across the health care delivery system to improve the value of health care to patients, the AMA continues to drive discussions with leaders of our nation's largest integrated health care systems and hospitals, including in discussions with the American Hospital Association (AHA), to strengthen the role of physicians as leaders in new integrated delivery system models of care. Further, in partnership with Rand, the AMA is researching the effects of alternative health care payment models on physician practices to help guide efforts to make improvements to current and future alternative payment models and provide tools and resources to physician practices, regardless of their mode of practice, to succeed in these new payment models.

Board of Trustees - 24 June 2015

This work is aligned with AMA's ongoing federal and state legislative activities to shape better payment and care delivery models, which will create a more sustainable environment that better serves physicians and patients under their care. By identifying and supporting current and emerging payment and care delivery models that work best for physicians across a variety of practice settings, the AMA is playing a vital role in helping physicians provide high-quality care and achieve professional satisfaction.

ADVOCACY

Payment and Delivery Reform

For several years in the debate about how to replace the flawed sustainable growth rate (SGR) formula, there has been a lack of consensus on options to replace it. Due to AMA advocacy and the support of more than 600 medical societies, this debate was finally resolved in 2014 when both chambers and parties in Congress agreed on legislative policy for creating a permanent SGR replacement that is a significant improvement over current law. This replacement policy continues to have broad support in the 114th Congress. In the polarized political environment in Congress, this was a major accomplishment. The AMA's payment and delivery reform achievements also include the following:

- The Centers for Medicare & Medicaid Services (CMS) will award \$840 million for new clinical networks to improve care, under its Transforming Clinical Practice Initiative. Our AMA has been urging CMS to assist physician practices in their efforts to adopt new payment and delivery models under physician leadership, which this initiative advances.
- CMS adopted new codes and began paying for monthly complex chronic care management beginning January 1, 2015. The codes were developed by workgroups of the Current Procedural Terminology (CPT®) editorial panel and the AMA/Specialty Society RVS Update Committee (RUC).
- An AMA-backed, bipartisan law was enacted to address veterans' urgent health care needs and allow them access to care outside of the VA health system when necessary.

Regulatory Relief

The AMA reduced administrative burdens on physician practices by securing a number of key regulatory improvements, which included:

- Securing another one-year extension of meaningful use stage 2, and the addition of significant new hardship exemptions to help physicians avoid penalties
- Reversing a government proposal to mandate that industry report unrestricted funding they provide to support independent continuing medical education as part of the Sunshine Act
- Increasing due process protections for physicians under Medicare's Recovery Audit Contractor (RAC) program, and ensuring that RACs can no longer receive their contingency fees during the appeals process
- Lowering payment penalties under the value-based modifier from 4 percent to 2 percent in 2017, for practices with fewer than 10 physicians

State-Level Advocacy

Working in collaboration with state and specialty medical societies across the nation, the AMA achieved more than 75 state legislative and regulatory victories:

- Advocated for physician and patient safeguards in public and private health plans that utilize "narrow networks" around the country
- Promoted physician-led, team-based care in 15 states
- Created 11 model state bills to advance AMA policy in state legislatures
- Directly influenced national policy making organizations (including the National Association of Insurance Commissioners, the National Governors Association, the National Conference of Insurance Legislators) on key topics, such as network adequacy, drug diversion and telemedicine

Grassroots Activity

Thousands of physicians and patients voiced their opinions to lawmakers in successful AMA grassroots campaigns:

- The Patients' Action Network surpassed 1 million members
- "Save GME" Week generated more than 46,000 social media impressions and 3,300 email and phone contacts to Congress
- More than 1 million physician and patient emails were sent to Congress on resolving the SGR problem, since the launch of the "Fix Medicare Now" campaign
- FixMedicareNow.org was honored by the Webby Awards and Academy of Interactive & Visual Arts' Communicator Awards

AMPAC Activity

In 2014, the bipartisan political action committee of the AMA:

- Spent more than \$2.2 million in support of pro-medicine candidates
- Co-hosted seven regional grassroots seminars with state medical societies, and conducted its candidate workshop and campaign school
- Created hundreds of opportunities for lobbyists and local physicians to meet with key members of Congress

Practice Tools and Research

The AMA developed new resources to help physician practices adapt to the changing health care environment, including:

- A checklist on ACA implementation, developed in collaboration with the Medical Group Management Association
- A Physician Payments Sunshine Act ("Open Payments" program) toolkit
- Electronic payment resources for practices on utilizing electronic funds transfer (EFT) and knowing their rights related to virtual credit card payments from health insurers
- The Health Workforce Mapper, which illustrates the geographic location of physicians and other health care providers
- Digital health tools to help practices make the most of meaningful use, health information exchanges, telemedicine, mobile health, and HIPAA privacy and security compliance.

The AMA Economic Impact Study revealed that each US physician supports 13.84 jobs on average and contributes \$2.2 million in economic output. A 2014 update to the AMA *Competition in Health Insurance Study* found that in 41 percent of metropolitan areas, a single health insurer had at least 50 percent share of the commercial health insurance market. And a report commissioned by the AMA found that the estimated cost of implementing ICD-10 increased significantly for most physicians.

Litigation Center

The Litigation Center of the AMA and the state medical societies continued its activities at a high level of intensity across a wide spectrum of legal issues of concern to physicians, most particularly in cases that defend hard won reforms of the tort system, the right of organized medical staff self-governance, and physician interests in prompt and fair payment for services provided. On December 31, 2014, the Minnesota Supreme Court in a landmark decision held that, as an unincorporated association, a hospital medical staff had the legal capacity to sue a hospital. It further held that medical staff bylaws can be legally enforced as contracts between the medical staff and the hospital. The Litigation Center filed two amicus briefs to support the legal position of the medical staff and also assisted the medical staff with financial support and legal counseling.

Also in 2014, the AMA filed an amicus briefs before the United States Court of Appeals in Wollschlaeger v. Governor of Florida. The AMA brief explained why a Florida law which limited the right of physicians to discuss firearm ownership with their patients could interfere with physicians' care for their patients.

PRACTICE TOOLS

Business Services Group

Business Services Group (BSG) provides substantial funding for AMA's mission-focused activities and operations by delivering high value, best-in-class product solutions to physicians and the healthcare industry.

BSG continues to fortify our core businesses by strengthening our strategic relationships with large, influential customers in the healthcare industry while we look to expand our leadership applying the latest health information technology to our full product line. BSG's focus is threefold; 1) Grow, enhance and strengthen our Coding and Reimbursement and Evaluation product lines building on the already rich content to deliver more high value, digitized content to the industry. CPT will continue its evolution from a US based classification system to a fully integrated international healthcare classification system, 2) Enrich and build upon our existing Physician Database and Physician Verification Services business significantly upgrading and enhancing application of state-of-the-art database management technology creating innovative new products and services that empower physicians practice of medicine and enhance communication with their patients, and 3) Leverage our insights, brand and reputation to the consumer market through products and services that promote access to effective, high quality and accessible healthcare.

Periodical Publishing

Having firmly established The JAMA Network brand in 2013 with the re-naming and redesign of the journal, periodical publishing made the decision in 2014 to expand the portfolio of journals with the addition of JAMA Oncology, launched in Q1 2015. The addition of JAMA Oncology – the first new journal in the family since 1999 – firmly establishes The JAMA Network in a critical field of medicine.

New article types and features aimed at engaging a clinical audience debuted across all publications, including the Diagnostic Test Interpretation, Guide to Statistics and Methods, an increase in the number of CME offerings (CME by state), and the inclusion of content from The Medical Letter in JAMA.

Landmark articles in 2014 included the JAMA study: Prevalence of Childhood and Adult Obesity in the United States, 2011-2012. Theme issues focused on 50 Years of Tobacco Control, Neurology, Child Health, Diabetes, HIV/AIDS, Infectious Disease, Cardiovascular Disease, and Medical Education.

The JAMA Network continues to expand globally on the institutional licensing front, with the JAMA Network Reader and the JAMA Network Challenge apps offering readers reasons to create personal accounts that allow them to engage with our content on a deeper level.

To support online innovation and growth, periodical publishing implemented critical back-end system improvements, including a finished goods repository for our content, an upgrade to our fulfillment and access control system, and single sign-on authentication for all JAMA Network sites.

COMMUNICATIONS AND OUTREACH

In 2014, AMA's Enterprise Communications and Marketing (ECM) achieved notable gains in engaging more people, more often in helping the AMA improve the health of the nation. Whether increasing impact of earned media efforts or expanding reach in AMA's owned channels, ECM made remarkable impact in improving the visibility, influence and impact of its efforts on behalf of the nation's physicians.

Notably, efforts to increase strategy and effectiveness of AMA's earned media efforts, overall media clips increased by over 23 percent to nearly 30,000 clips; meanwhile media clips related to AMA's strategic focus areas increased by 135% to 2,800 clips. ECM increased targeted outreach to media influencers to inform notable editors, columnists and editors about AMA's strategic work, and premium placements were secured in publications including Wall Street Journal, Forbes, and Medscape, among many others. ECM also worked in conjunction with the Advocacy team to manage communications associated with advancing the Fix Medicare Now campaign and built a steady drumbeat which led to bicameral, bipartisan support for the Medicare reform legislation that would repeal SGR.

In terms of ongoing improvements to AMA's owned communications channels, ECM launched several new enewsletters to provide news and information to the physician community and refined its approach to several others. To highlight the organization's unique moments of impact, ECM launched AMA Wire Alert, and issued 17 at various points of the year when AMA had important or new offerings to the physician community and could be a resource. ECM also reconcepted the Advocacy Update product, which consolidated several newsletters into a single, more cohesive product that highlights all ways AMA advocates for the physician community, including Litigation Center and ARC. An enhanced MedEd Update was also launched to create a stronger, and more engaging product that is consistent with the family of additional newsletter products AMA is currently providing to its core audiences. At perhaps one of the most defining moments for public health in the United States in 2014, ECM launched an Ebola Resource Center for physicians looking for answers about the disease as a result considerable interest as the disease was discovered domestically. Altogether, more than 44,000 people have visited this resource center since its launch.

In terms of the AMA Morning Rounds newsletter, ECM made important strides to increase the audience for its flagship daily publication, and increased the number of subscribers from 234,000 at the beginning of the year to 400,000 at the end of the year. AMA's member only newsletter, Morning Rounds Weekend Edition, also maintains a strong audience with its open rate increasing a full percentage point over the course of the year, to a remarkable 26 percent. ECM also made strong gains increasing followers in social media by improving the quality of content and refining the frequency of content. Altogether, the number of Twitter followers increased 29 percent year-over-year to more than 446,000, Facebook likes increased 203 percent year over year to more than 248,000, and LinkedIn followers increased 60 percent to more than 10,600.

Perhaps most important for the future of the organization, ECM in conjunction with IT led the development of an Enterprise Digital Strategy that will be executed in 2015 and beyond. With this strategy, AMA is striving to provide a best-in-class experience that fully capitalizes on the connectivity and interactivity of digital channels – engaging the public in a robust discussion of health and empowering health care providers and innovators – to improve the health of the nation.

GOVERNANCE

During 2014, the Medical Student Section executed a virtual reference committee process, which eliminated the traditional in-person reference committee hearing. Similarly, the Senior Physicians Section hosted online elections along with a virtual Assembly Meeting. The growing role of virtual processes among the AMA Sections saves time during on-site meetings, improves the quality of the deliberative process, and gives members an opportunity for input.

The Organized Medical Staff Section (OMSS) worked to educate physicians about revisions to the Medicare Conditions of Participation that hold significant implications for the physician-hospital relationship. For example, these changes permit a multi-hospital health system to have a unified, system-wide medical staff, rather than a separate medical staff at each hospital. The revisions also minimize requirements for interaction between the medical staff and the hospital governing body. The OMSS produced expert resources, including model bylaws language, to guide hospital medical staffs through the process of implementing these changes in a physician-friendly manner.

In September, the Women Physicians Section hosted successful Women in Medicine (WIM) Month campaign, which resulted in a record number of connections and raised the profile of the AMA as a champion of women physicians and patients. Overall, 40 Inspirational Physician Award honorees were nominated, there was a 53% increase in traffic to the WIM webpage, and Facebook posts totaled 534,327 impressions, including 2,145 "likes."

The Young Physicians Section, working with the Council on Medical Education, surveyed the Federation to determine the effect that Maintenance of Certification/Osteopathic Continuous Certification (MOC/OCC) requirements could have on the physician workforce and the type of role the AMA could have in helping physicians. The Section presented the following at an AMA-ABMS conference in June: (a.) Although requirements for Part II, Lifelong Learning and Self-Assessment could be satisfied through CME or Self-Assessment Modules (SAMs), the majority indicated CME was "helpful," while SAMs were perceived as less helpful; (b.) Part III, Cognitive Expertise could be modified to make it more practice relevant (e.g., provide Internet access and "open-book" format); and (c.)

Part IV, Practice Performance Assessment (e.g., practice improvement modules, chart audits, etc.) were not thought to be very helpful in identifying gaps in and/or improving practices.

In collaboration with the AMA Washington Office, the Medical Student Section held its second SaveGME campaign in September 2014. The week generated more than 3,320 letters and phone calls to representatives in DC to deliver the important message that GME funding should be maintained.

The AMA partnered with the Food and Drug Administration, through its Professional Affairs and Stakeholder Engagement Staff (PASES), to offer two exclusive four-week elective rotations—one for an AMA medical student member and one for an AMA resident or fellow member. This is a valuable new learning opportunity and benefit that is now available to our medical student, resident and fellow members, which enhances two-way communication and collaboration with health care professionals, patients, patient groups, and others on issues concerning drug development, drug review, and drug safety.

The 12th Annual AMA Research Symposium, held at the 2014 Interim Meeting, was expanded to include networking activities and an educational session with a speaker from JAMA. For the first time, abstracts were judged prior to the event. Increased promotion included ads in JAMA. The AMA continues to host this increasingly popular event to increase involvement of those student, resident, fellow, and ECFMG-certified members interested in research and to promote AMA membership as a requirement of participation.

The Minority Affairs Section's (MAS) Doctors Back to SchoolTM program reached more than 10,000 minority children during 2014 through nationwide school visits, which provided face to-face encounters and inspiring information about pursuing careers in medicine. Additional efforts by the MAS throughout the year include kicking off a social media campaign during Black History Month by highlighting firsts in medical Black history and hosting the first-ever AMA Diversity Google Hangout and a Tweet Chat with the Robert Wood Johnson Foundation's Health Equity initiative which drew over 230,000 Twitter impressions. Local premed students participated in the MAS's Mock Medical School Admission Interviews and this outreach activity was adopted by the Commission to End Health Care Disparities at its meetings. The MAS partially funded an additional \$10,000 Minority Scholars Award in 2014. The MAS Governing Council served as the minority scholars award's selection committee and the ten Minority Scholars received their awards at the MAS's Annual Meeting in June held in collaboration with the AMA Foundation.

International Relations

The World Medical Association (WMA) accepted the AMA's invitation to host the WMA Assembly Meeting in Chicago in October 2017. The meeting includes business sessions and an educational program. The educational program will present the AMA's ACE initiative and will include speakers addressing other countries' changes in undergraduate medical education. AMA members are invited to attend. A selection of other recently developed or adopted WMA policies include ethical guidelines for the international recruitment of physicians, non-commercialization of human reproductive material, aesthetic surgical procedures, and Ebola viral disease.

AMA COUNCILS

Council on Constitution on Bylaws

In 2014, the Council on Constitution and Bylaws (CCB) presented two key documents to the House of Delegates: a newly renumbered AMA Bylaws and Guidelines for Medical Society Bylaws. The latter was based on guidelines issued in 1998 but expanded to be equally useful to state and county societies, specialty societies and professional interest medical associations. CCB also updated the House of Delegates Reference Manual: Procedures, Policies and Practices with changes from the 2014 Annual and Interim Meetings.

For the 2014 Annual Meeting, the CCB and CLRPD submitted three reports, which resulted in the consolidation of 30 policies, sunset 115 policies due to consolidation, rescinded 44 policy directives, which had been accomplished in part; and sunset 104 policy directives because they were obsolete, redundant or accomplished.

Council on Ethical and Judicial Affairs

A report by the Council on Ethical and Judicial Affairs (CEJA) updating existing ethics policy was adopted by the AMA House of Delegates in 2014, amending Opinion E-9.02, "Restrictive Covenants." The House also adopted CEJA Report 2-A-14, "Ethically Sound Innovation in Medical Practice," CEJA Report 4-A-14, "Health Promotion and Preventive Care," and CEJA Report 1-I-14, "Physician Exercise of Conscience." In addition, CEJA Report 3-I-14 presented the draft modernized *Code of Medical Ethics* to the House of Delegates for consideration.

Council on Science and Public Health

The Council on Science and Public Health developed 9 reports for the House of Delegates in 2014. Reports on the "Genomics of Hypertension" and "Genomic-based Approaches to the Risk Assessment, Management and Prevention of Type 2 Diabetes" interfaced with the Improving Health Outcomes strategic focus; a version of the latter report was published as a review article in *The Application of Clinical Genetics*. The report on "Biosimilar Product Approval and Marketing" updated AMA policy in this area, provided importance guidance for advocacy activities, received significant attention in the trade press, and served as a resource document for the Federal Trade Commission. The Council report on "Guidelines for Mobile Medical Applications and Devices" established new AMA policy in this important evolving clinical arena, and outlined a framework for future engagement of the Association. Two other reports focused on important public health issues. The report on "Electronic Cigarettes, Vaping, and Health" reviewed current trends in this emerging market, and provided guidance for the AMA's public comments regarding regulation of these nicotine delivery devices. The report on the "Role of Pharmacists in Improving Immunization Rates" successfully supported the view that pharmacists play an important public health role in vaccinating adult patients and promoting influenza vaccination, and therefore have responsibilities to ensure vaccine safety, maintain proper recordkeeping and communicate with the patient's medical home. Articles based on these two reports have been submitted for peer-reviewed publication.

Council on Long Range Planning and Development

Recent changes in AMA bylaws charged the Council on Long Range Planning and Development (CLRPD) with evaluating the delineated sections every 5 years to ensure their continued relevance to the Association. The CLRPD completed the first such review in 2014, assessing the Section on Medical Schools in 2014, which was renewed as a section.

Along with the Council on Medical Service and the Council on Legislation, CLRPD contributed to the Council on Science and Public Health report on the role of pharmacists in improving immunization rates, which established strong policy on this public health problem.

The 2013-14 edition of CLRPD's Health Care Trends is posted on the AMA Online Learning Center, and physicians are eligible to receive 1 AMA PRA Category 1 CreditTM for each chapter at no cost. The material can be accessed at ama-assn.org/go/healthcaretrends.

MEMBERSHIP

AMA membership had a fourth consecutive year of growth in 2014 with an overall increase of 1.9% for a total of 232,126 members.

EVP COMPENSATION

During 2014, pursuant to his employment agreement, total cash compensation paid to James L. Madara, MD as AMA Executive Vice President was \$941,630 in salary and \$715, 726 in incentive compensation and a \$208,107 payment of prior years' vested deferred compensation. Other taxable amounts per the contract were paid as follows: \$7,524 for life insurance, \$3,960 for executive life insurance, \$2,700 for health club fees and \$2,400 for parking. An \$81,000 contribution to a deferred compensation account was made by the AMA. This will not be taxable until vested pursuant to provisions in the deferred compensation agreement.

Board of Trustees - 25 June 2015

25. ABOLISH DISCRIMINATION IN LICENSURE OF IMGS (RESOLUTION 317-A-14)

Reference committee hearing: see report of <u>Reference Committee C.</u>

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

WITH CHANGE IN TITLE

IN LIEU OF RESOLUTION 317-A-14 AND REMAINDER OF REPORT FILED

See Policies H-255.966, H-255.983, H-255.988, H-255.994 and H275.955

At the 2014 Annual Meeting of the AMA House of Delegates, the Michigan Delegation introduced Resolution 317-A-14, Abolish Discrimination Against IMGs in Medical Licensing Requirements. The resolution asked that our AMA advocate that medical societies in states that require unequal amounts of graduate medical education (GME) for initial licensure of international medical graduates (IMGs) versus US medical school graduates (USMGs) seek legislation in their state legislatures to establish parity in the requirements and to eliminate any other discriminatory requirements mandated for IMGs solely. In addition, the resolution asked that our AMA 1) lobby the Federation of State Medical Boards (FSMB) to vigorously promote its policy of equal requirements for IMGs and USMGs and 2) ask the FSMB to seek changes in laws in each state to eliminate unequal GME requirements that discriminate against IMGs.

In reference committee deliberations on this item, testimony was heard in favor of the need for parity between USMGs and IMGs in the requirements for licensure. It was noted that this is a state-based issue, and requires changes to individual states' medical practice acts, but the disparity and discrimination inherent in this discrepancy among many states need to be addressed through an equitable, evidence-based solution. Other testimony reflected the variations in quality among foreign medical schools (although these may be equalized by review of United States Medical Licensing Examination scores and other measures) as well as the trend in GME towards achievement of competency-based milestones versus a rigid, time-based requirement. Further, the resolution's language calling on our AMA to "lobby" the FSMB to seek changes in state laws is problematic; more appropriate would be for our AMA to work with the FSMB to determine the scope of the problem and the rationale (if any) for the continued existence of such laws—and then, if needed, to call for those states that are outliers in this regard to change their practices. Accordingly, due to the complexity of these issues and the need for additional study, the House of Delegates referred this item for a report by the Board of Trustees.

BACKGROUND

Contributions of IMGs to the US Health Care System

About one quarter of US physicians in practice are international medical graduates (IMGs). An IMG may be a foreign national (born outside the US) or a US citizen who attended a medical school outside the US. According to 2009 data from the AMA Physician Masterfile, India is the largest contributor of IMGs to the US; physicians from this country comprise more than 20 percent of the IMG population in the US. The Philippines is next, at 8.3 percent, followed by Mexico (5.6 percent), Pakistan (4.9 percent), and the Dominican Republic (3.2 percent).

A position paper by the AMA-IMG Section Governing Council¹ details the many unique contributions of IMGs to the US health care system. For example, the paper cites peer-reviewed studies providing evidence that IMGs:

- are more likely to serve in medically underserved areas;
- perform a unique safety-net function by caring for the uninsured and the indigent populations in inner city and rural areas:
- comprise more than 30 percent of the workforce in primary care specialties; and
- comprise close to 40 percent of the physician workforce in inner-city areas in large metropolitan cities.

Aside from their role in providing clinical care to many Americans, IMGs also make significant contributions in academic medicine and research. In addition, the paper notes, "The diverse backgrounds of IMGs are especially valuable in caring for a multiethnic and increasingly diverse US population. Not only do IMGs have diverse language capabilities and heightened sensitivity in caring for members of different ethnic groups, but they also are able to assist in developing sensitivity and understanding of cross-cultural issues among their non-IMG colleagues."

US immigration policies have helped ensure the continued international migration of physicians from other countries to the US to meet our nation's health care needs, writes Robert Aronson in the AMA's 2014 edition of *State Medical Licensure Requirements and Statistics*. "When all is said and done, we as a nation have complex and ever-expanding needs for physicians, particularly those willing to serve in isolated areas and those willing to treat minorities, ethnic populations, and the indigent. Over the years, foreign physicians have been one of the most effective physician population groups for addressing medically underserved populations, and our immigration laws have developed several meaningful and effective initiatives intended to facilitate the relocation of foreign physicians into positions of maximum benefit to various US population groups."

State-to-state Variations in Licensure Requirements for USMGs versus IMGs

A review of the licensure requirements among the states and jurisdictions that license physicians shows significant variations in the GME requirements from one state to the next. Data from the AMA's licensure book illustrate these discrepancies. The 50 states—plus the District of Columbia, Guam, the Northern Mariana Islands, Puerto Rico and the US Virgin Islands—comprise the 55 jurisdictions that issue licenses to physicians for practice in those jurisdictions. (The data below do not include the Northern Mariana Islands.) A review of the GME requirements for each licensing board shows that 17 out of 54 have equivalent requirements for GME between USMGs and IMGs:

	Years of GME required
State	for initial licensure
Connecticut	2
Georgia	1
Illinois	2
Kentucky	2
Maine	3
Michigan	2
Nevada	2
New Hampshire	2
New Jersey	2
New Mexico	2
Puerto Rico	1
South Dakota	3
Utah	2
Virgin Islands	1
Washington	2
Wisconsin	1
Wyoming	2

Of the remaining 37 licensing boards, the GME requirements for initial licensure for IMGs versus USMGs are from one to two years longer, as shown.

	Years of GME Required for Initial		
	Licensure		
State	USMGs	IMGs	Discrepancy
Alabama	1	3	2
Alaska	2	3	1
Arizona	1	3	2
Arkansas	1	3	2
California	1	2	1
Colorado	1	3	2
Delaware	1	3	2
DC	1	3	2
Florida	1	2	1
Guam	2	3	1
Hawaii	1	2	1
Idaho	1	3	2

Indiana	1	2	1
Iowa	1	2	1
Kansas	1	3	2
Louisiana	1	3	2
Maryland	1	2	1
Massachusetts	2	3	1
Minnesota	1	2	1
Mississippi	1	3	2
Missouri	1	3	2
Montana	2	3	1
Nebraska	1	3	2
New York	1	3	2
North Carolina	1	3	2
North Dakota	1	2.5	1.5
Ohio	1	2	1
Oklahoma	1	2	1
Oregon	1	3	2
Pennsylvania	2	3	1
Rhode Island	2	3	1
South Carolina	1	3	2
Tennessee	1	3	2
Texas	1	2	1
Texas Vermont	1 1	3	1 2
		3 2	
Vermont	1	3	2

For these 37 states, the average GME requirement for USMGs for initial licensure is 1.2 years, versus 2.7 years for IMGs

Aside from the variation in GME requirements, other measures are in place for IMGs versus USMGs. For example, as the AMA's licensure book indicates, about half of boards require IMG candidates to have graduated from a state-approved foreign medical school; several boards also maintain and use a list of approved/unapproved foreign medical schools for decisions on initial licensure. Further, a majority of jurisdictions also may require an interview or oral examination prior to licensure endorsement.

FSMB Policy on Equivalency in Licensure Requirements

The Federation of State Medical Boards (FSMB), which is composed of the 70 medical boards of the US states and territories, has policy that addresses the issue of discrepant GME requirements among the states. This policy, approved by the FSMB house of delegates at its April 2013 annual meeting, calls on the FSMB to, "in collaboration with other stakeholders, examine the benefits as well as the potential harms and unintended consequences that could occur as a result of requiring all applicants for licensure to have completed 36 months of progressive postgraduate medical training." Currently, as seen in the data from the AMA's licensure book, only Maine and South Dakota require three years of GME for licensure of both USMGs and IMGs.

Furthermore, a 1998 position statement from the FSMB states, "All applicants for licensure should have satisfactorily completed a minimum of three years of postgraduate training in an ACGME- or AOA-approved postgraduate training program, including completion of PGY3 level training prior to full and unrestricted licensure." The document notes the "wide variation in the timing and sequence of the various training elements" among residency programs. It also notes that 25 states require IMGs to complete three years of GME for initial licensure, while only one state has the same requirement for US and Canadian medical school graduates. "The three-year requirement," the statement adds, "would alleviate concerns of discrimination as related to physician licensure and establish uniform standards for all applicants for licensure."

AMA Model Resolution for Licensure Parity and States' Efforts to Change Licensure Requirements

To assist efforts to change discrepant licensure requirements at the state level, the AMA IMG Section developed a model resolution for use by state medical associations at their respective house of delegates' meetings. The resolution, Parity for International Medical Graduates with US Medical Graduates in Years of GME Requirement for Licensure (see Appendix A), was used in Michigan and Texas to successfully advocate for changes in these states' GME requirements to ensure licensure parity for IMGs and USMGs.

DISCUSSION

One question for consideration is the impact of the move towards competency-based medical education at both the undergraduate and graduate medical education levels (as embodied in the work of the AMA's Accelerating Change in Medical Education strategic focus area). As medical educators move away from time-based measures, the question arises as to how (or if) time-based GME requirements should be adjusted. Unless and until valid, verifiable and standardized measures become available, state licensure boards may prefer to maintain more prescriptive, time-based parameters.

Another question raised by the research for this report is whether the AMA should support a three-year GME requirement for all licensees or simply support parity in each state between USMGs and IMGs (whether one, two or three years). As noted earlier, the three-year requirement is the policy of the FSMB. Current AMA policy (H-275.985, Graduate Medical Education Requirement for Medical Licensure) states that applicants for full and unrestricted licensure should complete "at least one year of an accredited program of graduate medical education in the US." This policy was reaffirmed in 2005. Given that only two states currently require that USMGs complete three years of GME, it would be difficult to change this policy in the absence of more research that would suggest that such a change is needed. More likely is that the AMA would continue to support its policy of seeking legislative action to eliminate any disparity in the GME requirement for USMGs and IMGs in those states (currently 37) where such disparities exist.

Finally, it should be noted that research suggests that not all IMGs are the same with regard to the quality of care they may eventually provide. In a 2010 article in *Health Affairs*, Norcini *et al.* conclude that "patients of doctors who graduated from international medical schools and were not US citizens at the time they entered medical school had significantly lower mortality rates [for selected conditions] than patients cared for by doctors who graduated from US medical schools or who were US citizens and received their degrees abroad." The authors note that this finding is not surprising, in light of previous research that US-citizen IMGs "have lower scores on the cognitive portions of the licensing examination sequence, lower ratings from training program directors, and lower rates of specialty board certification." These data underscore the potential value of moving towards a system of competency-based assessment and required achievement of core competencies by all students and residents as part of the licensure and certification processes.

EXISTING AMA POLICY

The AMA has a number of policies related to discrimination in licensure of IMGs (see Appendix B). Many of these policies duplicate each other; others are outdated and/or superseded by more recent policy. Because of duplication in some of these policies, this report calls for development of a new, inclusive policy, as shown in Recommendation 1, below, and recission/editing of a number of existing policies, as shown in Recommendation 5 and Appendix B. Adopting this new policy will aid AMA advocacy efforts in the future by ensuring a single, more comprehensive source for policy on IMG licensure issues.

SUMMARY AND RECOMMENDATIONS

The additional required years of GME completion increase the "burden of proof" for IMGs seeking to practice medicine in the US. Some would argue that these items are essential to ensure the quality of potential physicians from non-US medical schools; others (such as the authors of Resolution 317-A-14) would counter that such regulations present an undue burden on physicians who are equally as qualified as their US-educated counterparts. In any event, the AMA already has significant policy on this topic, and supports at least one year of GME for all licensees. For those 37 states that have discrepant GME requirements for USMGs and IMGs, AMA policy urges uniformity, whether one, two or three years.

Board of Trustees - 25 June 2015

Therefore, the Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 317-A-14 and that the remainder of this report be filed.

1. That our American Medical Association (AMA) adopt the following policy:

MEDICAL LICENSURE OF INTERNATIONAL MEDICAL GRADUATES

Our AMA supports the following principles related to medical licensure of international medical graduates (IMGs):

- State medical boards should ensure uniformity of licensure requirements for IMGs and graduates of US and Canadian medical schools, including eliminating any disparity in the years of graduate medical education (GME) required for licensure and a uniform standard for the allowed number of administrations of licensure examinations.
- 2) All physicians seeking licensure should be evaluated on the basis of their individual education, training, qualifications, skills, character, ethics, experience and past practice.
- 3) Discrimination against physicians solely on the basis of national origin and/or the country in which they completed their medical education is inappropriate.
- 4) US states and territories retain the right and responsibility to determine the qualifications of individuals applying for licensure to practice medicine within their respective jurisdictions.
- 5) State medical boards should be discouraged from a) using arbitrary and non-criteria-based lists of approved or unapproved foreign medical schools for licensure decisions and b) requiring an interview or oral examination prior to licensure endorsement. More effective methods for evaluating the quality of IMGs' undergraduate medical education should be pursued with the Federation of State Medical Boards and other relevant organizations. When available, the results should be a part of the determination of eligibility for licensure.
- 2. That our AMA continue to work with the Federation of State Medical Boards to encourage parity in licensure requirements for all physicians, whether US medical school graduates or international medical graduates.
- 3. That our AMA continue to work with the Educational Commission for Foreign Medical Graduates and other appropriate organizations in developing effective methods to evaluate the clinical skills of IMGs.
- 4. That our AMA work with state medical societies in states with discriminatory licensure requirements between IMGs and graduates of US and Canadian medical schools to advocate for parity in licensure requirements, using the AMA International Medical Graduate Section licensure parity model resolution as a resource.
- 5. That the House of Delegates policies listed in Appendix B of this report be acted upon in the manner indicated.

APPENDIX A - Model Resolution for State Medical Associations

Whereas, Our (*insert name of state medical board*) requires IMGs (international medical graduates) to complete *** years of GME (graduate medical education) to be eligible for licensure while requiring only *** years of GME for US medical school graduates (USMGs, who graduate from medical schools accredited by the Liaison Committee on Medical Education); and

Whereas, Before being admitted into GME, IMGs must complete a rigorous credentialing and testing process by the Educational Council for Foreign Medical Graduates (ECFMG); and

Whereas, The qualifying examinations used by the ECFMG for testing IMGs assess basic science and clinical knowledge, problem solving, and clinical encounter skills and match or exceed the standards used for USMGs; and

Whereas, IMGs undergo the same GME as USMGs at the same Accreditation Council for Graduate Medical Education-accredited training programs, satisfying the same educational and performance standards; and

Whereas, The performance of the public assurance and protection goals and duties of our State License Board (write the name used in the State) are therefore adequately satisfied without imposing additional requirements on IMGs beyond those required for USMGs; and

Whereas, The requirement of additional years of GME for IMGs poses gratuitous hardship on IMGs in planning and starting a career after GME, such as delay of up to one academic year; and

Whereas, This unnecessary delay does not serve our patient population well and exacerbates patient access problems in the continuing physician workforce shortage in our country; therefore, be it

RESOLVED, That our (insert name of the state medical society/association) adopt a policy supporting parity in the number of years of GME required for IMGs and USMGs to obtain state medical licensure, and be it further

RESOLVED, That our (insert name of the state medical society/association) aggressively pursue, including by legislative means, parity in the required number of years of GME for IMGs and USMGs for licensure, and report back its progress within two years.

APPENDIX B - Recommended Actions on House of Delegates Policies

Our AMA (1) reaffirms its policy that it is inappropriate to discriminate against any physician because of national origin or geographical location of medical education; (2) continues to recognize the right and responsibility of states and territories to determine the qualifications of individuals applying for licensure to practice medicine within their respective jurisdiction; and (3) supports the development and distribution of model legislation to encourage states to amend their Medical Practice Acts to provide that graduates of foreign medical schools shall meet the same requirements for licensure by endorsement as graduates of accredited US and Canadian schools. (Res. 69, A-89; Rescinded: Sunset Report, A-00; Restored: CME Rep. 3, A-02; Reaffirmed: CME Rep. 7, A-04; Reaffirmed in lieu of Res. 320, A-04; Reaffirmed in Lieu of Res. 325, A-08; Reaffirmation A-10; Reaffirmed: CME Rep. 11, A-10; Reaffirmed: BOT Rep. 3, I-14) H-255.983, Graduates of Non-United States Medical Schools	escind; incorporate into new policy.
physician because of national origin or geographical location of medical education; (2) continues to recognize the right and responsibility of states and territories to determine the qualifications of individuals applying for licensure to practice medicine within their respective jurisdiction; and (3) supports the development and distribution of model legislation to encourage states to amend their Medical Practice Acts to provide that graduates of foreign medical schools shall meet the same requirements for licensure by endorsement as graduates of accredited US and Canadian schools. (Res. 69, A-89; Rescinded: Sunset Report, A-00; Restored: CME Rep. 3, A-02; Reaffirmed: CME Rep. 7, A-04; Reaffirmed in lieu of Res. 320, A-04; Reaffirmed in Lieu of Res. 325, A-08; Reaffirmation A-10; Reaffirmed: CME Rep. 11, A-10; Reaffirmed: BOT Rep. 3, I-14) H-255.983, Graduates of Non-United States Medical Schools	
int	
should be evaluated for purposes of entry into graduate medical education we	etain, as this policy encompasses entry ato graduate medical education programs and hospital medical staff privileges, as well as licensure, but reflect in the new tolicy in section 1.2.
(1) The AMA reaffirms its support of current US visa and immigration requirements applicable to foreign national physicians who are graduates of medical schools other than those in the United States and Canada. (2) The AMA continues to support current regulations governing the issuance of exchange visitor visas to foreign national IMGs, including the requirements for successful completion of the USMLE. (3) The AMA reaffirms its policy that the US and Canada medical schools be accredited by a nongovernmental accrediting body. (4) The AMA continues to support cooperation in the collection and analysis of information on medical schools in nations other than the US and Canada. (5) The AMA supports continued cooperation with the ECFMG and other appropriate organizations to disseminate information to prospective and current students in foreign medical schools. (6) The AMA continues to support working with the ECFMG and other appropriate organizations in developing effective methods to evaluate the clinical skills of IMGs. (7) The AMA strongly supports the policy that the core clinical curriculum of a foreign medical school should be provided by that school and that US hospitals should not provide substitute core clinical experience for students attending a foreign medical school. (8) The AMA continues to support working with the	escind item 14 and incorporate into new olicy; rescind item 16, as the Fifth athway was discontinued in 2009; and enumber succeeding items: (14) The AMA strongly reaffirms existing policy urging the U. S. licensing athorities to focus on the individual eademic and personal achievements when evaluating IMGs for the purposes of censure. More effective methods for evaluating the quality of the indergraduate medical education of IMGs mould be pursued and, when available, are results should be a part of the etermination of eligibility for licensure. 15) The AMA reaffirms its support for the requirement that all medical school raduates complete at least one year of raduate medical education in an accredited US program in order to qualify

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not deviate from established standards when evaluating graduates of foreign medical schools. (9) The AMA, in cooperation with the ACGME and the FSMB, supports only those modifications in established graduate medical education or licensing standards designed to enhance the quality of medical education and patient care. (10) The AMA continues to support the activities of the ECFMG related to verification of education credentials and testing of IMGs. (11) Special consideration should be given to the limited number of IMGs who are refugees from foreign governments that refuse to provide pertinent information usually required to establish eligibility for residency training or licensure. (12) The AMA reaffirms its existing policy supporting the use of accreditation standards to enhance the quality of patient care and medical education. Also the AMA opposes the use of such standards for purposes of regulating physician manpower. (13) AMA representatives to the ACGME, residency review committees and to the ECFMG should support AMA policy opposing discrimination. In particular, these AMA representatives should emphasize that AMA policy does not prohibit the appointment of qualified graduates of foreign medical schools to residency training programs. (14) The AMA strongly reaffirms existing policy urging the U. S. licensing authorities to focus on the individual academic and personal achievements when evaluating IMGs for the purposes of licensure. More effective methods for evaluating the quality of the undergraduate medical education of IMGs should be pursued and, when available, the results should be a part of the determination of eligibility for licensure. (15) The AMA reaffirms its support for the requirement that all medical school graduates complete at least one year of graduate medical education in an accredited US program in order to qualify for full and unrestricted licensure. (16) The AMA supports continued monitoring of the effectiveness of the Fifth Pathway program, including to the degree possible any measurable impact of the program on enrollments in Caribbean and Central American medical schools. (17) The AMA reaffirms and supports publicizing existing policy concerning the granting of staff and clinical privileges in hospitals and other health facilities. (18) The AMA reaffirms its support of the participation of all physicians, including graduates of foreign as well as US and Canadian medical schools, in organized medicine. (19) The AMA encourages the constituent medical societies to support qualified IMGs for nominations to AMA committees and councils. (20) The AMA supports studying the feasibility of conducting peer-to-peer membership recruitment efforts aimed at IMGs who are not AMA members. (21) The AMA is committed to using its existing publications to highlight policies and activities of interest to IMGs, stressing the common concerns of all physicians. (22) The AMA supports demonstrating its interests in issues related to IMGs by publicizing its many relevant resources to all physicians, especially to nonmember IMGs. (23) The AMA supports expansion of its efforts to prepare and disseminate information about requirements for admission to accredited residency programs, the availability of positions, and the problems of becoming licensed and entering full and unrestricted medical practice in the US that face IMGs. This information should be addressed to college students, high school and college advisors, and students in foreign medical schools. (24) The AMA continues to recognize the common aims and goals of all physicians, particularly those practicing in the US, and supports making every effort to include all physicians who are permanent residents of the US in the mainstream of American medicine. (25) The AMA is committed to identifying and publicizing resources within the AMA that will respond to inquiries from IMGs. (26) The AMA is committed to providing leadership to promote the international exchange of medical knowledge as well as cultural understanding between the US and other nations. (27) The AMA urges institutions that sponsor exchange visitor programs in medical education, clinical medicine and public health to tailor programs for the individual visiting scholar that will meet the needs of the scholar, the institution, and the nation to which he will return. (28) The AMA is committed to informing foreign national IMGs that the availability of training and practice opportunities in the US is limited by the availability of fiscal and human resources to maintain the quality of medical education and patient care in the US. (BOT Rep. Z, A-86; Reaffirmed: Res. 312, I-93; Modified: CME Rep. 2, A-03; Reaffirmation I-11; Reaffirmed: CME Rep. 1, I-13)

of the effectiveness of the Fifth Pathway program, including to the degree possible any measurable impact of the program on enrollments in Caribbean and Central American medical schools.

(1715) The AMA reaffirms ...

(1816) The AMA reaffirms ...

(1917) The AMA encourages ...

(2018) The AMA supports ...

(2119) The AMA is ...

 $(22\overline{20})$ The AMA supports ...

(23<u>21</u>) The AMA supports ...

(2422) The AMA continues ...

(2523) The AMA is...

(2624) The AMA is ...

(27<u>25</u>) The AMA urges ...

(2826) The AMA is"

H-255.992, Discrimination Against Physicians

Our AMA: (1) believes that the quality of a physician's medical education is an appropriate consideration in the recruitment and licensure of physicians and

Rescind; item 1 is reflected in the new policy; item 2 is superseded by D-255.982, Oppose Discrimination in Residency Selection Based on

discrimination against physicians on the basis of the country in which they International Medical Graduate Status, completed their medical education is inappropriate; and (2) affirms that the which is more definitive, and all residency residency application process should be free of discrimination, including applications are now electronic. discrimination arising from the electronic submission of applications. (Sub. Res. 44, A-85; Reaffirmed: CLRPD Rep. 2, I-95; Appended: Sub. Res. 305 and Reaffirmation A-00; Reaffirmed: CME Rep. 2, A-10; Reaffirmation I-11) H-255.994, Physician Exemption from Medical School Standards and Performance Rescind item 2, which is covered in the **Evaluation Requirements** new policy: "(1) The AMA recommends to medical (1) The AMA recommends to medical licensing boards that those physicians who licensing boards that those physicians are foreign medical graduates currently duly licensed by any licensing jurisdiction who are foreign international medical graduates currently duly licensed by any in the US should not be denied endorsement of their licenses, or denied admission to reexamination when this is required by law, solely because they are unable to licensing jurisdiction in the US should not provide documentation of graduation from a school meeting "equivalent standards be denied endorsement of their licenses, and performance evaluation requirements" to those of programs accredited by the or denied admission to reexamination Liaison Committee on Medical Education. (2) The AMA encourages licensing when this is required by law, solely boards, in reviewing applications for licensure endorsement, to take into account a because they are unable to provide physician's ethical standards and his or her having practiced medicine of an documentation of graduation from a acceptable quality. (Sub. Res. 108, A-83; Reaffirmed: CLRPD Rep. 1, I-93; school meeting "equivalent standards and Reaffirmed: CME Rep. 2, A-05) performance evaluation requirements" to those of programs accredited by the Liaison Committee on Medical Education. (2) The AMA encourages licensing boards, in reviewing applications for licensure endorsement, to take into account a physician's ethical standards and his or her having practiced medicine of an acceptable quality." H-255.995, International Medical Graduates Rescind; covered in new policy. The AMA believes that reduced requirements for licensure should not be applied under any circumstances to graduates of foreign medical schools. (Res. 23, A-82; Reaffirmed: CLRPD Rep. A, I-92; Modified: CME Rep. 5, A-04; Reaffirmed: CME Rep. 2, A-14) H-275.928, Arbitrary Exclusion of International Medical Schools Which Impacts Rescind; covered in new policy. Physician Licensure Our AMA opposes the practice by state medical boards of creating arbitrary and non criterion-based lists of approved or unapproved international medical schools. (Res. 310, A-05; Reaffirmed: CME Rep. 11, A-10) H-275.935, Licensure of IMGs Rescind; covered in new policy. Our AMA asks the Federation of State Medical Boards to ask all the state licensing boards to adopt a uniform standard governing the allowed number of administrations of the licensure examinations. (Res. 314, A-99; Reaffirmed: CME Rep. 2, A-09) H-275.955, Physician Licensure Legislation Rescind item 1; covered in new policy: "Our AMA (1) reaffirms its policies Our AMA (1) reaffirms its policies opposing discrimination against physicians on opposing discrimination against the basis of being a graduate of a foreign medical school and supports state and physicians on the basis of being a territory responsibility for admitting physicians to practice; and (2) reaffirms earlier graduate of a foreign medical school and policy urging licensing jurisdictions to adopt laws and rules facilitating the supports state and territory responsibility movement of physicians between states, to move toward uniformity in requirements for admitting physicians to practice; and (2) reaffirms earlier policy urging for the endorsement of licenses to practice medicine, and to base endorsement of medical licenses on an assessment of competence rather than on passing a written licensing jurisdictions to adopt laws and examination of cognitive knowledge. (CME Rep. B, A-90; Reaffirmation A-00; rules facilitating the movement of Reaffirmed: CME Rep. 2, A-10; Reaffirmed: CME Rep. 11, A-10; Reaffirmed: physicians between states, to move BOT Rep. 3, I-14) toward uniformity in requirements for the endorsement of licenses to practice medicine, and to base endorsement of medical licenses on an assessment of competence rather than on passing a written examination of cognitive knowledge."

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H-275.985, Graduate Medical Education Requirement for Medical Licensure

The AMA reaffirms its policy that all applicants for full and unrestricted licensure should be required to provide evidence of satisfactory completion of at least one year of an accredited program of graduate medical education in the US. (CME Rep. E, I-85; Reaffirmed by CLRPD Rep. 2, I-95; Reaffirmed: CME Rep. 2, A-05)

D-275.976, Arbitrary Exclusion of International Medical Schools Which Impacts Physician Licensure

Our AMA will, in close consultation with its IMG Section, work with the Federation of State Medical Boards in its current efforts to study methods to evaluate international medical schools for licensure of their graduates. (Res. 310, A-05)

Rescind; already reflected in H-255.988 (15), Report of the Ad Hoc Committee on Foreign Medical Graduates, as well as H-275.934 (2), Alternatives to the Federation of State Medical Boards Recommendations on Licensure.

Rescind; covered in new policy.

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- Federation of State Medical Boards, Policy 150.004 Setting Higher Standards for Unrestricted Licensure. April 2013. Available at: fsmb.org/Media/Default/PDF/FSMB/Advocacy/GRPOL_Public_Policy_compendium.pdf (page 11). Accessed February 16, 2015.
- 3 Position of the Federation of State Medical Boards In Support of Postgraduate Training and Licensure Standards. Available at: fsmb.org/Media/Default/PDF/FSMB/Advocacy/1998_grpol_Postgraduate_Training_Licensure.pdf. Accessed February 16, 2015.
- 4 Norcini et al. Evaluating The Quality Of Care Provided By Graduates Of International Medical Schools. *Health Affairs*. 29, No. 8 (2010): 1461–1468. Available at: at: content.healthaffairs.org/content/29/8/1461.full. Accessed March 11, 2015.

26. UNCOUPLING OF CPT FROM ICD-10 (RESOLUTION 206-A-14)

Reference committee hearing: see report of <u>Reference Committee B</u>.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS

IN LIEU OF RESOLUTION 206-A-14 AND REMAINDER OF REPORT FILED

See Policy D-70.947

INTRODUCTION

At its 2014 Annual Meeting, the House of Delegates adopted Policy D-70.949, "Stop the Implementation of ICD-10." In doing so, however, a portion of the underlying resolution, which had been introduced by Oklahoma, was referred. The referred language recommended for the Comptroller General of the Government Accountability Office (GAO) to address uncoupling the International Classification of Diseases (ICD) diagnosis code system from the Current Procedural Terminology (CPT®) procedures and services coding systems. That proposal was referred for further review.

This Board of Trustees (BOT) report will address the question of feasibility of uncoupling the ICD code system from the procedure codes that are used to determine physician payments. The report will provide an overview of the GAO's recent report on the International Classification of Diseases, Tenth Revision (ICD-10), the health care reimbursement system, and the quality measurement system.

ADVOCACY ON ICD-10

The AMA has worked vigorously to stop the implementation of ICD-10 since the passage of Policy D-70.952 in November 2011. In 2012, following letters the AMA sent to Congress and the Secretary of Health and Human Services (HHS), HHS initiated a regulatory change to delay the ICD-10 implementation date until October 1, 2014. The AMA published in February 2014 a study it funded on the updated costs for physician practices to implement ICD-10. The findings show that, in some cases, costs are nearly three times what had been predicted in the 2008

study. Using this updated data, the AMA sent another letter to HHS expressing its concerns with the implementation of ICD-10 and the likely disastrous financial implications of it on physicians.

Legislation signed into law last March that implemented the 17th patch to the Medicare physician payment formula included another delay in the ICD-10 mandate—with implementation now set for October 1, 2015.

The implementation of ICD-10 continues to be a divisive issue. While many physicians have concerns about the costs and burden of ICD-10, there are some physicians and other stakeholders, including government agencies, researchers, large payers, large health system providers and public health entities, that support the conversion. The AMA has continued to voice its concerns to HHS and Congress on a wide variety of ICD-10 implementation issues, including reducing the burden on physician practices and the need for more appropriate testing, additional education, and adequate contingency plans.

GAO REPORT

On February 6, 2015, the GAO released a report titled "CMS's Efforts to Prepare for the New Version of the Disease and Procedure Codes." The scope of the report is an evaluation of the Center for Medicare and Medicaid Services' (CMS) activities to support the ICD-10 transition and describe stakeholders' concerns and recommendations related to CMS' activities. The report concludes that CMS has taken multiple steps to prepare the industry for the October 1, 2015 deadline; Medicare's fee-for-service claims processing systems have been updated; and CMS has worked with state Medicaid agencies to ensure they are ready, but many states have remaining work to complete with testing.

Overall, the report was fairly favorable of CMS' efforts to ensure a successful transition to ICD-10; however, the AMA's concerns to reduce the number of codes, delay implementation until other regulations are implemented, and for Medicare to adopt a two-year implementation period were not considered in this report.

CMS ICD-10 TESTING

Despite the conclusions of the GAO report, the AMA and 99 state and specialty societies sent a letter to CMS in early March 2015 to address several of their concerns about the potential impact of the transition to the ICD-10 code set. The groups stated that there are not sufficient contingency plans in place to avoid anticipated failures that could result in a significant, multi-billion dollar disruption for physicians and serious access to care issues for Medicare patients.

CMS recently released end-to-end testing results showing that the claims acceptance rate would fall from 97 percent to 81 percent if ICD-10 was implemented at that time. That change in Medicare's acceptance rate could potentially cause a catastrophic backlog of millions of unpaid Medicare claims. Because the testing represents less than one percent of all Medicare claims and likely involved providers who are significantly more prepared for ICD-10 than many of their peers, the acceptance rate could actually be much worse and result in the rejection of nearly one in five of the millions of claims that go through our complex health care system each day. Robust contingency plans must be ready on day one of the ICD-10 switchover to reduce unnecessary administrative tasks that take valuable time and resources away from patient care.

The groups also called on CMS to consider how the transition to ICD-10 will impact quality reporting programs such as the Physician Quality Reporting System (PQRS) and Meaningful Use (MU). Because PQRS and MU quality reporting periods are based on the calendar year and the switch to ICD-10 will be occurring more than three quarters of the year in, the quality measures for 2015 will be reported and tabulated with both ICD-9 and ICD-10 codes. This will especially be problematic for measures that capture encounters pre and post visit for services that straddle the October 1st transition deadline where physicians will be required to report ICD-9 for the first segment of care and ICD-10 for the final.

The letter expressed concerns that the administration is underestimating the impact the transition to ICD-10 will have on the regulatory tsunami that is already burdening physicians and threatening access to quality care. Despite the training, educational tools and other efforts by CMS to prepare physicians for the ICD-10 transition, it is clear that more information is needed about how the shift will impact quality reporting so physicians can avoid penalties.

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HEALTH CARE REIMBURSEMENT SYSTEM

The US health care reimbursement system inextricably links a patient's diagnosis, coded with ICD, to the service or procedure provided, most frequently coded with the Healthcare Common Procedure Coding System (HCPCS) or the ICD procedure code set for hospital inpatient procedures. The patient's diagnosis is the underpinning of reimbursement for the service provided both in the established fee-for-service model and in new alternative payment models. Health care payers use the diagnosis to identify services covered, which then leads to identifying reimbursement rates for those services.

In the fee-for-service model, health plans, employers, and other entities establishing health care insurance coverage determine the services and care that are covered or not covered by the policy. Health care payers then identify that a service is a covered benefit based on the patient's diagnosis. For example, cosmetic surgery is often a non-covered service by health plans, except when medically necessary. A patient's diagnosis of bilateral breast cancer establishes that breast implants billed under the procedure coding system are in fact medically necessary and thus covered by insurance. A patient's diagnosis of glaucoma identifies that a vision service is covered under the medical insurance instead of vision insurance.

After establishing that a service is a covered benefit, the health care payer processes the claim for reimbursement. The diagnosis code included in the claim supports the medical necessity for the service or level of service provided. The need for a patient's foot exam is supported by the diagnosis of diabetes. A patient with diagnoses of hypertension, diabetes, and renal failure explain the higher level of service billed.

Alternative payment models are becoming more prevalent. CMS announced in January 2015 that HHS has set a goal that 30 percent of Medicare payments will be in alternative payment models by the end of 2016 and 50 percent by the end of 2018. In alternative payment models, reimbursement is based on negotiated rates between the payer and physicians and other health care providers for specific conditions or discrete events, e.g., care for end-stage renal disease, hip replacement, cardiac procedure, etc. The diagnosis code included on the claim is necessary to identify that the service is an episode of care included in the payment model.

Without a diagnosis code included in the claim, payers would be unable to quickly and efficiently identify that a service is covered under the patient's insurance plan and that the service provided was medical necessary. Payers would likely hold the processing of a claim and request documentation from the physician, which would be burdensome, costly, and inefficient for both physicians and payers.

QUALITY MEASUREMENT SYSTEM

Various health care services have been, for over a decade and increasingly more today, measured for quality purposes. Aspects of pay-for-performance have become established in current reimbursement and care delivery systems. The basis of quality measurement relies on the patient's diagnosis. The diagnosis establishes if the patient is included or not included in a specific population. The diagnosis and inclusion in a population drives the expected care for the patient based on established care guidelines, such as the measurement of hemoglobin A1c for all patients with diabetes or control of blood pressure in patients with hypertension. The majority of quality measurement data is collected through claims data where the patient's diagnosis can be linked to the service provided.

CONCLUSION

Today's reimbursement system and future efforts in alternative payment models and pay-for-performance require pairing a patient's diagnosis to the service provided. Because of this, it would not be feasible to uncouple the diagnosis coding system from the services and procedures coding system.

RECOMMENDATION

The Board of Trustees recommends that that the Comptroller General of the Government Accountability Office not address uncoupling the ICD diagnosis code from the CPT procedure code at the present time but this may be reconsidered in the future if new mechanisms are developed for payment of physician services and that the remainder of this report filed.

27. AMA PARTICIPATION IN REDUCING MEDICAL SCHOOL DEBT UPDATE

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

AMA Policy D-305.956, "AMA Participation in Reducing Medical School Debt," adopted at the 2014 Annual Meeting asked:

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

Based on the work plan outlined in Board of Trustees Report 4-I-14, our AMA considered and evaluated all viable options for student debt consolidation and origination. Discussions are underway with a vendor that if successful would establish an affinity relationship that would provide for a hosted program platform that will be competitive within the banking industry for the refinancing of student loans for medical students, residents and young physicians. This type of solution achieves the intent of the policy. We hope to have a program ready to be announced and launched to AMA members mid- to late-summer of 2015.

28. ANNUAL UPDATE ON ACTIVITIES AND PROGRESS IN TOBACCO CONTROL: MARCH 2014 - FEBRUARY 2015

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

This report summarizes American Medical Association (AMA) activities and progress in tobacco control from March 2014 through February 2015 and is written pursuant to AMA Policy D-490.983 "Annual Tobacco Report."

TOBACCO USE IN THE UNITED STATES: CDC MORBIDITY AND MORTALITY WEEKLY REPORTS

The Centers for Disease Control and Prevention (CDC) released 13 Morbidity and Mortality Weekly Reports (MMWR) in 2014-15 related to tobacco use. Among the topics were smoking rates, clinical intervention for youth cessation, EHR usage and increases in adult cessation, disparities associated with secondhand smoke exposure, restrictions of electronic nicotine delivery systems (ENDS) and smokefree home rules.

Smoking Rates Still a Concern Despite Declines

Tobacco use remains the leading preventable cause of disease and death in the United States, and nearly all tobacco use begins during youth and young adulthood. Two MMWR reports focused on smoking rates in youth and adults.

The November 14, 2014 MMWR released data from the National Youth Tobacco Survey which is a cross-sectional, school-based questionnaire administered to US middle school (grades 6–8) and high school (grades 9–12) students. Among US youth, cigarette smoking has declined in recent years; however, the use of some other tobacco products has increased and nearly half of tobacco users use two or more tobacco products. These products include cigarettes, cigars, hookahs, smokeless tobacco, electronic cigarettes, pipes, snus, bidis, kreteks, and dissolvable tobacco. In 2009, 23.9 percent of high school students and 8.2 percent of middle school students reported current tobacco use. In 2013 the rate was 22.9 percent and 6.5 percent respectively. Cigars were cited as the second most used tobacco product next to cigarettes with a little more than 12 percent of high school students reporting current cigar usage. Among middle school students, 3.1 percent reported current use of cigars, and non-Hispanic black students are more than twice as likely to report current use of cigars as cigarettes. The policy recommendations include funding for

comprehensive tobacco control programs at the state and federal levels, ongoing surveillance of emerging tobacco products and FDA regulation of e-cigarettes focused on manufacturing and marketing.

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http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a2.htm?s cid=mm6345a2 w

The November 28, 2014 MMWR analyzed data from the National Health Interview Survey which is an annual, nationally representative, in-person survey of the US adult population. Current cigarette smoking among US adults declined from 20.9 percent (an estimated 45.1 million persons) in 2005 to 17.8 percent (42.1 million) in 2013. Cigarette smoking prevalence was higher among certain subpopulations, including adults who are male, younger, multiracial or American Indian/Alaska Native, have less education, live below the federal poverty level, live in the South or Midwest, have a disability/limitation, or are lesbian, gay or bisexual. According to the authors, these disparities underscore the importance of enhancing the implementation and reach of proven strategies to prevent and reduce tobacco use among these groups, as well as expanding questions on surveillance tools to better capture data on subpopulations with the greatest burden of tobacco use.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a4.htm

Youth Tobacco Users Not Receiving Assistance From Physicians to Quit Smoking

Approximately 88 percent of adults who smoke daily began smoking by the age of 18 years. Although tobacco cessation is beneficial at any age, intervening as early as possible is important to maximize potential health benefits. After years of steady progress in decreasing smoking prevalence, decreases in smoking among youth and young adults have slowed in recent years and quit attempts among youth declined. CDC staff led by Ahmed Jamal, MBBS, Office on Smoking and Health, reviewed an analysis of the combined 2004–2010 data from the National Ambulatory Medical Care Survey (NAMCS) for patients aged 11-21 years. NAMCS is a national probability survey of outpatient visits made to office-based physicians that measures health care use with various health care providers. The findings indicate that tobacco use screening occurred during the majority of visits to outpatient physician offices. However, during visits by current tobacco users, only 19.8 percent received any cessation assistance, including counseling, medications, or both. The Public Health Service (PHS) guidelines recommend that clinicians ask children and adolescents about their tobacco use, provide a strong prevention message, and provide adolescent smokers with counseling to help them quit. The authors believe the findings in this report will assist health care providers to develop protocols to improve adherence to the PHS guidelines. This intervention would have a lasting impact on preventing adult tobacco-related health consequences because a large proportion of adolescents and young adults make annual visits to a physician's office.

http://www.cdc.gov/mmwr/preview/mmwrhtml/su6302a11.htm?s_cid=su6302a11_w

EHRs Can Facilitate Smoking Cessation Into Routine Clinical Care

A study by the New York Department of Health and Mental Hygiene (DHMH) concluded that community health centers (CHCs) can improve their treatment of tobacco dependence by utilizing their EHR. According to the authors, EHRs can facilitate clinical smoking cessation interventions in three ways: prompt health care providers to screen for and document tobacco use and intervene; facilitate referral of patients to the state quitline; and increase quit rates. From 2010-2012, DHMH initiated an EHR-based pay-for-improvement initiative in 19 CHCs in New York City to increase smoking status documentation and cessation interventions. At the end of the initiative, the mean proportion of patients who were documented as smokers in CHCs had increased from 24 percent to 27 percent, whereas the mean proportion of documented smokers who received a cessation intervention had increased from 23 percent to 54 percent. The authors determined that public health programs and health systems should consider implementing strategies to equip and train clinical providers to use information technology to increase delivery of cessation interventions.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6341a2.htm?s_cid=mm6341a2_e

Inequities Exist in Secondhand Smoke Exposure

According to the February 5, 2015 MMWR, secondhand smoke (SHS) exposure has declined by half since 1999-2000. Despite the scientific evidence that there is no safe level of exposure to SHS, 58 million persons were still exposed to SHS during 2011–2012, and exposure remains higher among children, non-Hispanic blacks, those living in poverty, and those living in rental apartment units. CDC staff led by David Homa, PhD, MPH, in the CDC Office of Smoking and Health, analyzed data from the 1999–2012 National Health and Nutrition Examination Survey to assess the most recent trends of SHS exposure among nonsmokers aged \geq 3 years. Declines in exposure over time

have been slow and the study concluded that continued efforts to promote and implement comprehensive statewide laws prohibiting smoking in workplaces and public places, and smokefree policies in multiunit housing are critical to protect nonsmokers, especially the most vulnerable.

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http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6404a7.htm?s_cid=mm6404a7_w

States Move to Enact Restrictions on Sales and Use of Electronic Nicotine Delivery Systems (ENDS)

The 2014 Surgeon General's report on the health consequences of smoking indicated that experimentation with and current use of ENDS, including e-cigarettes, has risen sharply among youth and adults in the United States. Youth access to and use of ENDS is of particular concern given the potential adverse effects of nicotine on adolescent brain development. Additionally, ENDS use in public indoor areas exposes non-users to nicotine and other potentially harmful constituents. The December 12, 2014 MMWR examined laws that explicitly prohibit: 1) sales of ENDS to minors; and 2) use of ENDS in indoor public places and worksites. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6349a1.htm

Smokefree Home Policies Increase

To assess progress toward increasing the proportion of households with smokefree home rules, CDC analyzed the most recent data from the Tobacco Use Supplement to the Current Population Survey. The analysis found that the national prevalence of smokefree home rules increased from 43 percent during 1992–1993 to 83 percent during 2010–2011. Over the same period, the national prevalence of smokefree home rules increased from 56.7 percent to 91.4 percent among households with no adult cigarette smokers and from 9.6 percent to 46.1 percent among households with at least one adult smoker. Making homes completely smokefree reduces secondhand smoke exposure among nonsmokers, particularly children, and can help adult smokers quit.

Although substantial progress has been made in increasing the prevalence of smokefree home rules, fewer than half of households with smokers have adopted such rules leaving nonsmoking family members and roommates exposed. The only effective way to eliminate this exposure is by creating 100 percent smokefree indoor environments. To encourage this, efforts are warranted to educate the public about the dangers of SHS and to promote the adoption of smokefree home rules, particularly among subpopulations at greatest risk for exposure, such as those living in households with smokers and in multi-unit housing.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6335a1.htm?s_cid=mm6335a1_w

AMA TOBACCO CONTROL ACTIVTIES

AMA Submits Comments on FDA Deeming Rules

On April 24, 2014, the US Food and Drug Administration (FDA) released its proposed deeming rule that would hold products meeting the statutory definition of "tobacco product" to the same regulatory standards of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

The FDA announced its intent to publish the deeming rules in 2011 but it took three years for them to send the rules to the White House Office of Management and Budget. The AMA was one of many public health organizations concerned about this delay in releasing the proposed rules for public comment.

The AMA comments expressed support for the FDA's intent to protect consumers, especially children, from tobacco products that include enticing flavors which are marketed in ways that misrepresent their harmful nature. The AMA also outlined where the rules needed to be strengthened to align with the FDA's intent. These included cigar sales and marketing, e-cigarettes and characterizing flavors in all tobacco products.

The AMA joined with public health groups and other medical and health care organizations in urging the FDA to accelerate the review process and issue a final deeming rule within one year of publishing its Proposed Rule. Continuing to delay action provides the tobacco industry with wide reign in designing, marketing and selling tobacco products. It is unclear why the FDA has not published a final rule. This continued delay subjects more children and youth to unregulated marketing and advertising, leaves smokers confused about the risks associated with e-cigarettes, and exposes nonsmokers to toxic chemicals from e-cigarette vapors.

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AMA Releases Update of 2010 E-Cigarettes Report

When the AMA Council on Science and Public Health released its first report on electronic cigarettes in 2010, the market was in its infancy and the primary public health concern was on the manufacturers' practice of marketing to smokers as a proven cessation device and of the potential health consequences of exposure to the vapor. Since then, tobacco companies have entered the market and have engaged in the deceptive promotional practices previously used to market their tobacco products to youth, minorities, women and young adults. The updated report informed development of a hard hitting AMA policy H-495.973, which calls for stronger regulations over e-cigarette sales, marketing and manufacturing including the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes. The policy also supports restrictions on product claims of reduced risk or effectiveness as tobacco cessation tools, until credible evidence is available, evaluated, and supported by the FDA and prohibits the use of characterizing flavors enhance the appeal of such products to youth.

Collaborations

The AMA is a member of a national tobacco control partnership that includes public health and advocacy organizations, as well as medical specialty societies. Among the activities this partnership engaged in 2014 was support for eliminating the use of smokeless tobacco at baseball venues. In June 2014, following the death of Baseball Hall of Famer Tony Gwynn, who died from cancer associated with his use of chewing tobacco, the AMA was one of the signatories on a letter to Bud Selig, Commissioner of Major League Baseball, and Tony Clark, Executive Director of Major League Baseball Players Association, calling on them to agree to a prohibition on tobacco use at ballparks and on camera. Recent studies by CDC show an increase in use of smokeless tobacco products by youth. Use of smokeless tobacco by baseball players and coaches sets a terrible example for the millions of young people who watch baseball at the ballpark or on television.

29. SPECIALTY SOCIETY REPRESENTATION IN THE HOUSE OF DELEGATES: FIVE YEAR REVIEW

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

See Policy D-600.984

The Board of Trustees (BOT) has completed its review of the specialty organizations seated in the House of Delegates (HOD) scheduled to submit information and materials for the 2015 American Medical Association (AMA) Annual Meeting in compliance with the five-year review process established by the House of Delegates in Policy G-600.020 and AMA Bylaw 8.5.

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

The following organizations were reviewed for the 2015 Annual Meeting:

American Academy of Disability Evaluating Physicians

American Academy of Otolaryngic Allergy

American College of Chest Physicians

American College of Legal Medicine

American College of Mohs Surgery

American College of Phlebology

American College of Physicians

American College of Preventive Medicine

American College of Radiology

American College of Surgeons

American Congress of Obstetricians and Gynecologists American Society of Hematology American Society of Retina Specialists Heart Rhythm Society International Society of Hair Restoration Surgery Society of Hospital Medicine Undersea and Hyperbaric Medical Society

The American College of Chest Physicians and the American Hematology Society were reviewed at this time because they failed to meet the requirements of the review in 2014.

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

The materials submitted indicate that the: American Academy of Disability Evaluating Physicians, American Academy of Otolaryngic Allergy, American College of Chest Physicians, American College of Legal Medicine, American College of Mohs Surgery, American College of Phlebology, American College of Physicians, American College of Preventive Medicine, American College of Radiology, American College of Surgeons, American Congress of Obstetricians and Gynecologists, American Society of Retina Specialists, Society of Hospital Medicine, and Undersea and Hyperbaric Medical Society meet all guidelines and are in compliance with the five-year review requirements of specialty organizations represented in the HOD.

The materials submitted also indicate that the American Society of Hematology, Heart Rhythm Society, and International Society of Hair Restoration Surgery do not meet the membership requirements for specialty organizations represented in the HOD, and therefore, are not in compliance with the five-year review requirements.

RECOMMENDATIONS

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

- 1. That the American Academy of Disability Evaluating Physicians, American Academy of Otolaryngic Allergy, American College of Chest Physicians, American College of Legal Medicine, American College of Mohs Surgery, American College of Phlebology, American College of Physicians, American College of Preventive Medicine, American College of Radiology, American College of Surgeons, American Congress of Obstetricians and Gynecologists, American Society of Retina Specialists, Society of Hospital Medicine, and Undersea and Hyperbaric Medical Society retain representation in the American Medical Association House of Delegates.
- 2. That the Heart Rhythm Society, the International Society for Hair Restoration Surgery and the American Society of Hematology be given a grace period of one year to meet the membership requirements to retain their position in the American Medical Association House of Delegates.

APPENDIX

Organization

Exhibit A - Summary Membership Information

Exilion 11 Summary Memoership information

American College of Physicians

American Academy of Disability Evaluating Physicians American Academy of Otolaryngic Allergy American College of Chest Physicians American College of Legal Medicine American College of Mohs Surgery American College of Phlebology AMA Membership of Organization's Total Eligible Membership

> 244 of 840 (29%) 337 of 1,173 (29%) 2,132 of 13,371 (16%) 125 of 423 (30%) 297 of 1,186 (25%) 342 of 1,272 (27%) 20,592 of 89,118 (23%)

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American College of Preventive Medicine 577 of 2.184 (26%) American College of Radiology 6,524 of 31,773 (20%) American College of Surgeons 9,538 of 43,326 (22%) American Congress of Obstetricians and Gynecologists 11,385 of 44,843 (25%) American Society of Hematology 936 of 6,286 (15%) American Society of Retina Specialists 577 of 1,870 (30%) Heart Rhythm Society 496 of 2,983 (17%) International Society of Hair Restoration Surgery 86 of 377 (26%) Society of Hospital Medicine 1,358 of 9,279 (15%) Undersea and Hyperbaric Medical Society 188 of 824 (23%)

Exhibit B - Summary of Guidelines for Admission to the House (Policy G-600.020)

Specialty Societies

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

Exhibit C

- 8.2 Responsibilities of National Medical Specialty Societies and Professional Interest Medical Associations. Each national medical specialty society and professional interest medical association represented in the House of Delegates shall have the following responsibilities:
 - 8.2.1 To cooperate with the AMA in increasing its AMA membership.
 - 8.2.2 To keep its delegate(s) to the House of Delegates fully informed on the policy positions of the society or association so that the delegates can properly represent the society or association in the House of Delegates.
 - 8.2.3 To require its delegate(s) to report to the society on the actions taken by the House of Delegates at each meeting.

8.2.4 To disseminate to its membership information as to the actions taken by the House of Delegates at each meeting.

8.2.5 To provide information and data to the AMA when requested.

Exhibit D – AMA Bylaws on Specialty Society Periodic Review

- 8 Representation of National Medical Specialty Societies and Professional Interest Medical Associations in the House of Delegates
 - 8.5 Periodic Review Process. Each specialty society and professional interest medical association represented in the House of Delegates must reconfirm its qualifications for representation by demonstrating every 5 years that it continues to meet the current guidelines required for granting representation in the House of Delegates, and that it has complied with the responsibilities imposed under Bylaw 8.2. The SSS may determine and recommend that societies currently classified as specialty societies be reclassified as professional interest medical associations. Each specialty society and professional interest medical association represented in the House of Delegates must submit the information and data required by the SSS to conduct the review process. This information and data shall include a description of how the specialty society or the professional interest medical association has discharged the responsibilities required under Bylaw 8.2.
 - 8.5.1 If a specialty society or a professional interest medical association fails or refuses to provide the information and data requested by the SSS for the review process, so that the SSS is unable to conduct the review process, the SSS shall so report to the House of Delegates through the Board of Trustees. In response to such report, the House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates by majority vote of delegates present and voting, or may take such other action as it deems appropriate.
 - 8.5.2 If the SSS report of the review process finds the specialty society or the professional interest medical association to be in noncompliance with the current guidelines for representation in the House of Delegates or the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will have a grace period of one year to bring itself into compliance.
 - 8.5.3 Another review of the specialty society's or the professional interest medical association's compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2 will then be conducted, and the SSS will submit a report to the House of Delegates through the Board of Trustees at the end of the one-year grace period.
 - 8.5.3.1 If the specialty society or the professional interest medical association is then found to be in compliance with the current guidelines for representation in the House of Delegates and the responsibilities under Bylaw 8.2, the specialty society or the professional interest medical association will continue to be represented in the House of Delegates and the current review process is completed.
 - 8.5.3.2 If the specialty society or the professional interest medical association is then found to be in noncompliance with the current guidelines for representation in the House of Delegates, or the responsibilities under Bylaw 8.2, the House may take one of the following actions:
 - 8.5.3.2.1 The House of Delegates may continue the representation of the specialty society or the professional interest medical association in the House of Delegates, in which case the result will be the same as in Bylaw 8.5.3.1.
 - 8.5.3.2. The House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates. The specialty society or the professional interest medical association shall remain a member of the SSS, pursuant to the provisions of the Standing Rules of the SSS. The specialty society or the professional interest medical association may apply for reinstatement in the House of Delegates, through the SSS, when it believes it can comply with all of the current guidelines for representation in the House of Delegates.
 - 8.6 Discontinuance of Representation. A specialty society or a professional interest medical association that has been granted representation in the House of Delegates will automatically have its representation terminated if it is not represented by a properly certified and seated delegate at 3 of 5 consecutive meetings of the House of Delegates. The specialty society or the professional interest medical association may continue as a member of the SSS pursuant to the provisions of the Standing Rules of the SSS, and may apply for representation in the House of Delegates after 3 additional years as a member of the SSS, under all of the provisions for a new application.

Speakers' Report June 2015

REPORT OF THE SPEAKERS

The following report was presented by Andrew W. Gurman, MD, Speaker; and Susan R. Bailey, MD, Vice Speaker:

RECOMMENDATIONS FOR POLICY RECONCILIATION

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Recommended actions accomplished

In accord with American Medical Association (AMA) Policy <u>G-600.111</u>, your Speakers present this report dealing with inconsistencies and obsolete language in AMA policy.

RECOMMENDED RECONCILIATIONS

Death Certificate Coding

In reviewing actions taken at House of Delegates (HOD) meetings in 2014, we uncovered a glaring inconsistency in policies dealing with ICD-10. At the Annual Meeting, a number of existing policy statements on death certificates were consolidated into new Policy <u>H-85.953</u>, Improving Death Certification Accuracy and Completion, which reads:

- 1. Our AMA: (A) acknowledges that the reporting of vital events is an integral part of patient care; (B) urges physicians to ensure completion of all state vital records carefully and thoroughly with special attention to the use of standard nomenclature, using legible writing and accurate diagnoses; and (C) supports notifying state medical societies and state departments of vital statistics of this policy and encouraging their assistance and cooperation in implementing it.
- 2. Our AMA also: (A) supports the position that efforts to improve cause of death statistics are indicated and necessary; (B) endorses the concept that educational efforts to improve death certificates should be focused on physicians, particularly those who take care of patients in facilities where patients are likely to die, namely in acute hospitals, nursing homes and hospices; and (C) supports the concept that training sessions in completion of death certificates should be (i) included in hospital house staff orientation sessions and clinical pathologic conferences; (ii) integrated into continuing medical education presentations; (iii) mandatory in mortality conferences; and (iv) included as part of in-service training programs for nursing homes, hospices and geriatric physicians.
- 3. Our AMA further: (A) promotes and encourages the use of ICD-10-CM codes among physicians as they complete medical claims, hospital discharge summaries, death certificates, and other documents; (B) supports cooperating with the National Center for Health Statistics (NCHS) in monitoring the four existing models for collecting tobacco-use data; (C) urges the NCHS to identify appropriate definitions, categories, and methods of collecting risk-factor data, including quantification of exposure, for inclusion on the U.S. Standard Certificates, and that subsequent data be appropriately disseminated; and (D) continues to encourage all physicians to report tobacco use, exposure to environmental tobacco smoke, and other risk factors using the current standard death certificate format.

Insofar as our AMA has articulated myriad reservations about the adoption of ICD-10 (see, for example, Policy D-70.949, Stop the Implementation of ICD-10, also adopted at the 2014 Annual Meeting, as well as Policies H-70.916, D-70.952, D-70.948 and D-70.951), the specific language of part A of paragraph 3 of Policy H-85.953 referring to ICD-10-CM will be changed, making the reference simply "ICD codes" and leaving the remainder of Policy H-85.953 intact. Paragraph 3 of the revised policy will read:

3. Our AMA further: (A) promotes and encourages the use of ICD codes among physicians as they complete medical claims, hospital discharge summaries, death certificates, and other documents;...

The language to be changed dates from the 1998 Interim Meeting, long before the complexities and obstacles of moving to ICD-10 had been recognized. The revised policy, however, maintains support for the use of proper coding, without addressing a particular version of the ICD.

Policies Dealing with AMA Publications

In our report at the last Interim Meeting, we noted that the bylaws (§1.1.1.4) still reference American Medical News. The Council on Constitution and Bylaws has brought forward a report to delete the offending language, but a number of policy statements still make reference to AMNews and other defunct vehicles or contain outdated references to the "Archives journals." This report will delete references to AMNews in three policies and insert current language for the former Archives journals in two policies. These are editorial changes, with additions underscored and deletions shown with strikethrough; paragraphs will be renumbered as necessary.

D-165.946, Presidential Candidates' Views on Health System Reform

Our AMA will use its communications vehicles such as AMNews, AMA Voice and the AMA Web site website, to publicize the health care positions of the major US Presidential candidates and encourage physicians to become more informed voters.

<u>G-630.100</u>, Conservation, Recycling and Other "Green" Initiatives

AMA policy on conservation and recycling includes the following: (1) Our AMA directs its offices to implement conservation-minded practices whenever feasible and to continue to participate in "green" initiatives. (2) It is the policy of our AMA to use recycled paper whenever reasonable for its in-house printed matter and publications, including AMNews, JAMA and materials used by the House of Delegates, and that AMA printed material using recycled paper should be labeled as such. (3) During meetings of the American Medical Association House of Delegates, our AMA sections, and all other AMA meetings, recycling bins, where and when feasible, for white (and where possible colored) paper will be made prominently available to participants.

G-630.090, AMA Publications

AMA policy on its publications includes the following: (1) *JAMA* and other AMA scientific journals should display a disclaimer in prominent print that the editorial views are not necessarily AMA policy. (2) Our AMA continues to support AMNews and a disclaimer in prominent print be displayed that it does not reflect official AMA policy. (3) Our AMA, in all of its publications and correspondence, will use the correct title for the medical specialist. (4) Our AMA recommends that medical journal articles using acronyms should have a small glossary of acronyms and phrases displayed prominently in the article. (5) The House of Delegates affirms that *JAMA* and the Archives The JAMA Network journals shall continue to have full editorial independence as set forth in the AMA Editorial Governance Plan.

H-405.968, Clarification of the Term "Provider" in Advertising, Contracts and Other Communications

1. Our AMA supports requiring that health care entities, when using the term "provider" in contracts, advertising and other communications, specify the type of provider being referred to by using the provider's recognized title which details education, training, license status and other recognized qualifications; and supports this concept in state and federal health system reform. 2. Our AMA: (a) considers the generic terms "health care providers" or "providers" as inadequate to describe the extensive education and qualifications of physicians licensed to practice medicine in all its branches; (b) will institute an editorial policy prohibiting the use of the term "provider" in lieu of "physician" or other health professionals for all AMA publications not otherwise covered by the existing *JAMA* Editorial Governance Plan, which protects editorial independence of the Editor in Chief of *JAMA* and the Archives The JAMA Network journals; and (c) will forward to the editorial board of *JAMA* the recommendation that the term "physician" be used in lieu of "provider" when referring to MDs and DOs.

The changes outlined above will be implemented when this report is filed.