

REPORTS OF THE BOARD OF TRUSTEES

The following reports, 1–9, were presented by Barbara L. McAneny, MD, Chair:

1. PAP TESTING GUIDELINES: HEDIS VERSUS USPSTF (RESOLUTION 118-A-13)

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 118-A-13 AND REMAINDER OF REPORT FILED

See Policies [H-410.953](#) and [H-450.947](#).

Resolution 118-A-13, introduced by the Michigan Delegation and referred by the House of Delegates, asked:

That our American Medical Association (AMA) urge third party payers not to withhold payment to physicians for preventive health services that fall under accepted guidelines, even if they differ from the payer's own guidelines.

At the time the resolution was introduced, clinical guidelines for cervical cancer screening by cytology (Pap smear), developed by several medical specialty societies and by the United States Preventive Services Task Force (USPSTF), were inconsistent with the Health Effectiveness Data and Information Set (HEDIS) cervical cancer screening measures. The intent of the resolve was to urge health insurers using HEDIS measures as a benchmark for performance not to penalize physicians who were following clinical guidelines for cervical cancer screening by withholding quality incentive payments. Referral was based on the reference committee's belief that the term "accepted guidelines" was not well defined. This report briefly reviews the clinical practice guidelines and HEDIS measures for cervical cancer screening, and addresses the widely accepted definition of a "clinical practice guideline."

CLINICAL GUIDELINES FOR CERVICAL CANCER SCREENING

In 2012, the USPSTF;¹ the American Cancer Society (ACS), American Society for Colposcopy and Cervical Pathology (ASCCP), and American Society for Clinical Pathology (ASCP);² and the American College of Obstetricians and Gynecologists (ACOG)³ released updated guidelines on screening for cervical cancer. The guidelines are nearly identical and include the following key points:

- Cervical cancer screening should begin at age 21 years. Women aged younger than 21 years should not be screened regardless of the age of sexual initiation or other risk factors.
- Women aged 21–29 years should be tested with cervical cytology (Pap smear) alone, and screening should be performed every 3 years.
- For women aged 30–65 years, co-testing with cytology and human papillomavirus (HPV) testing every 5 years is preferred; screening with cytology alone every 3 years is acceptable.
- Women aged 65 years and older who have had adequate prior screening and are not otherwise at high risk for cervical cancer should not be screened by any modality.

The aforementioned recommendations apply to women with a cervix regardless of sexual history, but do not apply to women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised and/or HIV-positive.

HEDIS MEASURES

HEDIS is a set of performance measures developed and maintained by the National Committee for Quality Assurance (NCQA).⁴ HEDIS consists of 81 measures across 5 domains of care; the measures are used by more than 90 percent of health insurers to measure performance on quality of care and access to care. HEDIS results can be used to compare health plan performance to other health plans and to national benchmarks, and also to track year-to-

year performance of each plan. Many insurers determine quality incentive payments to physician practices by assessing their performance on a set of HEDIS measures.

The HEDIS measurement set is updated annually by the NCQA's Committee on Performance Measurement, a broad-based group representing employers, consumers, health plans and others. In 2014, the HEDIS measures on cervical cancer screening were updated to reflect the 2012 USPSTF, ACS/ASCCP/ASCP, and ACOG clinical guidelines.⁵ The current measures are:

- The percentage of women 21–65 years of age who were screened with cytology within the past three years and women 30–65 years of age who were screened with cytology/HPV co-testing within the past five years.
- The percentage of adolescent females 16–20 years of age who were not screened for cervical cancer.

Prior to 2014, the HEDIS cervical cancer screening measures did not reflect the recommendation that cytology/HPV co-testing in women ages 21-29 years was inappropriate. This inconsistency formed the basis of the concern expressed in Res 118-A-13. Since the HEDIS measures have been updated, the inconsistency is no longer present. Physicians should not fear that following USPSTF, ACS/ASCCP/ASCP, or ACOG cervical cancer screening guidelines will result in non-payment of quality incentives related to HEDIS cervical cancer screening measures. Further, AMA policy H-450.947 “Pay-for-Performance Principles and Guidelines” states that performance measures must be kept current and reflect changes in clinical practice, and encourages organizations to periodically review and update measures using evidence-based information. (The full text of H-450.947 is found in Appendix I.)

DEFINITION OF CLINICAL PRACTICE GUIDELINE

In 2011, after a multi-year, multi-stakeholder process, the Institute of Medicine (IOM) released a report entitled “Clinical Practice Guidelines We Can Trust.”⁶ As part of the process, the IOM updated its definition of a clinical practice guideline to reflect the methodologically rigorous, transparent, and evidence-based characteristics of clinical practice guidelines, as opposed to other forms of clinical guidance. The definition is: *Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.*

The IOM report also included standards that guidelines-making entities should follow in developing trustworthy clinical practice guidelines. The standards address procedures for transparency (in process and funding), management of conflict of interest, composition of the guideline development group, systematic review requirements, evidence foundations, recommendation articulation, external review, and methods for updating guidelines. (The full set of standards is listed in Appendix II.) The National Guideline Clearinghouse, a database of evidence-based clinical practice guidelines maintained by the Agency for Healthcare Research and Quality, uses the definition of clinical practice guidelines developed by the IOM and has established criteria for inclusion in its database that are based on the IOM standards.⁷

AMA policy H-420.953 “Ethical Considerations in the Development of Medical Practice Guidelines” echoes many of the clinical practice guideline development standards set forth by the IOM. (The full text of H-420.953 is found in Appendix I.) Several other AMA policies support the use of sound science and evidence in the development of clinical practice guidelines, but none explicitly define clinical practice guidelines.

CONCLUSIONS

Since the HEDIS cervical cancer screening measures have been recently updated, there should no longer be concern about inconsistency in the measures compared to the guidelines of several medical specialty societies and the USPSTF. More broadly, the principle that performance measures should be kept current and reflect changes in clinical practice is addressed by policy H-450.947 “Pay-for-Performance Principles and Guidelines.” To underscore the principle that incentive payments should not be withheld from physicians who are following current guidelines, even when measures do not reflect current guidelines, the Board of Trustees recommends an amendment to H-450.947.

AMA policy H-410.953 “Ethical Considerations in the Development of Medical Practice Guidelines” sets out key fundamentals for the development of trustworthy clinical practice guidelines. However, the term “clinical practice guidelines” is not defined in that policy or in other AMA policies. The IOM has developed a widely supported

definition of “clinical practice guidelines,” and the Board of Trustees believes that addition of this definition to AMA policy would provide clarity to AMA policies referring to clinical practice guidelines.

RECOMMENDATIONS

The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 118-A-13:

1. That Policy H-450.947, Pay-for-Performance Principles and Guidelines, be amended by addition in the section entitled “Program Rewards” to read as follows:

H-450.947, Pay-for-Performance Principles and Guidelines

...

Program Rewards

- Programs must be based on rewards and not on penalties.
- Program incentives must be sufficient in scope to cover any additional work and practice expense incurred by physicians as a result of program participation.
- Programs must offer financial support to physician practices that implement IT systems or software that interact with aspects of the PFP program.
- Programs must finance bonus payments based on specified performance measures with supplemental funds.
- Programs must reward all physicians who actively participate in the program and who achieve pre-specified absolute program goals or demonstrate pre-specified relative improvement toward program goals.
- Programs must not reward physicians based on ranking compared with other physicians in the program.
- Programs must provide to all eligible physicians and practices a complete explanation of all program facets, to include the methods and performance measures used to determine incentive eligibility and incentive amounts, prior to program implementation.
- Programs must not financially penalize physicians based on factors outside of the physician’s control.
- Programs utilizing bonus payments must be designed to protect patient access and must not financially disadvantage physicians who serve minority or uninsured patients.
- Programs must not financially penalize physicians when they follow current, accepted clinical guidelines that are different from measures adopted by payers, especially when measures have not been updated to meet currently accepted guidelines.

2. That Policy H-410.953, Ethical Considerations in the Development of Medical Practice Guidelines, be amended by addition and deletion to read as follows:

H-410.953 Ethical Considerations in the Development of ~~Medical~~ Clinical Practice Guidelines

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. ~~Medical~~ Clinical practice guidelines help inform physician judgment and decision making by physicians and patients. Clinical ~~P~~ractice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, clinical practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable. To that end, the development or updating of ~~medical~~ clinical practice guidelines should meet the following expectations: 1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed. 2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations. 3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups. 4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline. 5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest

by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided. 6. Guidelines are subject to rigorous, independent peer review. 7. Clear statements of methodology, conflict of interest policy and procedures, and disclosures of panel members' conflicts of interest relating to specific recommendations are published with any guideline or otherwise made public. 8. Guidelines are in the first instance disseminated independent of support from or participation by individuals or entities that have a direct interest in the recommendations.

REFERENCES

1. Moyer VA, on behalf of the U.S. Preventive Services Task Force. Screening for Cervical Cancer: U.S. Preventive Services Task Force. *Ann Intern Med.* 2012;156:880-91.
2. Saslow D, Solomon D, Lawson HW, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin.* 2012;62(3):147-72.
3. American College of Obstetricians and Gynecologists Committee on Practice Bulletins – Gynecology. *Obstet Gynecol.* 2012;120(5):1222-38.
4. National Committee for Quality Assurance. HEDIS and Performance Measurement. Available at <http://www.ncqa.org/HEDISQualityMeasurement.aspx>. Accessed 7-15-14.
5. National Committee for Quality Assurance. 2014 HEDIS Measures. Available at http://www.ncqa.org/Portals/0/HEDISQM/HEDIS2014/List_of_HEDIS_2014_Measures.pdf. Accessed 7-15-14.
6. Institute of Medicine. *Clinical Practice Guidelines We Can Trust.* 2011. Washington, DC: The National Academies Press.
7. National Guidelines Clearinghouse. Inclusion Criteria. Available at <http://www.guideline.gov/about/inclusion-criteria.aspx>. Accessed 7-15-14.

Appendix I. – Text of policies H-450.947 and H-410.953

H-450.947 Pay-for-Performance Principles and Guidelines

(1) The following Principles for Pay-for-Performance and Guidelines for Pay-for-Performance are the official policy of our AMA.

PRINCIPLES FOR PAY-FOR-PERFORMANCE PROGRAMS

Physician pay-for-performance (PFP) programs that are designed primarily to improve the effectiveness and safety of patient care may serve as a positive force in our health care system. Fair and ethical PFP programs are patient-centered and link evidence-based performance measures to financial incentives. Such PFP programs are in alignment with the following five AMA principles:

1. Ensure quality of care - Fair and ethical PFP programs are committed to improved patient care as their most important mission. Evidence-based quality of care measures, created by physicians across appropriate specialties, are the measures used in the programs. Variations in an individual patient care regimen are permitted based on a physician's sound clinical judgment and should not adversely affect PFP program rewards.
2. Foster the patient/physician relationship - Fair and ethical PFP programs support the patient/physician relationship and overcome obstacles to physicians treating patients, regardless of patients' health conditions, ethnicity, economic circumstances, demographics, or treatment compliance patterns.
3. Offer voluntary physician participation - Fair and ethical PFP programs offer voluntary physician participation, and do not undermine the economic viability of non-participating physician practices. These programs support participation by physicians in all practice settings by minimizing potential financial and technological barriers including costs of start-up.
4. Use accurate data and fair reporting - Fair and ethical PFP programs use accurate data and scientifically valid analytical methods. Physicians are allowed to review, comment and appeal results prior to the use of the results for programmatic reasons and any type of reporting.
5. Provide fair and equitable program incentives - Fair and ethical PFP programs provide new funds for positive incentives to physicians for their participation, progressive quality improvement, or attainment of goals within the program. The eligibility criteria for the incentives are fully explained to participating physicians. These programs support the goal of quality improvement across all participating physicians.

GUIDELINES FOR PAY-FOR-PERFORMANCE PROGRAMS

Safe, effective, and affordable health care for all Americans is the AMA's goal for our health care delivery system. The AMA presents the following guidelines regarding the formation and implementation of fair and ethical pay-for-performance (PFP) programs. These guidelines augment the AMA's "Principles for Pay-for-Performance Programs" and provide AMA leaders, staff and members with operational boundaries that can be used in an assessment of specific PFP programs.

Quality of Care

- The primary goal of any PFP program must be to promote quality patient care that is safe and effective across the health care delivery system, rather than to achieve monetary savings.
- Evidence-based quality of care measures must be the primary measures used in any program.
 1. All performance measures used in the program must be prospectively defined and developed collaboratively across physician specialties.
 2. Practicing physicians with expertise in the area of care in question must be integrally involved in the design, implementation, and evaluation of any program.
 3. All performance measures must be developed and maintained by appropriate professional organizations that periodically review and update these measures with evidence-based information in a process open to the medical profession.
 4. Performance measures should be scored against both absolute values and relative improvement in those values.
 5. Performance measures must be subject to the best-available risk- adjustment for patient demographics, severity of illness, and co-morbidities.
 6. Performance measures must be kept current and reflect changes in clinical practice. Except for evidence-based updates, program measures must be stable for two years.
 7. Performance measures must be selected for clinical areas that have significant promise for improvement.
- Physician adherence to PFP program requirements must conform with improved patient care quality and safety.
- Programs should allow for variance from specific performance measures that are in conflict with sound clinical judgment and, in so doing, require minimal, but appropriate, documentation.
- PFP programs must be able to demonstrate improved quality patient care that is safer and more effective as the result of program implementation.
- PFP programs help to ensure quality by encouraging collaborative efforts across all members of the health care team.
- Prior to implementation, pay-for-performance programs must be successfully pilot-tested for a sufficient duration to obtain valid data in a variety of practice settings and across all affected medical specialties. Pilot testing should also analyze for patient de-selection. If implemented, the program must be phased-in over an appropriate period of time to enable participation by any willing physician in affected specialties.
- Plans that sponsor PFP programs must prospectively explain these programs to the patients and communities covered by them.

Patient/Physician Relationship

- Programs must be designed to support the patient/physician relationship and recognize that physicians are ethically required to use sound medical judgment, holding the best interests of the patient as paramount.
- Programs must not create conditions that limit access to improved care.
 1. Programs must not directly or indirectly disadvantage patients from ethnic, cultural, and socio-economic groups, as well as those with specific medical conditions, or the physicians who serve these patients.
 2. Programs must neither directly nor indirectly disadvantage patients and their physicians, based on the setting where care is delivered or the location of populations served (such as inner city or rural areas).
- Programs must neither directly nor indirectly encourage patient de-selection.
- Programs must recognize outcome limitations caused by patient non-adherence, and sponsors of PFP programs should attempt to minimize non-adherence through plan design.

Physician Participation

- Physician participation in any PFP program must be completely voluntary.
- Sponsors of PFP programs must notify physicians of PFP program implementation and offer physicians the opportunity to opt in or out of the PFP program without affecting the existing or offered contract provisions from the sponsoring health plan or employer.
- Programs must be designed so that physician nonparticipation does not threaten the economic viability of physician practices.
- Programs should be available to any physicians and specialties who wish to participate and must not favor one specialty over another. Programs must be designed to encourage broad physician participation across all modes of practice.
- Programs must not favor physician practices by size (large, small, or solo) or by capabilities in information technology (IT).
 1. Programs should provide physicians with tools to facilitate participation.
 2. Programs should be designed to minimize financial and technological barriers to physician participation.
- Although some IT systems and software may facilitate improved patient management, programs must avoid implementation plans that require physician practices to purchase health-plan specific IT capabilities.
- Physician participation in a particular PFP program must not be linked to participation in other health plan or government programs.
- Programs must educate physicians about the potential risks and rewards inherent in program participation, and immediately notify participating physicians of newly identified risks and rewards.

- Physician participants must be notified in writing about any changes in program requirements and evaluation methods. Such changes must occur at most on an annual basis.

Physician Data and Reporting

- Patient privacy must be protected in all data collection, analysis, and reporting. Data collection must be administratively simple and consistent with the Health Insurance Portability and Accountability Act (HIPAA).

- The quality of data collection and analysis must be scientifically valid. Collecting and reporting of data must be reliable and easy for physicians and should not create financial or other burdens on physicians and/or their practices. Audit systems should be designed to ensure the accuracy of data in a non-punitive manner.

1. Programs should use accurate administrative data and data abstracted from medical records.

2. Medical record data should be collected in a manner that is not burdensome and disruptive to physician practices.

3. Program results must be based on data collected over a significant period of time and relate care delivered (numerator) to a statistically valid population of patients in the denominator.

- Physicians must be reimbursed for any added administrative costs incurred as a result of collecting and reporting data to the program.

- Physicians should be assessed in groups and/or across health care systems, rather than individually, when feasible.

- Physicians must have the ability to review and comment on data and analysis used to construct any performance ratings prior to the use of such ratings to determine physician payment or for public reporting.

1. Physicians must be able to see preliminary ratings and be given the opportunity to adjust practice patterns over a reasonable period of time to more closely meet quality objectives.

2. Prior to release of any physician ratings, programs must have a mechanism for physicians to see and appeal their ratings in writing. If requested by the physician, physician comments must be included adjacent to any ratings.

- If PFP programs identify physicians with exceptional performance in providing effective and safe patient care, the reasons for such performance should be shared with physician program participants and widely promulgated.

- The results of PFP programs must not be used against physicians in health plan credentialing, licensure, and certification. Individual physician quality performance information and data must remain confidential and not subject to discovery in legal or other proceedings.

- PFP programs must have defined security measures to prevent the unauthorized release of physician ratings.

Program Rewards

- Programs must be based on rewards and not on penalties.

- Program incentives must be sufficient in scope to cover any additional work and practice expense incurred by physicians as a result of program participation.

- Programs must offer financial support to physician practices that implement IT systems or software that interact with aspects of the PFP program.

- Programs must finance bonus payments based on specified performance measures with supplemental funds.

- Programs must reward all physicians who actively participate in the program and who achieve pre-specified absolute program goals or demonstrate pre-specified relative improvement toward program goals.

- Programs must not reward physicians based on ranking compared with other physicians in the program.

- Programs must provide to all eligible physicians and practices a complete explanation of all program facets, to include the methods and performance measures used to determine incentive eligibility and incentive amounts, prior to program implementation.

- Programs must not financially penalize physicians based on factors outside of the physician's control.

- Programs utilizing bonus payments must be designed to protect patient access and must not financially disadvantage physicians who serve minority or uninsured patients.

(2) Our AMA opposes private payer, Congressional, or Centers for Medicare and Medicaid Services pay-for-performance initiatives if they do not meet the AMA's "Principles and Guidelines for Pay-for-Performance." (BOT Rep. 5, A-05; Reaffirmation A-06; Reaffirmed: Res. 210, A-06; Reaffirmed in lieu of Res. 215, A-06; Reaffirmed in lieu of Res. 226, A-06; Reaffirmation I-06; Reaffirmation A-07; Reaffirmation A-09; Reaffirmed: BOT Rep. 18, A-09; Reaffirmed in lieu of Res. 808, I-10; Modified: BOT Rep. 8, I-11; Reaffirmed: Sub. Res. 226, I-13)

H-410.953 Ethical Considerations in the Development of Medical Practice Guidelines

Medical practice guidelines help inform physician judgment and decision making by physicians and patients. Practice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable. To that end, the development or updating of medical practice guidelines should meet the following expectations: 1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed. 2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations. 3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified

clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups. 4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline. 5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and c) clearly defined strategies for eliminating or mitigating the influence of identified conflicts of interest (such as prohibiting individuals from participating in deliberations, drafting, or voting on recommendations on which they have conflicts) in those limited circumstances when participation by an individual with a conflicting interest cannot be avoided. 6. Guidelines are subject to rigorous, independent peer review. 7. Clear statements of methodology, conflict of interest policy and procedures, and disclosures of panel members' conflicts of interest relating to specific recommendations are published with any guideline or otherwise made public. 8. Guidelines are in the first instance disseminated independent of support from or participation by individuals or entities that have a direct interest in the recommendations. (BOT Rep. 2, A-11)

APPENDIX II – IOM Standards for Developing Trustworthy Clinical Practice Guidelines

STANDARD 1: Establishing transparency

- 1.1 The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible.

STANDARD 2: Management of conflict of interest (COI)

- 2.1 Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG.
 - Disclosure should reflect all current and planned commercial (including services from which a clinician derives a substantial proportion of income), non-commercial, intellectual, institutional, and patient/public activities pertinent to the potential scope of the CPG.
- 2.2 Disclosure of COIs within GDG
 - All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work.
 - Each panel member should explain how their COI could influence the CPG development process or specific recommendations.
- 2.3 Divestment
 - Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations.
- 2.4 Exclusions
 - Whenever possible GDG members should not have COI.
 - In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
 - Members with COIs should represent not more than a minority of the GDG.
 - The chair or co-chairs should not be a person(s) with COI.
 - Funders should have no role in CPG development.

STANDARD 3: Guideline development group composition

- 3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG.
- 3.2 Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient and a patient advocate or patient/consumer organization representative in the GDG.
- 3.3 Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.

STANDARD 4: Clinical practice guideline–systematic review intersection

- 4.1 CPG developers should use systematic reviews that meet standards set by the Institute of Medicine's Committee on Standards for Systematic Reviews of Comparative Effectiveness Research.
- 4.2 When systematic reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach, and output of both processes.

STANDARD 5: Establishing evidence foundations for and rating strength of recommendations

- 5.1 For each recommendation, the following should be provided:
 - An explanation of the reasoning underlying the recommendation, including:
 - A clear description of potential benefits and harms.

- A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
- An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation.
- A rating of the strength of the recommendation in light of the preceding bullets.
- A description and explanation of any differences of opinion regarding the recommendation.

STANDARD 6: Articulation of recommendations

- 6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed.
- 6.2 Strong recommendations should be worded so that compliance with the recommendation(s) can be evaluated.

STANDARD 7: External review

- 7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g., federal government), patients, and representatives of the public.
- 7.2 The authorship of external reviews submitted by individuals and/or organizations should be kept confidential unless that protection has been waived by the reviewer(s).
- 7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers' comments.
- 7.4 A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.

STANDARD 8: Updating

- 8.1 The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.
- 8.2 Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.
- 8.3 CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For example, a CPG should be updated if new evidence shows that a recommended intervention causes previously unknown substantial harm, that a new intervention is significantly superior to a previously recommended intervention from an efficacy or harms perspective, or that a recommendation can be applied to new populations.

2. 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 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 those activities occurring since Board of Trustees Report 24-A-14 was presented to the HOD at the 2014 Annual Meeting.

PAY-FOR-PERFORMANCE

Following the failure of the United States Congress to enact the “SGR Repeal and Medicare Provider Payment Modernization Act of 2014,” no congressional activity has occurred to make improvements to the current pay-for-performance program. This bipartisan legislation contained significant improvements to existing pay-for-performance programs. Conversations with Congressional leaders continue regarding the possibility of returning to the legislation during the lame duck session of Congress.

The 2015 Medicare Physician Fee Schedule Proposed Rule contains several significant proposals related to pay-for-performance programs. The potential negative impact of these changes highlights the importance of moving forward with repeal of the SGR and the associated pay-for-performance reforms that are included in SGR repeal legislation.

Benefits of the legislative approach include better alignment of pay-for-performance programs and limitations on the total impact that may be experienced by any one provider or practice.

REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR

As discussed above, efforts to enact repeal and replacement of the SGR are ongoing with the next opportunity to move legislation coming during the lame duck session of Congress. The willingness of Congress to address SGR during that session will depend greatly on the outcome of the 2014 elections and early positioning for the 2016 election cycle.

REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

The “Protecting Seniors’ Access to Medicare Act” (H.R. 351/S. 1316) introduced by Rep. Phil Roe, MD (R-TN) and Sen. John Cornyn (R-TX) has not been scheduled for action before either body of Congress, despite the fact that the House version of the bill has 227 cosponsors, more than enough for passage in that body. Our AMA continues to urge Congressional leaders to move this legislation at any opportunity.

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

The “Medicare Patient Empowerment Act” (H.R. 1310/S. 236), introduced by Rep. Tom Price, MD (R-GA) and Sen. Lisa Murkowski (R-AK) has not been considered by the relevant committees of Congress. The House bill has 28 cosponsors and the Senate bill has five cosponsors.

Though several bills have been introduced to support and expand Medical Savings Accounts and Flexible Spending Accounts, the committees of jurisdiction have yet to advance this legislation.

STEPS TO LOWER HEALTH CARE COSTS

No significant efforts to lower health care costs have been taken by the Congress in the period covered by this report. The rate of growth in health care spending and the Medicare program in particular has declined significantly. Analysts are uncertain about the cause and continuation of the lower health spending trend.

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

The “Protect Patient Access to Quality Health Professionals Act of 2013” by Rep. Andy Harris, MD (R-MD) has not been taken up by the Committee on Energy and Commerce.

On June 5, 2013, our AMA submitted extensive comments in response to a Centers for Medicare & Medicaid Services Request for Information on provider non-discrimination. The response clearly outlined that Section 2706(a) of the ACA does not expand the state-conferred scope of practice or require contracting with all types of health care providers, consistent with similar statutory language for Medicare Advantage and Medicaid managed care plans.

3. FACILITATING STATE LICENSURE FOR TELEMEDICINE SERVICES

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

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

*See Policies [H-255.982](#), [H-275.955](#), [H-275.962](#), [H-275.973](#), [H-275.977](#), [H-275.978](#),
[H-480.946](#), [H-480.969](#), [D-275.994](#), [D-275.995](#) and [D-480.999](#).*

Policy D-480.971, “Facilitating State-Based Licensure for Telemedicine Services,” directs our American Medical Association (AMA) to study issues associated with state-based licensure and portability of state licensure for telemedicine services with report back at the 2014 Interim Meeting. This report summarizes requirements for state

licensure, discusses methods of obtaining multiple state licenses, outlines AMA policy relevant to state licensure and telemedicine and presents policy recommendations.

STATE LICENSURE

In the United States, medicine is a licensed profession regulated by the individual states. The nation's medical boards license both allopathic (MD) and osteopathic (DO) physicians. Our AMA has long opposed a single national federalized system of medical licensure and opposes the enactment of any federal legislation that promotes these objectives (Policy D-480.999).

Our AMA also recognizes the right and responsibility of states and territories to determine the qualifications of individuals applying for licensure to practice medicine within their respective jurisdiction (Policy H-255.982). While specific requirements for obtaining a medical license vary between jurisdictions, state medical boards review applicants' credentials and look closely at a number of factors, including medical education, medical training, performance on national licensing examinations, and fitness to practice. Most boards charge processing, application, and administrative fees for this work.

The following is a snapshot of information relevant to license portability and is not intended as a comprehensive list of state medical licensure requirements. To help physicians navigate the licensure process and provide up-to-date information on licensure requirements across all US states and jurisdictions, our AMA publishes annually a compendium of State Medical Licensure Requirements and Statistics.¹

Medical Education

All jurisdictions require that candidates for physician licensure have obtained an MD or DO degree. Candidates of international medical schools may present the equivalent of the MD degree (e.g., Bachelor of Medicine, Bachelor of Surgery or MBBS). Acquisition of an MD or DO degree does not automatically confer a license to practice medicine, as the medical practice in most jurisdictions restricts individuals holding a physician credential from publicly representing themselves as physicians unless they hold a medical license in that jurisdiction.

Medical Training

All state medical boards require candidates to complete at least one year of postgraduate training to be eligible for a full and unrestricted medical license. In some jurisdictions, the requirement is even higher—physicians must complete residency training to obtain their license. In some jurisdictions, successful completion of the licensing examination sequence and acquisition of a full, unrestricted license is a prerequisite to entering a designated stage of post-graduate training.

State medical boards require that medical training be completed in a residency program accredited by the Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA). In 2014, the AOA, ACGME, and American Association of Colleges of Osteopathic Medicine (AACOM) agreed to a single accreditation system for graduate medical education (GME) programs in the United States, which will be implemented between 2015 and 2020.²

Licensing Examination

All state medical boards require completion of the United States Medical Licensing Examination (USMLE) or the Comprehensive Osteopathic Licensing Examination-USA (COMLEX-USA). Many state medical boards impose specific criteria relative to the number of attempts and the time utilized by the physician to complete the licensing sequence.

Fitness to Practice

All state medical boards are concerned with the physical, mental, and moral fitness of prospective licensure candidates. The licensure application in each state commonly asks questions about the personal history and background of the applicant, including work history, physical and/or mental conditions that might impact their

ability to practice, and criminal record. Many boards also conduct criminal background checks at the time of application.

Specialty Certification

A physician's license is for the general, undifferentiated practice of medicine. Certification in a medical specialty is not required to obtain a medical license. Our AMA opposes the use of board certification as a requirement for licensure (Policy H-275.950).

Credential Verification

When a physician submits an application and fee for a medical license, state medical board staff will verify credentials, confirm passage of licensing exams, query the Federation of State Medical Boards (FSMB) disciplinary data bank and review the physician's responses to questions on the licensure application for missing or inconsistent information. In some instances, the board may request that the applicant appear for a formal interview before the board. The AMA has encouraged FSMB to increase standardization of credentials requirements for licensure (Policy D-275.994), and endorses the use of pluralistic approaches to the verification and validation of physicians' credentials (Policy H-275.977).

A credentials verification system established by FSMB—the Federation Credentials Verification Services (FCVS)—offers a repository of primary-source verified core credentials for physicians, including medical education and training records, examination history, disciplinary history, board specialty certification, and identity. The FCVS allows a physician to establish a portfolio which can be forwarded (for a base fee of \$350) to any medical board or health care entity that has established an agreement with FCVS. To date, the FCVS is accepted by 53 state medical boards and is required by 14 state medical boards,³ and has been used by more than 167,000 physicians.⁴ Our AMA supports recognition of FCVS by all licensing jurisdictions (Policy D-275.995).

Reregistration

The majority of boards require physicians licensed in the state to reregister (or renew) their licenses every one to two years, with a handful of jurisdictions on a three-year reregistration interval. The average reregistration fee is around \$360, or \$220 when averaged by year.⁵

Most boards require completion of a specified number of hours of continuing medical education (CME) for reregistration. Some states also mandate specific CME content, such as HIV/AIDS, risk management, and end of life palliative care.⁶ Many states also require that a certain percentage of CME be *AMA PRA Category 1 Credit™* or equivalent. AMA policy encourages voluntary CME as part of a physician's lifelong learning, and supports the expansion and enhancement of funding resources for CME on a local, regional, and national basis (Policies H-350.958, H-300.994, H-300.998 and D-300.996).

MULTISTATE LICENSURE

Many physicians have more than one active license. For example, 878,194 physicians held an active license to practice medicine in the US in 2012. Of these physicians, 78 percent held one active license; 16 percent held active licenses in two jurisdictions; and six percent held active licenses in three or more jurisdictions.

Currently, a physician who wants to practice in more than one state must apply directly to each of the medical or osteopathic boards in the desired state(s) of practice. Our AMA has urged licensing jurisdictions to streamline this process by adopting laws and rules facilitating the movement of licensed physicians between states and limiting physician movement only for reasons related to protecting the health, safety, and welfare of the public (Policy H-275.955, Policy H-275.978).

Uniform Application for Physician State Licensure

AMA policy adopted in 2001 encouraged FSMB to develop a standardized medical licensure application form for those data elements that are common to all applications (Policy D-275.992). In 2004, FSMB released the Uniform

Application for Physician State Licensure (UA), a web-based application that standardizes the medical licensure application process without replacing unique state-level requirements.

FSMB developed the UA as part of a license portability demonstration project funded by a grant from the federal Office of the Advancement of Telehealth, within the Health Resources and Services Administration. The UA initiative is a part of FSMB's License Portability Project, an ongoing effort by FSMB and state medical and osteopathic boards to develop tools and procedures to streamline the licensure process. The convenience factor of the UA is relevant for physicians who participate in the FCVS, which auto-populates more than 70 percent of the core UA application.⁷

Twenty-two states currently use the UA.⁸ Physicians who wish to use the UA are subject to a one-time service fee of \$50. Since 2011, more than 18,600 physicians have successfully submitted their application for licensure utilizing the form.⁹

Federal Agencies

Federal agencies offer a highly portable system of medical licensure. For example, physicians employed by the armed services, Department of Veterans Affairs, or Public Health Service need only to possess a current, unrestricted and valid license from one of the 50 states, District of Columbia, the Commonwealth of Puerto Rico, the US Virgin Islands or Guam to provide health care services independently within the scope of the licenses, in addition to other requirements. These agencies also have in common the authority to maintain and enforce standards of conduct, share records, and take disciplinary action in response to adverse events within their systems.

Licensure by Endorsement

Endorsement is the process through which a state issues an unrestricted license to practice medicine to an individual who holds a valid unrestricted license in another jurisdiction. Licensure endorsement is generally based on documentation of successful completion of approved examinations, authentication of required core documents, and completion of any additional requirements assessing the applicant's fitness to practice medicine in the new jurisdiction.

Our AMA has long opposed the imposition of federally mandated restrictions on the ability of individual states to determine the qualifications of physician candidates for licensure by endorsement (Policy H-295.973). In 2001, our AMA adopted policy that encouraged FSMB to develop mechanisms for greater reciprocity between state licensing jurisdictions, and to increase the number of reciprocal relationships among licensing jurisdictions (Policy D-275.994, Policy D-275.995). Our AMA has also encouraged FSMB and individual medical licensing boards to pursue uniformity in the acceptance of examination scores and in other requirements for licensure by endorsement (Policy H-275.978).

In 2004, FSMB adopted policy¹⁰ recommending that state medical boards offer an expedited licensure by endorsement process to physicians meeting the following qualifications:

- Full and unrestricted licensure (in all jurisdictions where a medical license is held);
- Free of disciplinary history, license restrictions, or pending investigations (in all jurisdictions where a medical license is or has been held);
- Graduation from an approved medical school or hold current Educational Commission for Foreign Medical Graduates (ECFMG) certification;
- Passage of a licensing examination acceptable for initial licensure within three attempts per step/level and within a seven year time period;
- Completion of three years of progressive postgraduate training in an accredited program; and/or;
- Current certification from a medical specialty board recognized by the American Board of Medical Specialties (ABMS) or AOA. Lifetime certificate holders who have not passed a written specialty recertification examination must demonstrate successful completion of the Special Purpose Examination (SPEX), Comprehensive Osteopathic Medical Variable-Purpose Examination (COMVEX), or applicable recertification examination.

State requirements vary somewhat for licensure by endorsement. For example, a few boards require that a license be endorsed within a certain time period after examination (usually 10 years), and require the SPEX or COMVEX if the time limit has expired. In addition, most state medical boards require candidates for licensure endorsement to appear for an interview and/or oral examination. Finally, some states require IMGs seeking licensure by endorsement to hold a certificate from ECFMG, and to have graduated from certain state-approved foreign medical schools. Fees for licensure by endorsement, including processing, application, and administrative fees, average close to \$400.

Interstate Compacts

An interstate compact is a legally binding agreement between states, as well as a component of state law. Compacts are created when an offer is made by one state, usually by statute that adopts the terms of a compact requiring approval by one or more other states to become effective. Other states accept the offer by adopting identical compact language. Once the required number of states have adopted the pact, the “contract” among them is valid and becomes effective as provided. Compacts therefore represent an opportunity for multistate cooperation, reinforcing state sovereignty and avoiding federal intervention.¹¹

Compacts afford states the opportunity to develop dynamic, self-regulatory systems while maintaining control through a coordinated legislative and administrative process that can evolve to meet new and increased challenges that arise over time. The National Council of State Boards of Nursing (NCSBN) Nurse Licensure Compact (NLC) and FSMB Interstate Compact for Medical Licensure present examples of the impact of compacts on the practice of medicine.

Nursing Licensure. The NLC, which was established in 2000, enables multistate licensure for registered nurses and licensed practical or vocational nurses. To date, 24 states have adopted the NLC. NCSBN endorsed a similar but separate process for advanced practice nurses (APRNs) in 2002; however, to date the APRN compact has not been implemented.

Pursuant to the NLC, a nursing license in a compact state automatically becomes a multistate license, so long as it is in good standing. A nurse licensed in a compact state must meet the licensure requirements in the home state. When practicing on a multistate privilege in a remote state, the nurse is accountable for complying with the nursing practice act of that state; nursing boards in compact states hold cross-state regulatory authority. The NLC thus allows a nurse to have a single license in his or her state of residency and practice and be regulated in other states, both physically and via telemedicine, without additional applications or fees.

Medical Licensure. The FSMB Compact (the Compact) has the potential to allow physicians to more rapidly become licensed to practice medicine in multiple states. FSMB finalized the Compact in September 2014, with the expectation that state legislatures will begin to consider enabling legislation in 2015 that will incorporate the Compact into state law. Our AMA submitted comments to FSMB on drafts of the Compact throughout FSMB’s development of the Compact.

Participation in the Compact will be voluntary for both physicians and state boards of medicine. The Compact’s expedited licensure process will be available only to those physicians who:

- Are graduates of a medical school accredited by the Liaison Committee on Medical Education, the Commission on Osteopathic College Accreditation, or a medical school listed in the International Medical Education Directory or its equivalent;
- Passed each component of the USMLE or the COMLEX-USA within three attempts, or any of its predecessor examinations accepted by a state medical board as an equivalent examination for licensure purposes;
- Successfully completed graduate medical education approved by the ACGME or AOA;
- Hold specialty certification or a time-unlimited specialty certificate recognized by the ABMS or AOA;
- Possess a full and unrestricted license to engage in the practice of medicine;
- Have never been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction;
- Have never held a license authorizing the practice of medicine subject to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action related to non-payment of fees related to a license;
- Have never had a controlled substance license or permit suspended or revoked by a state or the US Drug Enforcement Administration; and

- Are not under active investigation by a licensing agency or law enforcement authority in any state, federal, or foreign jurisdiction.¹²

A physician would designate a member state as the state of principal license, and if found eligible by that state's medical board, could apply for expedited licenses in other member states through a newly established Interstate Medical Licensure Compact Commission (Interstate Commission). The expedited license would be the same as the license a physician would receive if applying to another state directly—not a multistate license or a national license. The physician would select the states in which he or she is seeking licensure, and pay required fees to the states and the Interstate Commission.

The Compact also adopts the prevailing standard for licensure, that the practice of medicine occurs where the patient is located at the time of the physician-patient encounter, and therefore, requires the physician to be under the jurisdiction of the state medical board where the patient is located. Accordingly, a physician who obtains an expedited license through the Compact is bound to comply with the statutes, rules and regulations of each state wherein he or she chooses to practice, including those pertaining to CME.

Regulatory authority will remain with the participating state medical boards, and will not be delegated to the Interstate Commission. Any or all of the Compact states retain the authority to revoke or take action on the physician's license to practice. Medical boards from states participating in the Compact will be required to share complaint and investigative information.

DISCUSSION

The Board believes that FSMB's Interstate Compact for Medical Licensure (the Compact) is a reasonable approach to license portability which builds on the existing system of state medical licensure while not otherwise changing a state's existing medical practice act. Notably, the Compact is consistent with AMA policy that physicians delivering telemedicine services must be licensed in the state where the patient receives services, or provide these services as otherwise authorized by the state's medical board, and that such physicians should abide by the licensure and medical practice laws and requirements of the state in which the patient receives services (Policy H-480.946).

The success of the Compact in maximizing physicians' ability to obtain expedited multistate licensure will depend in large part on state participation in the Compact and on the speed in which the Interstate Commission gets up and running. The Interstate Commission charged with effectuating the Compact will not be established until seven states enact the Compact into law. As such, it is incumbent on states to pass enabling legislation, and for FSMB to secure funding to support creation of the Interstate Commission, as expeditiously as practicable.

Our AMA will continue to support the efforts of FSMB in implementing the Interstate Compact for Medical Licensure, and will work with FSMB to ensure expeditious adoption of the Interstate Compact and creation of the Interstate Commission. Our AMA will also work with interested medical associations to encourage state legislatures to adopt legislation effectuating the Compact.

While most states require a full and unrestricted license for the practice of telemedicine, several states have adopted specific telemedicine laws or regulation that allow for a special license, telemedicine license or certificate to allow for the practice of telemedicine.¹³ One state (Minnesota) allows physicians to practice telemedicine if they are registered to practice telemedicine or are registered to practice across state lines.

AMA policy relevant to medical licensure for the provision of telemedicine services provides that physicians must be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board; and that physicians must abide by licensure laws and medical practice laws and requirements in the state in which the patient receives services (Policy H-480.946). AMA policy further provides that, with exception,¹⁴ a physician's license for the practice of telemedicine should be full and unrestricted, unless there are other appropriate state-based licensing methods, with no differentiation by specialty, for physicians who wish to practice telemedicine in that state or territory (Policy H-480.969). AMA policy on medical licensure for telemedicine is thus consistent with FSMB's Interstate Compact for Medical Licensure, and provides further justification for AMA support of the Compact.

RECOMMENDATIONS

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

1. That our American Medical Association support the Federation of State Medical Boards Interstate Compact for Medical Licensure.
2. That our AMA work with interested medical associations, the Federation of State Medical Boards and other interested stakeholders to ensure expeditious adoption by the states of the Interstate Compact for Medical Licensure and creation of the Interstate Medical Licensure Compact Commission.
3. That our AMA reaffirm Policies H-255.982, H-275.955, H-275.962, H-275.973, H-275.977, H-275.978, H-480.946, H-480.969, D-275.994, D-275.995 and D-480.999.
4. That our AMA rescind Policy D-480.971, which requested this report.

REFERENCES

- ¹ Available for purchase at the AMA Store, <https://commerce.ama-assn.org/store>. This reference includes data tables on required examinations, training, graduate and CME, and fees. Also included are data on the numbers of initial and subsequent licenses awarded by state as well as information on key organizations involved in the licensure process, such as the FSMB, NBME, and ECFMG.
- ² ACGME, AOA, and AACOM press release. Allopathic and Osteopathic Medical Communities Commit to a Single GME Accreditation System. February 26, 2014. www.acgme.org/acgmeweb/portals/0/PDFS/Nasca-Community/SingleAccreditationRelease2-26.pdf. Accessed July 25, 2014.
- ³ A list of participating boards is available at www.fsmb.org/medical-professionals/fcvs/physboards.
- ⁴ AMA State Medical Licensure Requirements and Statistics 2014.
- ⁵ *Id.*
- ⁶ The AMA believes that the medical profession has the responsibility for setting standards and determining curricula in CME, and encourages state medical societies in states which already have a content-specific CME requirement to consider appropriate ways of rescinding or amending the statute (Policy H-300.953).
- ⁷ FSMB. UA History. <http://library.fsmb.org/ua-history.html>. Last accessed August 4, 2014.
- ⁸ A current list of participating boards is available at <http://library.fsmb.org/ua-use.html>.
- ⁹ AMA. State Medical Licensure Requirements and Statistics 2014.
- ¹⁰ FSMB Report of the Special Committee on License Portability. Adopted in 2002. www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/2002_grpol_License_Portability.pdf.
- ¹¹ Council of State Governments. Understanding Interstate Compacts. www.cslg.org/projects/water/compacteducation/understanding_interstate_compacts--csgncic.pdf. Accessed July 29, 2014.
- ¹² FSMB Understanding the Medical Licensure Compact. Available at www.fsmb.org/state-medical-boards/advocacy-policy/interstate-model-proposed-medical-lic. Last accessed August 11, 2014.
- ¹³ State-specific information is on file with the AMA Advocacy Resource Center and available upon request. *See also* FSMB. Telemedicine Overview: Board-by-Board Approach. June 2013.
- ¹⁴ State laws should exempt physicians from these licensure requirements for situations such as curbside consultations and emergent or urgent circumstances.

4. AMA PARTICIPATION IN REDUCING MEDICAL STUDENT DEBT

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Policy D-305.956, "AMA Participation in Reducing Medical School Debt,"

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); and

That 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; and

That our AMA HOD receive a progress report on these discussions by the 2014 Interim Meeting.

This informational report responds to a request for a status report.

BACKGROUND

Student Debt Statistics

The average medical school educational debt of the class of 2013 is \$169,901. Sixty three percent of indebted graduates have debt of at least \$150,000. Seventy-nine percent of indebted graduates have debt of at least \$100,000, and eighty-six percent of graduating medical students carry outstanding loans.

Medical education debt is driven by rising tuition. AAMC data shows that the median private medical school tuition and fees increased by 50 percent (in real dollars) in the 20 years between 1984 and 2004. Median public medical school tuition and fees increased by 133 percent over the same period. Other recent 20-year periods show similar trends. That being said, tuition is just one source of increasing debt burdens. Other causes include: (i) interest accrued on loans over time significantly adds to the total cost of student debt; (ii) students are now entering medical school with more education debt from undergraduate education; and (iii) increasing numbers of “non-traditional” students who have children to support.

Effect on Students and Patients

The increase in debt not only burdens medical students, but also can have effects on the entire health care system. Some of the correlations found include: (i) a decrease in primary care physicians, in which students with high debt may be less likely to pursue family practice and primary care specialties and instead seek specialties with higher income or more leisure time; (ii) Decreased diversity of physician workforce, where the cost of tuition can prevent students from low-income/minority and those with other financial responsibilities from attending medical school and physician diversity is necessary to address the needs of heterogeneous, multicultural patient populations; and (iii) Promoting unsafe physician behaviors as residents with high debt are more likely to moonlight and increasing debt leads to more cynicism and depression among residents.

AMA AFFINITY PROGRAMS

The American Medical Association Affinity program (MVP) brings vetted resources and savings that fit physicians’ personal and practice needs. The program currently has resources and savings on pharmaceuticals, medical supplies and equipment, tech products, travel, practice financing, and financial and insurance services.

In an affinity program, AMA licenses its name to a third party for purposes of that third party’s marketing of its products and services. The third party sets the prices and contracts with the customer. AMA is not a party to the customer agreement.

As a result, an affinity program covering student loans will carry market interest rates, subject to the credit environment and the credit worthiness of the customer, as determined by the lender.

PRODUCT DEVELOPMENT

Our AMA is pursuing two approaches to address this proposal after thoroughly researching the marketplace. During its evaluation, our AMA has reached out to major companies that are involved in both private and federal student loan refinance and private student loan origination, and an assessment is currently being done to determine which company or service would be the best fit for our AMA and its members.

The first possibility is a vendor that will offer multiple lender options through a vendor maintained platform, allowing multiple lenders to compete for AMA member business and the potential for higher approval ratings. This solution would also make the lending more transparent to the member and hopefully easier for them to make a choice.

The second possibility is to go directly with a single lender. The benefits to this option would include the ability to work directly with one lender on all service issues.

CONCLUSION

After a medical student graduates, he or she is faced with navigating the extreme complexities of both federal and private loan repayment and consolidation options. Many of the programs have different eligibility requirements and often acceptance is determined based upon one's credit worthiness, income, ability to have a cosigner and filing of yearly required paperwork. Serious consequences can occur because of an ill-advised decision. For example, use of a commercial vehicle to refinance or consolidate student loans will result in a loss of federal benefits under the federal loan programs including federal loan forgiveness.

The AMA is aware of other associations' programs and those will be part of the evaluation of options going forward. At the present time, the AMA has not yet been able to identify a meaningful member benefit that would accrue to the AMA member as a result of using an AMA sponsored program, but options are still under investigation.

AMA will continue to pursue these options under the affinity program and will report back at the 2015 Annual Meeting.

APPENDIX – Federal Medical Student Loans

The US Department of Education administers several loans programs for eligible medical students, the majority of which are authorized under Title IV of the Higher Education Act. These loans include: Direct Stafford loans, GradPLUS loans, Perkins loans, and HRSA Primary Care loans.

Direct Stafford Loan

Unsubsidized Stafford loans are available for graduate/professional students and have better interest rates and loan terms than many private loans, at a fixed 6.8 percent. Students are not required to make payments while in school, but interest accrues on unsubsidized Stafford loans during that period. Further, unsubsidized Stafford loans for Health Professions Students are limited to \$40,500 annually. The Budget Control Act of 2011 eliminated subsidized Stafford loans for graduate/professional students, the effect of which is estimated to increase repayment for medical students between \$10,000 and \$20,000 over the life of their loan.

GradPLUS Loan

Graduate students may also take out GradPLUS loans, which are unsubsidized loans with a fixed 7.9 percent interest rate. GradPLUS loans are limited to the total Cost of Attendance minus any other aid, as determined by the educational institution.

Perkins Loan

A Perkins loan is for undergraduate and graduate students with "exceptional" financial need and the interest rate is fixed at a low five percent. The Department of Education provides a set amount of funding to the participating institution. In turn, the school determines which students have the greatest need and combines federal funds with some of its own funds for loans to qualifying students. Perkins loans do not have origination fees and carry a longer grace period than other federal loans.

HRSA Primary Care Loan

Medical students interested in primary care are eligible for the HRSA Primary Care Loan program. The loan offers a five percent interest rate to students who agree to train and practice in primary care until loans are paid off (with a 10-year cap). Students who fail to complete the service requirement will revert to a seven percent interest rate.

**5. FDA REGULATION OF OFF-LABEL DRUG PROMOTION
(RESOLUTION 218-I-13)**

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 218-I-13 AND
REMAINDER OF REPORT FILED**
See Policy [H-120.988](#).

Resolution 218-I-13 introduced by the California Delegation and referred by the House of Delegates asked:

That our American Medical Association (AMA) support the Food and Drug Administration's (FDA) authority to prohibit medication off-label detailing.

BACKGROUND

Unlabeled Uses/Off-Label Prescribing

When the FDA approves a drug or device and its label, it does so for a specific indication. When a physician prescribes a drug for an indication that is not included in the product labeling, or at a dosage outside the recommended range, using a different route of administration, or in a patient population excluded from the label recommendation (e.g., pediatric), such uses are termed "unlabeled" or "off-label." Off-label prescribing is not illegal because the FDA does not regulate the practice of medicine (21 U.S.C. § 396). Once a drug product has been approved for marketing, physicians may prescribe it for uses or in treatment regimens or patient populations that are not included in the approved product labeling.

The prevalence and clinical importance of off-label prescribing are substantial. In general, off-label prescribing ranges from 10-20%, but is much higher in certain medical specialties (e.g., oncology) or patient populations (e.g., pediatrics, patients with rare diseases).¹⁻⁶ Accordingly, the spectrum of off-label uses is wide. They can be a source of innovation and new practices, represent primary therapy or the standard of care, or they may represent the only available therapy or be a therapy of last resort. Negative consequences include a lack of substantial evidence supporting safety and efficacy for many off-label uses and the potential for increased costs when newer branded drugs are used in this manner.^{1,6,7} In addition, a disincentive may exist for manufacturers to pursue FDA approval of off-label uses when their products are already being used in this manner. Under the 1962 amendments to the federal Food, Drug and Cosmetic (FD&C) Act, approved labeling is restricted to those uses for which the sponsor (usually the manufacturer) has provided adequate evidence to the FDA to substantiate the safety and efficacy of the product. However, manufacturers are not required to and may not seek FDA approval for all useful indications. A major reason is because the expense of regulatory compliance may be greater than the eventual revenues expected (e.g., if patent protection for the drug product has expired, or if the patient population affected by the new use is small). A sponsor also may not seek FDA approval because of difficulties in conducting controlled clinical trials (e.g., for ethical reasons, or due to the inability to recruit patients). Finally, even when a sponsor does elect to seek approval for a new indication, the regulatory approval process for the required SNDA is expensive and may proceed very slowly.

Resolution 218-I-13 was prompted, in part, by a recent court decision (*United States v. Caronia*) that has been interpreted as further eroding the ability of the FDA to strictly regulate and limit the ability of pharmaceutical manufacturers to communicate information about off-label uses to physicians and other entities in the health care system.⁸ AMA Policy H-120.996 addresses physician prescribing of drugs for off-label uses and the dissemination of information about such uses by the pharmaceutical industry.⁹ Based on a 1997 report from the Council on Scientific Affairs, this policy strongly supports the legal right of physicians to prescribe drugs off-label, and the establishment of specific criteria and a framework for the dissemination of information about off-label uses by pharmaceutical manufacturers and their representatives. This policy also addresses two tangential issues, namely incentives for manufacturers to pursue approval for unlabeled indications, and the compelling need to evaluate the safety and efficacy of drugs in pediatric patients.

Sources for Physicians of Information about Medicines

Physicians rely on several sources for information about prescription drugs. FDA-approved labeling is the foundation, especially for new and recently marketed drugs. The labeling, particularly if it contains a black box warning, or is associated with a risk evaluation and mitigation strategy, significantly influences prescribing practices. Other information about the clinical uses of prescription drugs may be obtained from journal articles, clinical trial and/or post-market safety and effectiveness data, clinical practice guidelines, cost effectiveness information, and continuing medical education (CME) activities, some of which may be funded and/or supplied by company representatives. Although physicians may obtain information about prescription drugs in many ways, “commercial sources play a prominent role in disseminating information to physicians and in influencing their therapeutic decisions.”^{10,11}

REGULATION OF OFF-LABEL DRUG PROMOTION

Promotion of off-label uses is not directly prohibited by the Food, Drug, and Cosmetic Act (FDCA) of 1938. However, the FDA has the authority to regulate the promotional materials and activities of pharmaceutical companies. Such regulation is intended to ensure that information provided by companies and their employees or representatives is truthful, balanced, and not misleading and is supported by substantial clinical evidence. To enforce its regulatory powers, the FDA relies on provisions that prohibit manufacturers from introducing a drug into interstate commerce without FDA approval, or from introducing “adulterated or misbranded drugs.”¹²⁻¹⁵ A drug is considered misbranded if its labeling contains misleading information, includes information about unapproved uses, or lacks information that is sufficient to support its safe use. Accordingly, if a company or its representative promotes an off-label use (or the action is perceived as having that intent), by definition the drug becomes misbranded because the label lacks sufficient information to ensure safe use for that indication. Importantly, FDA’s interpretation of labeling and advertising regulations (21 CFR §202.1) encompasses all materials containing drug information distributed and supplied by the manufacturer, and communications related to such information, including oral statements.^{16,17} Marketing drugs in a way that deviates from FDA-approved uses or that is not supported by current labeling (misbranding) is subject to regulatory action, and even criminal prosecution. This is not to be confused with the ability of manufacturers to respond to unsolicited requests for information about off-label uses.¹⁸

Historical View

Over time, the FDA’s regulatory strategy about promotional activities, especially the extent to which manufacturers may disseminate information about off-label uses, has varied. Little attention was paid to these practices before the 1980s.¹⁹ With increasing concern about industry practices, some safe harbors were created in the 1990s to allow information about off-label uses to be communicated during CME activities.²⁰ Additionally, the dissemination of reprints of scientific articles and textbooks was allowed, if the principal topic was an approved use and the nature of the off-label use was disclosed in a prominent fashion.²¹ The FDA Modernization Act of 1997 (FDAMA) allowed manufacturers to disseminate unabridged peer-reviewed scientific or medical journal articles as long as advance copies were provided to the agency, several other conditions related to data sources, distribution and disclosures were met, and the company was actively pursuing approval of the off-label indication. Current AMA policy was developed around this time.²² Subsequently, a series of legal challenges to existing guidance documents and the reprint provisions in FDAMA began to establish the view that existing policies were unduly restrictive and that dissemination of printed materials about off-label use and drug advertising constitutes commercial speech protected by the First Amendment. However, uncertainty remained about the ways and extent to which disseminating information about off-label uses could be restricted.²³⁻²⁶

The FDAMA provisions expired in September 2006, and with the likelihood of ongoing constitutional litigation and the prevailing need to establish a safe harbor for disseminating off-label materials, the FDA issued new guidance in 2009.²⁷ This guidance modified the regulatory approach, now explicitly allowing companies to disseminate unabridged scientific articles and textbooks focused on off-label uses to health care practitioners, again subject to several conditions. These conditions included requirements that the information should:

- be based on adequate and well-controlled clinical investigations;
- be truthful and not misleading or pose a significant public health risk if relied on;

- include prominent disclosure statements about sponsors, financial interests, and known risks not discussed in the publication;
- be published by an organization with published conflict of interest policies and an editorial board that involves experts and uses objective peer review processes, and not be derived from an industry-funded special supplement; and
- be provided separately from promotional information.

As noted by Mello et al, this guidance was largely supported by pharmaceutical companies and patient advocacy groups, and opposed by some consumer organizations, Public Citizen, and some insurers.¹⁹ Opposition was based, in part, on the grounds that peer review processes in place did not provide adequate protection against industry influence, and the guidance essentially allowed marketing practices for unlabeled uses to proceed disguised as science.^{19,28} These opposing views were buttressed by “revelations of ghostwriting of journal articles,” other industry-related manipulations of the peer review process revealed by litigation, and the practices of manufacturers to initiate and publish “seeding” trials.^{10,29-34} Seeding trials are clinical trials focused on off-label uses, but not intended to support a supplemental new drug application. Additionally, concerns existed that by allowing dissemination of information about off-label uses, companies would be less inclined to seek FDA approval for such uses. In commenting on the 2009 draft guidance, the AMA noted that “industry practices have been identified that threaten the credibility of the entire peer-review journal process. Such practices call into question whether physicians, patients, and the public can be assured that information provided is accurate and unbiased.”²² Strategies and practices targeting prescribers that may constitute off-label promotion include distorted presentation of supporting evidence, influence on CME programs, direct financial incentives, provision of free samples, and recruitment of physicians to conduct seeding trials.¹⁰

Enforcement Actions and First Amendment Concerns

Despite concerns about the possible erosion of FDA authority, the last decade has been marked by several successful, high profile enforcement actions by the federal government against companies for illegal off-label promotion with settlements against 17 different companies totaling more than \$16 billion.^{19,36} These settlements confirmed the government’s ability to extract large sums from companies without substantiating at trial the validity of the underlying legal theory, but have left unresolved the tension between the First Amendment protection of speech and the regulation of pharmaceutical products, including the right of manufacturers to provide truthful and not misleading information.

Subsequent court decisions have further tilted the balance toward the rights of pharmaceutical companies and their representatives to provide truthful and non-misleading information about off-label uses, the view that speech in aid of pharmaceutical marketing is a form of expression protected by the First Amendment, and the view that the First Amendment protects the truthful, non-misleading off-label promotion of pharmaceutical products by pharmaceutical representatives (*Caronia*).^{8,37}

In the aftermath of the *Caronia* decision, the FDA stated it did “not believe that the *Caronia* decision will significantly affect the agency’s enforcement of the drug misbranding provisions of the FDCA.” In fact, since the decision, the government has alleged false or misleading off-label promotion in each of the high profile cases it has settled, albeit many of which were already well underway in advance of *Caronia*.³⁸ Most enforcement actions, which are carried by the Department of Justice, are based on whistleblower activities or some source other than the FDA.¹⁷

2014 Draft Guidance

Nevertheless, realizing the conflicting but shared interests of the government and industry, and in response to stakeholder questions and citizen petitions, the FDA once again developed a new draft guidance for comment purposes in February 2014 titled “Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices.” A final guidance is expected later this year.^{39,40}

If the behavior of companies is “in accordance with the guidance, the FDA does not intend to use that distribution as evidence of the manufacturer’s intent that the product(s) be used for an unapproved new use.” The draft guidance contains separate provisions for scientific or medical journal articles, scientific or medical reference texts (including individual chapters), and clinical practice guidelines. According to the FDA, the guidance is an effort to “harmonize

the fundamental public health interests underlying FDA's mission and statutory framework with the interests in the dissemination of truthful and non-misleading information."

Industry has complained that the 2014 draft guidance removes language that "explicitly allowed the distribution of off-label information outside adequate and well-controlled trials."⁴¹ Such trials are the standard for establishing the safety and efficacy of drugs during the drug approval process, but recent, high quality data may be available from other sources. The 2014 guidance also lacks previous citations confirming the legality of off-label prescribing and the importance of communicating off-label information to physicians. For a summary of the draft guidance as it applies to scientific or medical journal articles please see Appendix A. For those interested in further reviewing the recommended practices for disseminating textbooks, chapters of textbooks and clinical practice guidelines, please consult the draft guidance.⁴⁰

DISCUSSION

The AMA recognizes the important need for physicians to have timely access to accurate and unbiased information about off-label uses of drugs and medical devices. Such information can serve as an important aid to clinical decision-making and the provision of appropriate care for patients. Therefore, the AMA has supported the dissemination by manufacturers of independently derived scientific information about off-label uses to physicians, if the independent information is provided in its entirety, is not edited or altered by the manufacturer, and is clearly distinguished from manufacturer-sponsored materials.

The AMA also recognizes the important need for the FDA to regulate this process to help ensure that the appropriate balance is established between physicians having access to timely and accurate information about new advances in treatment, and maintaining the important role that the FDA plays in protecting public health through a strong premarket approval process. Given that it is lawful and sometimes the standard of care for a physician to prescribe a drug off-label, the dissemination of truthful, non-misleading information on off-label uses to physicians should be permissible. Appropriate and viable solutions to this issue need to protect the integrity of the drug approval process while giving appropriate latitude for the exercise of First Amendment rights. The federal regulation of promotional statements made by pharmaceutical manufacturers is necessary to encourage rigorous evaluation of the uses of prescription drugs and protect the health of the public.¹⁰ More attention should be given to increasing clinical trial transparency by giving "responsible independent researchers access to patient level data to replicate studies and perform meta-analyses" and "requiring public release of clinical study reports" submitted to the FDA.⁴² Such practices would improve the evidence base needed to inform clinical decision-making.

RECOMMENDATIONS

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 218-A-13 and the remainder of the report be filed:

1. That Policy H-120.988 be amended by addition and deletion to read as follows:

H-120.988, Patient Access to Treatments Prescribed by Their Physicians

(1) The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label unlabeled indication when such use is based upon sound scientific evidence ~~and or~~ sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as ~~reasonable and necessary clinically appropriate~~ medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary.

~~The AMA recommends the following: Prescribing and Reimbursement for FDA Approved Drugs and Devices for Unlabeled Uses~~

~~(1) Our AMA reaffirms the following policies:~~

~~(a) A physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon sound scientific evidence and sound medical opinion (Policy H 120.988);~~

~~(b) When the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, and should fulfill their obligation to their beneficiaries by covering such therapy (Policy H-120.988); and~~

~~(c) Our AMA encourages the use of three compendia (AMA's Drug Evaluations*; United States Pharmacopeia-Drug Information, Volume I*; and American Hospital Formulary Service Drug Information) and the peer-reviewed literature for determining the medical acceptability of unlabeled uses (Policy H-165.896, #15). (*These two compendia currently are being merged as the result of an alliance between the American Medical Association and the United States Pharmacopeia.) Dissemination of Information about Unlabeled Uses of Drugs and Devices by Manufacturers.~~

(2) Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label ~~unlabeled~~ uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.

(3) Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, and scientifically sound, information and truthful and not misleading, about unlabeled uses by manufacturers to physicians, if ~~if~~ The independent information should be ~~is~~ provided in its entirety, is not be edited or altered by the manufacturer, and be is clearly distinguished and not appended to from ~~from~~ manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label unlabeled uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts. ~~Can be supported under the following conditions:~~

~~(a) Reprints of independently derived articles from reputable, peer reviewed journals that meet the following criteria:~~

~~(i) The article should be peer reviewed and published in accordance with the regular peer review procedure of the journal in which it is published;~~

~~(ii) The reprint should be from a peer reviewed journal that both has an editorial board and utilizes experts to review and objectively select, reject, or provide comments about proposed articles; such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal;~~

~~(iii) The journal is recognized to be of national scope and reputation, as defined by an advisory panel to the FDA; among its members, this advisory panel should have representatives from national medical societies;~~

~~(iv) The journal must be indexed in the Index Medicus of the National Library of Medicine;~~

~~(v) The journal must have and adhere to a publicly stated policy of full disclosure of any conflicts of interest or biases for all authors or contributors;~~

~~(vi) When the subject of the article is an unlabeled use, or the article contains other information that is different from approved labeling, the industry sponsor disseminating the reprint must disclose that the reprint includes information that has not been approved by the FDA and attach a copy of the FDA approved professional labeling with the reprint;~~

~~(vii) If financial support for the study and/or the author(s) was provided by the industry sponsor disseminating the article, and this is not already stated in the article, then this information should be clearly disclosed with the reprint.~~

~~(b) Reprints of monographs or chapters from the three compendia (AMA's Drug Evaluations; United States Pharmacopeia Drug Information, Volume I; and American Hospital Formulary Service Drug Information) named in federal statutes for determining the medical acceptability of unlabeled uses, provided:~~

~~(i) The monograph or chapter is reprinted in its entirety by the publisher of the compendia, and the reprints are then sent to the requesting industry sponsor;~~

~~(ii) The reprints are not altered in any way by the industry sponsor;~~

~~(iii) The industry sponsor disseminating the reprint discloses that the reprint includes information that has not been approved by the FDA and attaches a copy of the FDA approved professional labeling with the reprint.~~

~~(c) Complete textbooks that meet the following criteria:~~

- ~~(i) The reference text should not have been written, edited, excerpted, or published specifically for, or at the request of, a drug, device, or biologic firm; when financial support is provided by a drug, device, or biologic firm, it should be disclosed clearly in the textbook;~~
- ~~(ii) The content of the reference text should not have been edited or significantly influenced by a drug, device, or biologic firm, or agent thereof;~~
- ~~(iii) The reference text should be generally available for sale in bookstores or other distribution channels where similar books are normally available and should not be distributed only or primarily through drug, device, or biologic firms;~~
- ~~(iv) The reference text should not focus primarily on any particular drug(s), device(s), or biologic(s) of the disseminating company, nor should it have a significant focus on unapproved uses of drug(s), device(s), or biologic(s) marketed or under investigation by the firm supporting the dissemination of the text;~~
- ~~(v) Specific product information (other than the approved package insert) should not be physically appended to the reference text.~~

~~(d) Manufacturers should report to the FDA and share with all physicians any proprietary information that a drug is ineffective or unsafe when used for a specific unlabeled indication.~~

~~(e) Continuing medical education (CME) activities:~~

- ~~(i) The FDA should continue to support principles in the FDA Draft Policy Statement on Industry Supported Scientific and Educational Activities (Fed. Reg. 1992;57:56412-56414), which acknowledges the importance of relying on the professional health care communities, rather than the Agency, to monitor independent provider activities, and~~
- ~~(ii) The FDA should continue a policy of regulatory deference for industry-supported CME activities conducted by organizations accredited by the Accreditation Council for Continuing Medical Education (ACCME), state medical societies, specialty societies, and the American Academy of Family Physicians (AAFP), that follow the Essentials and Standards of the ACCME and that may be certified for AMA PRA credit under the auspices of the American Medical Association Physician's Recognition Award program.~~

~~(4) Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an unlabeled off-label use).~~

~~Improving the Supplemental New Drug Application (SNDA) Process~~

~~(5) Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.~~

~~(6) Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.~~

~~(6) Our AMA encourages the US Congress, the FDA, pharmaceutical manufacturers, the United States Pharmacopeia, patient organizations, and medical specialty societies to work together to ensure that Supplemental New Drug Applications (SNDAs) for new indications (efficacy supplements), including those for uses in special populations (e.g., pediatrics), are submitted and acted upon in a timely manner. Specific recommendations include:~~

- ~~(a) User fee legislation should be re-authorized to ensure that the FDA has the necessary resources to act on all efficacy supplements within 6 months of submission;~~
- ~~(b) The SNDA process should be streamlined as much as possible (e.g., basing review decisions on already published literature), without compromising the requirements for substantial evidence of efficacy and safety;~~
- ~~(c) Legislation should be enacted that provides extensions of marketing exclusivity for the product to manufacturers who submit and gain FDA approval of efficacy supplements, including mechanisms both to provide greater reward when the new indication is for a life-threatening disease (with limited or no alternatives), an orphan disease, or for a special population (e.g., pediatrics), and to prevent inappropriate use of the system by manufacturers (e.g., place a limit on total length of extended marketing exclusivity);~~
- ~~(d) For drugs no longer under patent and for which generic versions are available, the FDA, other governmental agencies (e.g., the National Institutes of Health), the pharmaceutical industry, the United States Pharmacopeia, patient organizations, and medical specialty societies should discuss and mutually agree on alternative~~

~~mechanisms to ensure that efficacy supplements will be submitted to and acted upon by the FDA in a timely manner; and~~

~~(e) Pharmaceutical manufacturers are urged to seek FDA approval for pediatric uses through the FDA's 1994 regulation that allows approval of pediatric uses based on adult efficacy studies (where the course of the disease and the effects of the drug are sufficiently similar in both populations) and additional information for pediatric use, usually pharmacokinetic studies for determination of dosage (Fed. Reg. 1994:59:64240-64250). Encouraging Clinical Research in Pediatrics~~

~~(7) Our AMA urges pharmaceutical manufacturers and the FDA to work with the American Academy of Pediatrics and experts in pediatric medicine to identify those investigational drugs that would have pediatric indications and set up a mechanism to ensure that necessary pediatric clinical studies are completed prior to submission of NDAs for approval of these drug products. Legislation should be enacted that provides extensions of marketing exclusivity for the product to manufacturers who complete pediatric studies that lead to pediatric labeling.~~

REFERENCES

1. Radley DC, Finkelstein SN, Stafford RS.. Off-label prescribing among office-based physicians. *Arch Int Med*. 2006;166:1021-26.
2. Bazzano AT, Mangione-Smith R, Schonlau M, Suttrop MJ, Brook RH . Off-label prescribing to children in the United States outpatient setting. *Acad Pediatr*. 2009;9:81-8.
3. Statement by Abbey S. Meyers, President, National Organization for rare Disorders (NORD), before the Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Reform and Oversight, U.S. House of Representatives, September 12, 1996.
4. Chen DT, Wynia MK, Moloney RM, Alexander GC. U.S. physician knowledge of the FDA-approved indications and evidence base for commonly prescribed drugs: Results of a national survey. *Pharmacoepidemiol Drug Safety*. 2009;18:1094-100.
5. Poole SG, Dooley MJ. Off-label prescribing in oncology. *Support Care Cancer*. 2004;302:
6. Egual T, Buckeridge DL, Winslade N, et al. Drug, patient, and physician characteristics associated with off-label prescribing in primary care. *Arch Int Med*. 2012;172:781-88.
7. Stafford RS. Regulating Off-label drug use – rethinking the role of the FDA. *New Engl J Med*. 2008;358:1427-29.
8. *U.S. v. Caronia*, 703F.3d 149 (2dCir. December 3, 2012)
9. Council on Scientific Affairs Report 3. Unlabeled Indications of Food and Drug Administration-Approved Drugs. American Medical Association Annual Meeting, Chicago, IL. 1997.
10. Kesselheim AS, Avorn J. Pharmaceutical promotion and First Amendment rights. *N Engl J Med*. 2008;359:536-7.
11. Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA*. 2000;283:373-80.
12. Federal Food, Drugs, and Cosmetics Act, 21 U.S.C. 355(a)(2008).
13. Definitions and interpretations, 21 C.F.R. § 310.3(h) (2008).
14. Prescription-drug advertisements, 21 C.F.R. § 202.1(e)(4) (2008).
15. Federal Food, Drugs, and Cosmetics Act, 21 U.S.C. 331 (2008).
16. Tyler RS, Poirot TE, Andrews AS, Parker BR. The first amendment and “off-label” promotion. For the Defense. 2012;Oct:34-38.
17. United States Government Accountability Office. Prescription Drugs. FDA's Oversight of the Promotion of Drugs for Off-Label Uses. July 2008.
18. FDA, Draft Guidance for Industry: Responding to Unsolicited Requests for Off-label Information about Prescription Drugs and Medical Devices (2011).
19. Mello M, Studdert DM, Brennan TA. Shifting terrain in the regulation of off-label promotion of pharmaceuticals. *New Engl J Med*. 2009;360:1557-1566.
20. Advertising and promotion; guidances. *Fed Reg*. 1996; 61(196):52800-1.
21. Final guidance on industry-supported scientific and educational activities. *Fed Reg*. 1997;62(232):64073.
22. Dissemination of information on unapproved/new uses for marketed drugs, biologics, and devices: final rule. *Fed Reg*. 1998;63:224:64556-88.
23. *Washington Legal Foundation v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).
24. *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).
25. *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998).
26. *United States v. Caputo*, 288 F Supp 2d 912 (N.D. Ill. 2003).
27. Office of the Commissioner, Office of Policy. Guidance for industry: good reprint practices for the distribution of medical journal articles and medical or scientific reference publications on unapproved new uses of approved drugs and approved or cleared medical devices. Silver Spring, MD: Food and Drug Administration, January 2009.
28. Mitka M. Critics say FDA's off-label guidance allows marketing disguised as science. *JAMA*. 2008;299:1759
29. Ross JS, Hill KP, Egilman DS, Krumholz HM. Guest authorship and ghostwriting in publications related to rofecoxib: a case study of industry documents from rofecoxib litigation. *JAMA*. 2008;299:1800-12.

30. Hill KP, Ross JS, Egilman DS, Krumholz HM. The ADVANTAGE seeding trial: a review of internal documents. *Ann Intern Med* 2008;149:251-8.
31. Greenland P, Lloyd-Jones D. Critical lessons from the ENHANCE trial. *JAMA* 2008;299:953-5.
32. Psaty BM, Kronmal RA. Reporting mortality findings in trials of rofecoxib for Alzheimer disease or cognitive impairment: A case study based on documents from rofecoxib litigation. *JAMA*. 2008;299(15):1813-1817.
33. Steinman MA, Bero LA, Chren, MM, Landefeld CS. Narrative review: The promotion of gabapentin: An analysis of internal industry documents. *Ann Intern Med*. 2006;145:284-293.
34. Healy D, Cattel D. Interface between authorship, industry and science in the domain of therapeutics. *Br J Psychiatry*. 2003;183:22-27.
35. Letter from Michael Maves, MD, to [Docket No. FDA-2008-D-0053]. April 15, 2008
36. ProPublica. Big Pharma's big fines. <http://projects.propublica.org/graphics/bigpharma>
37. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2659 (2011)
38. Inside Counsel. The aftermath of *Caronia* in pursuing off-label cases. March 10, 2014. <http://www.insidecounsel.com/2014/03/10/the-aftermath-of-i-in-oursuing-off-label>.
39. Letter from Leslie Kux, JD, Assistant FDA Commissioner for Policy re: Dockets Nos FDA-2011-P-0512 and FDA-2013-P-1079.
40. Food and Drug Administration. Guidance for Industry. Distributing Scientific and Medical Publications on Unapproved New Uses—Recommended Practices. February 2014. <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf>.
41. Busch A. Inside Health Policy. Drug industry irate that FDA reprints guide tightens off-label info limits. May 9, 2014.
42. Outterson KO. Clinical trial transparency—Antidote to weaker off-label promotion rules? *New Engl J Med*. 2014;371:1-3.

APPENDIX A – Table. Recommended Practices for Distributing Scientific and Medical Publications on Unapproved New Uses⁴⁰

Scientific or Medical Journal Articles	
<i>Should</i>	
Source	A scientific or medical journal article that includes information on unapproved uses and is distributed by manufacturers should first have been published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review by the organization. Experts should be independent of the organization and should review and objectively select, reject, or provide comments about proposed articles. Also, the organization should adhere to a publicly stated policy of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization.
Peer-review	Be peer-reviewed and published in accordance with the peer-review procedures of the organization.
Format	Be in the form of an unabridged reprint or copy of an article.
Evidence	Contains information that describes and addresses adequate and well-controlled clinical investigations that are considered scientifically sound by experts with scientific training and experience to evaluate the safety or effectiveness of the drug or device (excludes meta-analysis and lower evidentiary standards).
Ancillary Materials	Be disseminated with the approved labeling, a comprehensive bibliography, and representative publications that reach contrary or different conclusions (when such information exists), and separately from the delivery of information that is promotional in nature.
Disclose	Disclose the drug(s) or device(s) included in the journal reprint in which the manufacturer has an interest; that some or all uses of the manufacturer's drugs or devices described in the information have not been approved or cleared by FDA, as applicable; any authors with financial interests; and, funding source, all significant risks or safety concerns associated with the unapproved use known to the manufacturer but not discussed in the article.
<i>Must not</i>	
Content	Be false or misleading.
Safety	Contain information recommending or suggesting use of the product that makes the product dangerous to health when used in the manner suggested.
<i>Should not</i>	
Format	Be in the form of a special supplement or publication that has been funded, in whole or in part, by one or more of the manufacturers of the product that is the subject of the article.
Appearance	Be marked, highlighted, summarized, or characterized by the manufacturer, in writing or orally, to emphasize or promote an unapproved use.
Distribution	Be primarily distributed by a drug or device manufacturer; rather, it should be generally available in bookstores or other independent distribution channels (e.g., subscription, Internet) where periodicals are sold.
Origin	Be written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer.
Integrity	Be edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.
Attachments	Be attached to specific product information (other than the approved product labeling or the product's cleared indications for use statement).

APPENDIX B - Amended Policy H-120.988 will read as follows:

H-120.988 Patient Access to Treatments Prescribed by Their Physicians

- (1) The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA-approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate “off-label” uses of drugs on their formulary.
- (2) Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
- (3) Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
- (4) Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
- (5) Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.
- (6) Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

6. ECONOMIC IMPACT OF EHRs AND THE USE OF SCRIBES

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

At the 2012 Annual Meeting, the House of Delegates (HOD) referred Resolutions 722-A-12 and 725-A-12, “Cost and Benefit Analysis for Electronic Health Record Implementation” and “Understanding the Pitfalls of EHRs and Providing Strategies for Success.” The Texas Delegation and the Organized Medical Staff Section (OMSS) introduced the resolutions. These resolutions asked that our American Medical Association, among other things, conduct a comprehensive literature review and/or study to analyze the current costs and/or benefit of implementing an electronic health record (EHR) and survey a large number of physicians concerning the impact of EHRs and, in particular, the use of scribes.

In response, Board Report 24-A-13 was prepared. The report summarized the literature concerning costs and/or benefit of EHRs and presented AmericanEHR (AEHR) Partners survey data from 2013, the first year that included participation by AMA members. The HOD adopted Policy D 478.976, which, among other things, asked that our AMA “work with AmericanEHR (AEHR) Partners ... to modify the current survey to better address the economics of EHR use by physicians including the impact of scribes.”

The current report presents the results of the modified survey conducted in 2014.

BACKGROUND

The AMA is one of 17 participating physician associations and societies with AEHR. AEHR conducts their survey, in cooperation with these partners, and makes the results available to physicians through their website. The results

are an aid to physicians in their selection of a suitable EHR for their practice. The AEHR site also hosts a moderated blog where physicians can share experiences with specific EHRs and ask questions of colleagues. This relationship is timely given the recent AMA-sponsored RAND study, “Factors affecting physician professional satisfaction and their implications for patient care, health systems and health policy.”¹ 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, interference with face-to-face patient care, regulatory requirements, insufficient health information exchange and degradation of clinical documentation quality.” While the RAND study did not inquire about the economic impact of EHRs on physician practices, it is reasonable to infer that adverse economic impacts would contribute to physician dissatisfaction. The RAND study did not examine the use of scribes.

To pursue these topics, AMA engaged AEHR to conduct the 2014 survey. AMA Market Research staff collaborated with AEHR staff in the formulation of new questions designed to examine the economic impact of EHR use and the role of scribes. In order to keep the overall length of the 2014 survey at its current level, AMA and AEHR agreed to eliminate questions that were not effective and/or addressed in other parts of the AEHR 2013 survey. As part of the process to create the new questions, AMA staff also consulted with the Medical Group Management Association (MGMA). MGMA has extensive experience examining the finances of medical practice including the use of EHRs. Unlike AEHR, MGMA works directly with practice staff. As noted in Board Report 24-A-13, MGMA has found an economic benefit for physician practices attributable to EHR use.² This benefit is most associated with practices that have fully implemented their EHR and are investing resources in optimizing it for their practice. Practices that are still implementing and/or practices that are considering switching EHR have less favorable results.³

SURVEY RESULTS

As in 2013, the AEHR conducted the 2014 survey via email outreach directly to physicians. The goal was to obtain 1,000 completed surveys from AMA members. The final number of AMA members completing surveys was 598, based on initial emails to, approximately, 18,000 members. To get closer to the 1,000 completed surveys, survey results from an additional 342 physicians drawn from ACP and AAFP membership were also included. Of the 940 completed surveys, 25% were from solo physician practices, 18% from practices with 2-5 physicians, 5% from practices of 6-9 physicians, 4% from practices with 10-49 physicians and 40% from practices with greater than 50 physicians. While there was broad representation across specialties, 26% indicated that their primary specialty was general internal medicine and 23% general/family practice.

The original OMSS areas of inquiry corresponding to areas of the AmericanEHR Partners survey first reported at A-13 and the corresponding results from the current survey follow:

1. The amount of time per patient it takes to complete the EHR.

2013	2014
Physicians reported that it is “Very easy” (32%) or “Easy” (32%) to document a progress note. About one-quarter responded that it is either “Difficult” or “Very difficult.” Three quarters (76%) of physicians who had used an EHR for several years or more found documentation of a progress note to be easy.	Physicians reported that it is “Very easy” (21%) or “Easy” (26%) to document a progress note. About 36% responded that it is either “Difficult” or “Very difficult.” Again, years of experience with the EHR were associated with improvement in ease of documentation of a progress note.

2. Reimbursement before and after the EHR.

2013	2014
When asked about satisfaction with the billing function of their EHRs, 40% of physicians said they were “Satisfied” or “Very satisfied” compared to 7% who signaled they were “Very dissatisfied.”	When asked about satisfaction with the billing function of their EHRs, 35% of physicians said there were “Satisfied” or “Very satisfied” compared to 15% who signaled they were “Very dissatisfied.”

3. Quality of life before and after EHR adoption.

2013	2014
Nearly half (46%) of physicians indicated that their	Nearly 32% of physicians indicated that their EHR

EHR improved their efficiency (e.g., easier to access lab results and historical information). Yet, when responding to a question about workload, 46% indicated that they are “Disappointed” or “Very disappointed” that using an EHR has not decreased their workload. About one-quarter of physicians say they are not yet back to pre-EHR productivity levels. About 15% indicated that it took more than 6 months to return to pre-EHR productivity; one-third said it took three to six months. A majority (66%) were “Very satisfied” or “Satisfied” that they could access their EHR remotely.	improved their efficiency (e.g., easier to access lab results and historical information). When responding to questions about workload, 72% indicated that they are “Disappointed” or “Very disappointed” that using an EHR has not decreased their workload. About 43% of physicians say they are not yet back to pre-EHR productivity levels. About 10% indicated that it took more than 6 months to return to pre-EHR productivity; 25% said it took three to six months. Sixty-six per cent (66%) were “Very satisfied” or “Satisfied” that they could access their EHR remotely.
---	---

4. Confidence in coding within an EHR.

2013	2014
Nearly half of physicians (44%) indicated that it is either “Very easy” or “Easy” to use E/M coding support when charting a patient visit. Another 17 percent said it is “Neither easy nor difficult;” only 7% reported it to be “Very difficult.”	Nearly 38% of physicians indicated that it is either “Very easy” or “Easy” to use E/M coding support when charting a patient visit. Another 22% said it is “Neither easy nor difficult;” nearly 10% reported it to be “Very difficult.”

5. Use of templates.

2013	2014
With respect to creating templates for specific clinical conditions, about one-third indicated that it is “Very easy” or “Easy.” 12% said it is “Very difficult.”	23% of physicians indicated that it was either “Very easy” or “Easy” to create templates for specific clinical conditions. 18% said it is “Very difficult.”

Results for questions added to the 2014 survey follow:

1. Impact of EHR on staff time processing prescriptions and refills
42% of physicians reported that there was a positive or very positive impact on their practice while 31% said that it was either negative or very negative. Primary care physicians (whether defined as Internal Medicine, Pediatrics, General and Family Practice with or without Ob/Gyn) results (47%) differed from specialists (41%) and this difference was statistically significant. Top two box results (combining positive and very positive) for physicians who had used an EHR for less than 12 months were 28% compared to 38% for physicians who had used an EHR for 1-3 years (a statistically significant result). This result continued to improve over time with top two box results of 53% for physicians who had used an EHR for 5+ years.
2. Impact of EHR on the number of employees/staff
13% of physicians reported that there was a positive or very positive impact (fewer employees/staff) on their practice while 35% reported that it was either negative or very negative (more employees/staff). The results were not statistically different when comparing primary care vs. specialty practices. Top two box results went from 5% for practices using an EHR for 12 months or less to 11% for those using an EHR for 1-3 years (a statistically significant result) to a high of 19% for those using an EHR 5+ years.
3. Impact of EHR on claims denials
23% of physicians reported that there was a positive or very positive impact on their practice while 12% reported either a negative or a very negative impact. Primary care practices (including Ob/Gyn) reported top two box results of 28% vs. 21% for specialists (a statistically significant difference). Top two box results were 14% for practices using an EHR for less than 12 months. This improved to 24% by 3-5 years (a statistically significant difference) and 36% for 5+ years of EHR use.
4. Impact of EHR on delays in billing activities
35% of physicians reported a positive or very positive impact on their practice (decrease in billing delays) while 16% reported either a negative or a very negative impact. Primary care practices (with or without Ob/Gyn) reported top two box results of 40% vs. 31% for specialists (a statistically significant difference). Top two box

results were 24% for practices using an EHR for less than 12 months. This improved to 51% for EHR use of 5+ years (a statistically significant difference).

5. Impact of EHR on charge capture

39% of physicians reported a positive or very positive impact on their practice while 15% reported either a negative or a very negative impact. Primary care practices (with or without Ob/Gyn) reported top two box results of 42% vs. 35% for specialists (a statistically significant difference). Top two box results were 32% for practices using an EHR for less than 12 months. This improved to 55% for EHR use of 5+ years (a statistically significant difference).

6. Impact of EHR on unbilled services

27% of physicians reported a positive or very positive impact on their practice while 19% reported either a negative or a very negative impact. Primary care practices (with or without Ob/Gyn) reported top two box results of 30% vs. 26% for specialists (a statistically significant difference). Top two box results were 14% for practices using an EHR for less than 12 months vs. 26% for 3-5 years of use (a statistically significant difference). By 5+ years, top two box results were 42% (a statistically significant difference from 3-5 years of EHR use).

7. Impact of EHR on total operating costs

Only 9% of physicians reported a decrease in total operating costs while 54% reported an increase. There was not a significant difference between primary care and specialists. There was a statistically significant improvement in operating costs when comparing 3-5 years (14%) to 5+ years (19%).

8. Impact of scribes

13% of practices are currently using scribes. Among primary care practices, 9% (with or without Ob/Gyn) vs. 13% of specialist practices were using scribes (a statistically significant difference). Length of time using an EHR did not appear to be an important factor. Of interest, 78% of practices indicated that they did not use scribes and did not intend to use them. The mean number of scribes employed by practices was 3.8 (4 for specialists vs. 3 for primary care; a statistically significant difference). Among practices using scribes, 74% said they used them every day. Twenty-one per cent of practices reported the use of scribes had a positive or very positive impact on practice finances, while 56% reported a negative or very negative impact. Results for primary care and specialist practices were similar and the length of time using an EHR did not affect the results. Overall satisfaction with the use of scribes was 55% (top two box results) vs. 23% (bottom two box results).

DISCUSSION

There was a notable deterioration when comparing 2013 and 2014 survey results for the same items. While this might be the result of deteriorating quality of EHRs, it seems more likely that the proportion of EHR practices who were new users of EHRs could explain this effect. First movers behaviors are often more accepting than that of followers. It is possible that growing familiarity with an EHR is associated with raised expectations. Physicians increasingly comment on the lack of adequate health information exchange and data “lock in” as a source of dissatisfaction with current EHRs. It might also be the case that physician dissatisfaction with the additional requirements moving from stage 1 to stage 2 of meaningful use is a factor.

Of interest were the results of the new questions included in the 2014 survey. While we were not able to quantify the net financial impact (revenue less operating expense) of EHR use, the results of questions associated with revenue improvement (charge capture, billing delays, claims denials and unbilled services) are consistently more positive than negative. Although the impact on operating expenses was negative, the results of this survey are consistent with surveys conducted by MGMA that were better able to look at the net financial impact as a result of working directly with office staff. The results of the MGMA surveys demonstrated a net financial benefit to practices. While there were some interesting differences between primary care and specialty practices in the current AEHR survey, the most consistent finding was the improved results associated with the more time a practice had used their EHR.

While fewer practices than anticipated were using scribes, specialists use exceeded that of primary care physicians. Surprisingly, while the financial impact of scribes was quite negative, overall satisfaction was high. The results of the survey would not suggest that time is a factor in a practices use scribes.

CONCLUSION

Our AMA should continue to take a leadership role, in collaboration with other physician associations and industry leaders, to examine physician use and experience with EHRs focusing on usability, patient safety, quality of care and economic impact. Our AMA should continue to support efforts that will lead to the refinement of EHRs and promote more transparency in the vendor marketplace. Finally, our AMA should continue to advocate for more flexibility in the Meaningful Use program to allow physicians sufficient time to adapt to the use of EHRs.

REFERENCES

1. Friedberg M, Chen P, Van Busum K, Aunon F, Pham C, Caloyer J, Mattke S, Pitchforth E, Quigley D, Brook R, Crosson F, Tutty *M Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy*. Rand Health, October 2013.
2. Goedert, J., EHR Cuts Long Term Operating Costs. October 25, 2010. Available at healthdatamanagement.com/news/ehr-cuts-long-term-operating-costs-41218-1.html. Accessed March 4, 2013.
3. Margolis, J, Redling, B, *Electronic Health Records: Status, Needs and Lessons—2011 Report Based on 2010 Data*, Medical Group Management Association

7. 2015 STRATEGIC PLAN

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

In 2013, our AMA launched a multi-year strategy aimed at achieving significant positive impact for physicians, medical students and patients. The strategy outlined three areas of focus: Improving Health Outcomes, Accelerating Change in Medical Education, and Shaping Care Delivery and Payment for Professional Satisfaction and Practice Sustainability. These focus areas have been developed to implement in very tangible and meaningful ways our AMA's longstanding mission to promote the art and science of medicine and the betterment of public health. Through this report, the Board of Trustees affirms AMA's multi-year strategy (BOT Reports 9-I-12 and 10-I-13).

The first two years of work under this strategy have demonstrated both the urgency and complexity of our aspirations. Progress is promising and our commitment remains strong. AMA's 2015 Strategic Plan reaffirms the tripartite focus of AMA's strategy and highlights ways in which the focus areas and other core activities of our AMA align, complement and catalyze one another in support of the mission.

By design, implementation of this strategy draws upon and reinforces AMA's touchpoints with physicians through the House of Delegates, membership, practice tools, research and education, and advocacy. In particular, success going forward will depend on AMA's ability to:

- Interact effectively with physicians on their terms, reaching them where they are, offering service and content options that are responsive to their preferences and needs;
- Collaborate not only with physicians but with other aligned interests to drive wide-scale awareness, urgency, participation and outcomes; and
- Capture and transform data into information that continuously guides AMA's work and is compelling enough to motivate action by others.

Through a refreshed digital strategy and alignment of AMA services, AMA seeks to improve its ability to identify, communicate with, deliver products and services to, and engage with specific stakeholder groups using both traditional and digital channels. Our plans in 2015 call for constructive and appealing experiences that allow physicians and students to choose the time, place, duration, and depth of the experience at any point in time. More sophisticated monitoring of interactions also will yield insight into physician preferences so that we can continuously improve services to physicians, residents and fellows, and medical students so as to retain and grow our membership base.

Given the interconnectedness of health care delivery, success in the focus areas requires AMA to cultivate expanded collaboration with a diverse set of stakeholders who can amplify the impact of AMA's work, bring resources and capabilities that complement those of AMA, and provide external validation of our approaches and results. We will foster relationships that expand the national base of support for AMA's mission as well as the means to achieve it.

In 2015, AMA will continue to increase the sophistication with which we apply data analytics to identify options, inform choice, and measure results. This capability applies across the mission and business areas, with examples ranging from quantifying the value of specific practice workflow innovations to understanding and optimizing the purchasing behaviors of various customer segments across AMA product offerings. Another aspect of this capability involves understanding how data are being used across other health sectors and identifying ways to protect against adverse consequences for physicians and patients.

The remainder of this report provides information about 2015 plans in each of the focus areas along with highlights of related and complementary capabilities and services.

IMPROVING HEALTH OUTCOMES

The Improving Health Outcomes (IHO) focus area links directly to AMA's commitment to improving the health of the nation, reflected in the mission statement as "the betterment of public health." Concentrating on risk factors for cardiovascular disease and type 2 diabetes, our AMA has set out to help physicians and care teams control high blood pressure and prevent diabetes – conditions affecting millions of Americans at a cost to our health care system of more than \$500 billion annually.

In 2015, we will continue our collaboration with Johns Hopkins University to devise, test and spread evidence-based interventions to improve health outcomes among the 30 million people who have high blood pressure and a usual source of care, yet for whom high blood pressure remains uncontrolled. Work to date with ten clinical pilot sites has informed a framework for practice interventions that emphasize measuring accurately, acting rapidly, and partnering with patients (MAP). Significant effort in 2015 will be devoted to spreading these interventions in adoptable formats to additional clinical sites, with an emphasis on those serving populations experiencing disparities in care. The data collected through these programs will further develop the evidence base to support effectiveness of the MAP interventions.

Physician and community collaborations are central to our AMA's commitment to reducing the number of patients with prediabetes whose condition progresses to type 2 diabetes. In collaboration with the Center for Disease Control and Prevention (CDC) and the YMCA of the USA, and supported in part with funding from a Center for Medicare and Medicaid Innovation (CMMI) grant, our AMA has been working to increase the number of physicians who screen for prediabetes and then refer patients to evidence-based prediabetes programs in the community. Our work in 2014 involved first developing and testing physician referral programs in Delaware, Indiana and Minnesota. In 2015, we anticipate spreading these initiatives beyond the pilot communities to other locations where the CDC-recognized YMCA diabetes prevention program is offered. Pilots will also be developed with other evidence-based diabetes prevention programs which may include use of new technologies and virtual programs. Aided by growing evidence of the economic and health benefits of these programs, our interaction with payors and employers to advocate for coverage of diabetes prevention programs will also intensify.

ACCELERATING CHANGE IN MEDICAL EDUCATION

In 2015, students who are enrolled at 11 medical schools will begin their second year of medical training under the auspices of an AMA-sponsored education innovation program: Accelerating Change in Medical Education (ACE). Already, many students are experiencing unprecedented flexibility in learning plans that are focused on achieving competencies. They are experiencing new methods to achieve patient safety, performance improvement and patient-centered team-based care. They are developing a deep understanding of the health care system and health care environment. They are learning in environments whose sights are set on delivering the knowledge, skills and attitudes that will be most critical for the next generation of physicians.

These 11 schools, participants in AMA's five-year, \$11 million grant program, comprise a consortium tasked with testing innovations and developing best practices that can be shared and implemented in schools across the country. Accordingly, the schools have developed common evaluation criteria and are collecting data to monitor outcomes.

Marking the halfway point of this five-year grant program, 2015 plans include an external peer review, analysis and evaluation of lessons learned from the innovations created at consortium schools, and collation of findings in a format that permits broad discourse among education stakeholders. In addition, AMA will work to develop an expanded cohort of schools to further test consortium prototypes and enable rapid-cycle evolution of “best practice” approaches and tools.

Success of this focus area will be marked not only by the intramural achievements of the funded projects at individual schools, but also by evidence of widespread adoption of innovation that better aligns education results with the changing needs of our health care system. Initial advances in undergraduate medical education will be extended to include innovation across the continuum of physician training. Students matriculating to residency from the consortium school programs must, of course, be well prepared to care for patients. By engaging stakeholders including accreditors of undergraduate, graduate and continuing medical education, as well as state and specialty licensing authorities, AMA seeks to ensure ample high-quality opportunity for continued training and lifelong learning for residents, fellows and practicing physicians.

PROFESSIONAL SATISFACTION AND PRACTICE SUSTAINABILITY

Research completed in 2013 created an evidence base for, and national attention around, a conversation that previously had echoed largely only within the physician community: It is really hard to be a doctor these days...to fulfill not only a professional commitment but a personal vocation...devoting time, intellect, compassion and resource to quality patient care. The confounding forces are formidable: mandatory use of ill-fitting technology, unpredictable and inadequate payment methodologies, regulatory burdens, administrative overload, and for many physicians, evolving and sometimes counterproductive relationships with hospitals and health systems. The issue is not that physicians want the practice of medicine to stand still; it is that physicians want to practice medicine.

AMA’s strategies in this focus area cover a wide spectrum, from mitigating issues imposed by external factors such as payment instability and regulatory overload to helping physicians implement adjustments within their practices that enhance their capacity for patient care. Early in 2015, AMA will have results from a follow-on study by RAND Health examining how physician practices are implementing new payment models in a variety of practice settings, and how those changes affect the sustainability of medical practice and care delivered to patients. These data, along with AMA’s annual physician benchmark study and other research, will inform AMA’s work in care delivery and payment.

Advocacy continues to be a critical element of AMA’s strategy. In Washington, DC, our AMA will continue to advocate for reforming the Medicare physician payment system to ease regulatory burdens, mitigating exposure to financial penalties under multiple quality reporting and incentive programs, eliminating the sustainable growth rate (SGR) formula, supporting the Medicare Patient Empowerment Act, and creating a pathway for physicians to choose from a broad array of alternative payment and health care delivery models, including viable fee-for-service options.

AMA will promulgate the conclusions of an expert panel convened in 2014 to establish priorities for the electronic health record (EHR) industry to improve the usability of technology so it makes the practice of medicine better without making it harder. AMA will also make available the results of independent research in 2015 to inform physicians about relative ratings of various EHR systems and, importantly, to drive improvement in the industry.

While many barriers to practice satisfaction and sustainability are outside the control of the individual physician, AMA’s research shows that there are interventions which, when adopted at the practice level, can streamline workflow and allow physicians to spend more quality time with patients and concentrate on physician work. The challenge is to make these interventions available to physician practices using feasible, affordable, adoptable methods. Following the pilot of a new digital content delivery platform late in 2014, AMA plans for broader rollout of practice tools in 2015. Examples include tools to streamline the daily logistical burden of prescription renewals and best-practice use of staff roles in small practices.

An important challenge, we believe, is the fact that many health care organizations (hospitals, payors, etc.) lack physician participation and influence at the executive leadership and board levels. AMA will continue to engage with leadership of hospitals and health systems to devise governance models that bridge this representation gap. Other solutions under consideration for 2015 include innovative educational programming to prepare physicians to

enhance their leadership capabilities and roles in health care organizations of many types, including physician-owned practices of various sizes.

COMPLEMENTARY CAPABILITIES AND SERVICES

Through our focus area work as well as ongoing complementary capabilities and services, AMA continues its commitment to its mission through innovation, collaboration, and operational excellence. Other highlights of 2015 plans include:

- Growing the depth, breadth, reach and impact of AMA's publications portfolio, including expansion of the JAMA Network through launch of a new online journal, *JAMA Oncology*, in spring 2015;
- Upholding AMA's core values of leadership, excellence, integrity and ethical behavior, as evidenced by ongoing work to modernize the AMA's *Code of Medical Ethics*;
- Demonstrating the professional significance of AMA's work through publication of project results in peer-reviewed journals;
- Expanding the utility and reach of AMA's flagship products and services designed to improve the delivery of healthcare, including coding, credentialing, insurance, FREIDA, and continuing medical education offerings; and
- Implementing communication strategies that convey the breadth and value of AMA's work, making the case that AMA is actively contributing to improving affordability and quality of health care and inviting others to join us in this quest.

In summary: AMA's strategy plots a path forward toward a future that is better, stronger and healthier for America's patients and the physicians who care for them.

8. 2014 AMA ADVOCACY EFFORTS

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

At the 2014 American Medical Association (AMA) Annual Meeting, the House of Delegates (HOD) adopted policy G-640.005, AMA Advocacy Analysis. This policy calls on your Board of Trustees to provide a report to the HOD at each Interim Meeting highlighting the year's advocacy activities and should include efforts, successes, challenges, and recommendations/actions to further optimize advocacy efforts. The policy also calls for the 2014 report to include a summary of the review of the Advocacy Group that was performed in 2012. Your Board of Trustees has prepared the following report to fulfill this HOD directive.

SUMMARY OF 2012 ADVOCACY REVIEW

As part of a strategic repositioning of our AMA, the AMA EVP/CEO conducted reviews of all the major AMA operating units. A review of the AMA Advocacy Group was conducted in the summer of 2012. The review was conducted by AMA senior management and external reviewers. The external review group included:

- A highly regarded Republican health policy expert and contract lobbyist who previously served as a senior health advisor to congressional committees and leadership offices;
- An equally regarded Democratic health strategic advisor with past experience at the White House and in the US Senate;
- A health policy expert on the faculty of a top university who has authored numerous health policy research papers, currently leads national health coalitions and was previously confirmed by the Senate to serve in a senior policy position at the US Department of Health and Human Services; and
- Two individuals who have served as CEO of a state medical society.

The review confirmed that our AMA is:

- The leading voice for physicians in Washington;
- Viewed as a trusted and reliable negotiator;
- An effective advocate at the state and federal levels; and
- A strong collaborator.

The review also identified areas for improvement. The extended battle over the Sustainable Growth Rate (SGR) has forced our AMA to devote extensive resources to the issue, created perceptions that our AMA was pursuing a narrow agenda and obscured the extent of our AMA's contributions on other health policy issues. Even to health policy insiders, there is a lack of understanding about all of the work that our AMA does on a wide variety of issues. There was also recognition that the extensive list of directives that is expanded twice a year at HOD meetings dilutes resources, shifts attention from high priority issues and frequently sets unrealistic demands. There was also discussion of the need to shift the conversation around health care costs to the topics of complexity and fragmentation rather than pricing of physician services. Finally, the review indicated a need for continuing to build and protect strategic alliances.

Based on the input from the external review panel, AMA management developed a strategy, supported by your Board of Trustees and the SGR Task Force comprised of eight state and seven specialty organizations, to reposition SGR advocacy around the broader concept of delivery and payment reform. This repositioning addressed criticism of the lack of a sound policy framework to put in place of the SGR and highlighted the benefits for patients, taxpayers and policymakers in repealing the SGR. The public debate moved from "pigeon-holing" SGR as just a physician payment issue to the broader perspective that SGR repeal was an important step in health system reform. With the feedback and assistance of the SGR Task Force, our AMA forged a coalition of physician organizations that embraced a set of delivery and payment reform principles that guided negotiations on SGR repeal legislation and that resulted in a bipartisan, bicameral agreement that was supported by over 600 physician groups.

A good example of our AMA's efforts to include the SGR issue in the broader health system reform discussion was our support for and participation in two 2013 *National Journal* events that brought together diverse voices on health system innovation and created a dialogue around how best to reform the nation's health system. The SGR issue was widely discussed at these forums and identified by many of the presenters as a hindrance to physicians in their day-to-day practices and in the longer term as a hindrance to innovation. These events were very successful in helping to reframe the SGR discussion as a top problem for our health system and all of its stakeholders rather than as a stand-alone issue that only affects physicians.

Another issue that arose in the Advocacy Review was our AMA's capacity for addressing health information technology (HIT) advocacy issues. Our AMA had staff dedicated to this issue, but with the rapidly evolving nature of the work and the number of HIT regulations being issued, it was clear that additional staffing was required to meet this growing need. The Advocacy Group hired an HIT consultant to supplement our advocacy team and to provide us with further expertise and capacity on this issue. Our advocacy work also dovetails well with the ongoing work being accomplished in the Physician Satisfaction and Practice Sustainability focus area that has become heavily involved in HIT issues based on the findings in the AMA RAND Study.

CURRENT FEDERAL ENVIRONMENTAL SCAN

The deeply divided partisan climate in our nation's capital has thwarted action on a wide range of issues. Partisan-imposed inertia is not just affecting important physician issues, such as repeal of the SGR formula, it is affecting all elements of the health care sector. Government reimbursements to hospitals have been cut as part of the offsets for short-term SGR patches; device companies have been thwarted in attempts to repeal the medical device tax; drug companies have been stymied in their efforts to address the 340b outpatient drug issue; and health insurers have been unsuccessful in repealing the health insurance tax. Looking at the legislative climate more broadly, Congress has not been able to pass immigration reform, comprehensive trade legislation, tax reform, its annual appropriations bills, or a long term fiscal fix that moves the nation away from the political brinksmanship that results in government shutdowns.

SGR ACTIVITIES IN THE 113TH CONGRESS

In 2014, for the first time ever, both chambers and parties in Congress agreed on legislative policy for finally creating a permanent SGR replacement policy. In the current politically-divided environment, this was a major accomplishment. In December 2013, the chairs and ranking members of the three congressional committees with jurisdiction over Medicare reached agreement on a comprehensive proposal to: (1) eliminate the SGR formula; (2) provide positive annual payment updates for five years; and (3) facilitate the transition to new payment and delivery models. The final package also provided options for physicians to choose from a broad array of payment models including fee-for-service, and brought current Medicare quality incentive programs into closer alignment with AMA policy by reducing aggregate penalty risks and expanding opportunities for earning bonus payments. The overall framework was consistent with the one proposed by our AMA and the Federation. It reflected the principles developed by the SGR Task Force, which was comprised of eight state and seven specialty societies, and was endorsed by 111 Federation societies in the fall of 2012. Throughout the process of consideration by the committees, improvements were made to bring the final product closer to AMA policy. On March 5, 2014, 644 state and national medical societies and specialty organizations signed a joint letter sponsored by our AMA, offering their support for H.R. 4015/S. 2000, the “SGR Repeal and Medicare Provider Payment Modernization Act.”

As has been the case with many other issues, congressional leaders failed to seize this historic opportunity to permanently repeal the SGR formula. On March 27, the US House passed by voice vote H.R. 4302, the “Protecting Access to Medicare Act of 2014,” which postponed the imminent 24 percent Medicare physician payment cut for 12 months. The Senate followed suit on March 31. Members of Congress and our AMA are discussing opportunities to pass permanent repeal legislation in the lame duck session of Congress this November or early in the next Congress.

2014 SGR LAME DUCK PROSPECTS

The anticipated lame duck session of Congress (which will commence following the November elections) provides the next potential opportunity to secure passage of legislation based on the bicameral, bipartisan SGR repeal bills, H.R. 4015/S. 2000. Prospects are not ideal for final action this year; Congress tends to defer action until a deadline is imminent, and the current Medicare physician payment patch does not expire until April 1, 2015 (rather than the typical January 1). Further, the mood in Congress after the November elections may not be conducive for bipartisan action on SGR repeal in the lame duck session. Nonetheless, there are several factors that provide a strategic basis for pursuing action on SGR repeal in the lame duck that include the following:

- Medicine now enjoys the support of key congressional champions who continue to make public statements about passing SGR repeal this year. Our AMA should support their efforts, keeping in mind that some of our current champions will retire or lose their committee chairs in 2015.
- If these champions are successful in scheduling floor votes on SGR repeal legislation during the lame duck session, the Federation needs to be ready. A key part of this preparation will be to continue efforts to erode our remaining obstacles between now and November.
- Even if Congress ultimately decides to defer action until next year (2015), an effort to seek action in the lame duck session creates additional pressure for Congress to pass the bipartisan, bicameral policy developed this year.

The key elements of the lame duck strategy include:

- Keep congressional champions engaged and express the importance of acting before the end of the year.
- Maintain and improve Federation and grassroots engagement; coordinate messaging and tactics across physician organizations.
- An aggressive August recess strategy focusing on in-district meetings and communications.
- Maximize impact of AMPAC’s September meeting with a strong Federation presence for Hill visits.
- Spread our message regarding the fiscal irresponsibility of continued short-term patches to enhance congressional acceptance of a potential SGR repeal that may not be fully offset – as cited in the Feb. 18 *Wall Street Journal* editorial which called for passage of an SGR bill without pay-fors.

A more detailed review of our AMA’s lame duck strategy will be discussed at an open forum on November 8th following the opening session at the 2014 Interim Meeting.

AMA LEGISLATIVE EFFORTS IN THE 113TH CONGRESS

Our Washington office is fully engaged on a host of legislative issues on the Hill beyond just the SGR campaign. They are continually seeking ways to promote legislation that advances AMA policy. Our AMA's efforts to improve the Affordable Care Act (ACA) are detailed at length in Board of Trustees Report 2 provided to the HOD at this meeting. A few ACA topics, such as the Independent Payment Advisory Board (IPAB) and the ACA's provider non-discrimination provision, are highlighted below along with brief recaps of other legislation that our AMA is advocating for in the 113th Congress.

- Veterans health care bill enacted: Our AMA successfully pressed for reform of the Department of Veterans Affairs (VA) health system with the passage of the “Veteran’s Access, Choice, and Accountability Act of 2014.” The main goals of the bill are: to provide access to care in the private sector for veterans who are not able to secure an appointment at a VA facility within a prescribed amount of time or who live more than 40 miles from a VA facility; to provide for the hiring of additional physicians and other practitioners and acquisition of additional facilities; to add 1500 GME residency slots over five years at VA facilities; and to improve administrative functions throughout the system. Though the conference process proceeded mostly behind closed doors, our AMA was able to determine that the proposed language left significant ambiguity as to whether the Secretary would have the authority to enter into agreements with private physicians or rather, as we believed, only hospitals and other facilities. Our AMA worked with the relevant staff to eliminate this ambiguity with clarifying language to ensure that veterans meeting the criteria have access to private physicians.
- “Cutting Costly Codes Act of 2013” - ICD-10 repeal: Introduced by Sen. Tom Coburn, MD (R-OK) and Rep. Ted Poe (R-TX) as S. 972 and H.R. 1701, respectively, the “Cutting Costly Codes Act” would prohibit the Secretary of Health and Human Services from replacing the current ICD-9 with the new ICD-10 diagnostic code set. Our AMA is working closely with the bill sponsors on this legislation, and part of our efforts included commissioning an updated study by Nachimson Advisors that revealed the increased use of electronic medical records, among other factors, has raised the cost substantially of ICD-10 implementation. AMA efforts to highlight ICD-10 implementation concerns also played a direct role in the ICD-10 delay that was included in the SGR patch legislation which pushed the deadline back until October 2015.
- “Medicare Patient Empowerment Act” - Private contracting: The “Medicare Patient Empowerment Act,” introduced by Rep. Tom Price (R-GA) as H.R. 1310 and by Sen. Lisa Murkowski (R-AK) as S. 236, would allow patients to use their current Medicare coverage to help cover the cost of care provided by physicians who, for various reasons, are not accepting their Medicare insurance. Our AMA played a key role in developing legislative language and seeking bill sponsors and co-sponsors for these bills.
- “Protect Patient Access to Quality Health Professionals Act” - Provider non-discrimination clause: Introduced in the House as H.R. 2817 by Rep. Andy Harris, MD (R-MD), this bill would repeal Section 2706(a) of the Affordable Care Act. Section 2706(a) states that in making decisions about which providers can participate in—or will be covered under—a health plan, an insurer may not discriminate against those who are acting within their state scope-of-practice laws. While the ACA also includes language specifying that state scope-of-practice laws are not affected, some limited-license providers have cited this provision in their own state efforts to inappropriately expand their scope of practice. This bill has not advanced, but our AMA continues to support the legislation and will seek opportunities to promote it.
- “Protect Seniors’ Access to Medicare Act” - IPAB repeal: H.R. 351 and S. 351, introduced by Rep. Phil Roe, MD (R-TN) and Sen. John Cornyn (R-TX) respectively, would repeal a controversial provision of the Affordable Care Act that establishes an Independent Payment Advisory Board (IPAB). H.R. 351 has secured bipartisan co-sponsorship from a majority of US Representatives.
- Good Samaritan legislation introduced in the Senate: Sen. Lisa Murkowski (R-AK) introduced the “Good Samaritan Health Professionals Act of 2014” (S. 2196) on April 1. Rep. Marsha Blackburn (R-TN) had previously introduced this legislation in the House (H.R. 1733). The bills would provide liability protections to health care professionals, including physicians, who volunteer to help victims of federally-declared disasters.
- “Standard of Care Protection Act” introduced: In 2013, Sens. Pat Toomey (R-PA) and Tom Carper (D-DE) introduced S. 1769, the “Standard of Care Protection Act.” This legislation would clarify that any care standards and practice guidelines derived from the ACA and other federal programs cannot be used to create new causes of legal action against physicians providing care to their patients, nor could they supersede state liability laws. Similar legislation, H.R. 1473 and H.R. 4750 (Reps. Phil Gingrey, MD [R-GA] and Henry Cuellar [D-TX]) were introduced in 2014 to continue efforts on this issue. These provisions were included in the bipartisan, bicameral proposed SGR legislation as well.

- “The Medicare Diabetes Prevention Act of 2013” (S. 452/H.R. 962): The bill is sponsored by Sens. Al Franken (D-MN), Susan Collins (R-ME) and Jay Rockefeller (D-WV), as well as Rep. Susan Davis (D-CA). This act provides coverage for the National Diabetes Prevention Program under the Medicare program. Our AMA supports this important legislation that provides coverage for a proven prevention program, which can improve the lives of America’s seniors and our country’s fiscal health.

It is also worth noting two bills from earlier in the 113th Congress for which AMA support was instrumental to achieving a positive outcome.

- Drug compounding legislation enacted: The “Drug Quality and Security Act” (H.R. 3204) was signed into law on Nov. 27, 2013. Our AMA worked with both the House and Senate to ensure physicians and patients can continue receiving safe compounded drugs, and that the new regulatory framework would not exacerbate drug shortages. This legislation establishes new FDA regulatory oversight for those who compound sterile drugs, while ensuring that traditional compounding practices continue. Additionally, it strengthens the prescription drug supply chain, protecting Americans against counterfeit drugs.
- “HIV Organ Policy Equity (HOPE) Act” signed into law: The HOPE Act (S. 330), sponsored by Sens. Barbara Boxer (D-CA) and Tom Coburn, MD (R-OK), was signed into law on Nov. 21, 2013. Our AMA strongly supported this legislation, which repeals the federal ban on research into organ donations from HIV-positive donors to HIV-positive recipients. The bipartisan measure opens a pathway to the eventual transplantation of these organs and provides life-saving assistance to HIV-positive patients who are at risk of liver and kidney failure.

Please visit our [federal legislation website](#) for more information.

2014 FEDERAL REGULATORY ACTIVITIES

Our AMA is engaged in ongoing campaigns to improve the regulatory environment and reduce administrative burdens for physicians and their practices. This includes ongoing work with health information technology (electronic health records [EHRs] and electronic prescribing specifically), quality reporting, data transparency, and trying to minimize the impact of ICD-10 implementation. We are also actively engaged in helping to shape new health care payment and delivery models. Our work was instrumental in ensuring that over half of Medicare Accountable Care Organizations (ACOs) could be physician-led and that there was federal start-up money available for physician-led and rural ACOs. We also helped to ensure that \$1 billion in seed money is available to help with the development of specialty-specific ACOs. Further highlights of AMA regulatory accomplishments are included below.

- AMA advocates for CMS to address small practice needs: During remarks at our AMA’s National Advocacy Conference (NAC), the Centers for Medicare & Medicaid Services (CMS) Administrator announced a new initiative to seek input from physicians about the resources they need for transitioning to value-based models of care that can better serve their patients. The request for information (RFI) is a fact-finding step prior to soliciting funding for grants to fund physician proposals for new delivery and payment models.
- Stage 2 meaningful use extended for an additional year: CMS extended key dates for Stage 2 of the Meaningful Use (MU) program. Stage 2, originally scheduled to start in 2013, began on Jan. 1. Originally, CMS planned for Stage 2 to end after 2015, but now it will last an additional year, through the end of 2016. This is the second time that our AMA secured an extension.
- Additional meaningful use hardship exemption available to physicians: As a result of AMA advocacy, CMS announced there will be an additional hardship exemption available to physicians to avoid a financial penalty under the EHR MU incentive program. The exemption applies to those who have not received or were unable to implement updated, Version 2014 certified software. CMS stated it will interpret the exemption very broadly in order to help more physicians avoid a financial penalty.
- Medicare adopts new codes and relative values from the Chronic Care Coordination Workgroup: Responding to the need to address payment for care coordination and primary care, the CPT® Editorial Panel and our AMA/Specialty Society RVS Update Committee (RUC) created the Chronic Care Coordination Workgroup (C3W). As a result of these efforts, new codes and coverage of transitional care management began in 2013, with Medicare national payment ranging from \$164 to \$232 for the additional coordination in transitioning a patient from a facility to the home/community. On Jan. 1, 2015, Medicare will begin recognition of, and payment for, a new monthly chronic care management code.

- HHS extends EHR donation exception/safe harbor rules through 2021: The US Department of Health and Human Services (HHS) Office of the Inspector General (OIG) and CMS published companion rules that extend the regulatory exception/safe harbor allowing physicians to accept EHR donations without violating Stark self-referral and anti-kickback rules. The receiving physicians must pay at least 15 percent of the cost of the technology. The exception/safe harbor was scheduled to sunset on Dec. 31, 2013.
- AMA secures delay of “two-midnight” policy: Following significant AMA advocacy, CMS announced on Jan. 31 that enforcement of the new “two-midnight” inpatient hospital admission policy would be delayed through Sept. 30, 2014. During the enforcement delay, recovery audit contractors (RACs) and other Medicare review contractors could not conduct post-payment patient status reviews of inpatient hospital claims with dates of admission on or after Oct. 1, 2013, through Oct. 1, 2014. Our AMA continues to advocate in opposition to the two-midnight policy. In subsequent legislation (H.R. 4302), the HHS secretary would be given discretion to suspend the RAC program’s post-payment audits under the policy through March 2015. In February, our AMA filed an amicus brief in the matter of *Bagnall v. Sebelius*, a case concerning Medicare beneficiaries who were hospitalized but did not meet the three-day inpatient stay requirement for subsequent skilled nursing facility (SNF) coverage because they were classified as under observation. These AMA efforts to influence the impact of CMS’ inpatient admissions policies on patients and physicians recently led to CMS regulatory proposals exploring alternative short stay payment methodologies.
- Pressure on RACs builds as AMA urges reform: After our AMA submitted specific recommendations to CMS on ways to improve the RAC program, CMS announced that it would adopt several of these ideas in the new RAC contracts. For example, under the new guidelines, RACs have an incentive not to make erroneous overpayment determinations because if a provider appeals an overpayment, the RAC cannot receive their contingency fee until the second level of appeal. In addition, CMS added flexibility for physicians who want to exercise their option to have a discussion with a RAC contractor while also preserving their right to formally appeal. Our AMA was also successful in advocating before Congress on the burden of the RAC program, leading to heightened congressional scrutiny of the program as the House Ways & Means Committee and Energy & Commerce Committee, and the Senate Aging Committee all examined this topic with hearings this year. As these complementary advocacy efforts raised sensitivity to the program’s problems, the RAC program suspended operations over the summer while CMS evaluated additional modifications to the program.
- CMS moves to scrap home health face-to-face narrative requirement: Our AMA and others have expressed concern about the home health order face-to-face narrative requirement. In its 2015 home health proposed rule, CMS proposed to eliminate the duplicate narrative requirement in an effort to reduce the documentation burden on physicians.
- AMA seeks safeguards in Medicare physician claims data release: In early April, CMS posted searchable, physician-specific Medicare claims data on its website. Prior to the release of the data, our AMA developed and distributed a fact sheet to reporters outlining the limitations of the data, helping to better inform some of the media stories that followed the release. Elements of our AMA’s fact sheet were also incorporated into the CMS website. Our AMA has advocated strongly for certain safeguards to protect physicians and patients from the use of inaccurate or misleading data.
- CMS continues to improve the Physician Compare website: Based on AMA advocacy, CMS is only reporting on practices that are statistically valid and reliable, meet minimum sample size and are deemed suitable for public reporting. CMS has also agreed to not move to reporting individual physician performance until technically feasible.
- CMS calls for greater oversight of ACA exchange plans: For health plans being sold on the ACA health insurance exchanges, CMS said it will take a more active approach to requiring network adequacy in response to AMA advocacy.
- CMS strengthens network adequacy regulation: Due to AMA advocacy, CMS is taking action intended to ensure that beneficiaries participating in Medicare Advantage (MA) plans or private health insurance plans bought on the exchanges have accurate and reliable information to make health insurance elections during open enrollment periods.
- Medicare Drug Benefit Rule maintains protected drug classes: CMS withdrew its proposal to remove antidepressants, immunosuppressants and antipsychotics from their protected class status. All drugs in the six protected classes must be included on the formularies for all Medicare Part D drug plans.
- FDA tightens regulations on sunlamps: Our AMA successfully advocated for the FDA to reclassify sunlamp products from low-risk (class I) to moderate-risk (class II) devices, and to require that they carry a visible black-box warning explicitly stating that the device should not be used on persons under 18 years of age.
- AMA receives assurances from CMS on the Open Payments disputes dismissal process: After pressing agency officials, our AMA received assurances that CMS would clarify guidance that manufacturers and group

purchasing organizations (GPOs) are not authorized by the agency to unilaterally dismiss disputes that are the result of potentially erroneous Open Payments data.

- Department of Justice begins to pave the way for the use of naloxone: The Attorney General is urging all federal law enforcement agencies to identify, train and equip personnel who may interact with a victim of a heroin overdose with the drug naloxone.

For more information, please visit our AMA's [federal regulatory efforts website](#).

2014 STATE ADVOCACY ACTIVITIES

Our AMA also advocates aggressively at the state level in collaboration with our Federation partners to advance AMA policy on key legislative and regulatory issues. Our state work includes a wide range of issues including payment and delivery reform, health insurer regulation, medical liability reform, physician-led team-based care, and public health issues. Highlights of our 2014 efforts include:

- State “Standard of Care Protection Act” passed: Idaho and Oklahoma passed laws in 2014 based on AMA model state legislation that makes it clear that federal standards or guidelines designed to enhance access to high-quality health care cannot be used to invent new causes of action or liability exposure against physicians.
- States bring clarity to the grace period through AMA model legislation: Washington was the first state to enact legislation that will help physicians with the ACA’s 90-day grace period. Senate Bill 6016, based on AMA model legislation, among other provisions, requires a health plan, upon request by a physician, to provide information regarding an exchange enrollee’s eligibility status “in real-time.” Louisiana also enacted House Bill 506 that addresses the grace period. The grace period bill is part of an overall package of AMA model bills that aim to improve ACA implementation in the states.
- AMA working with NAIC to revise model network adequacy law: Our AMA has been participating actively in the National Association of Insurance Commissioners’ (NAIC) subgroup to revise its model network adequacy act, and efforts are based on [AMA principles](#) on this topic. The NAIC’s model act will provide lawmakers across the country with a highly detailed framework for legislative and regulatory guidance on network adequacy. Federal regulators are also invested in the outcome as potential guidance. In addition to our AMA’s call for stronger transparency requirements, our AMA is urging the NAIC to establish quantitative standards for measuring network adequacy; active evaluation and enforcement of adequate networks by state regulators; the incorporation of quality into network decisions; and clear definitions for terms such as “narrow network” and “high performance network.”
- AMA prescription drug abuse work influences national policy: AMA efforts in favor of a comprehensive approach to reduce prescription drug abuse, diversion, overdose and death have earned multiple wins recently. The National Conference of Insurance Legislators incorporated many of our AMA’s recommendations in its best practices to curb opioid abuse, and the National Governors Association (NGA) adopted a strong public health focus in its “Reducing Prescription Drug Abuse: Lessons Learned from an NGA Policy Academy.”
- States increase access to naloxone: Delaware, Louisiana, Maine, Minnesota, Ohio, Tennessee, and Wisconsin are among the most recent states that have enacted new laws this year—with support from our AMA—to increase the availability of naloxone and adoption of Good Samaritan provisions.
- AMA “Truth in Advertising” Campaign advances: In 2014, Utah and West Virginia enacted truth in advertising (TIA) legislation based on AMA model state legislation. These new bills will increase clarity and transparency for patients when they seek health care services by requiring clinicians to wear a name badge or clothing that identifies the clinician’s name and license type, and prohibiting deceptive or misleading advertising. Since the inception of this campaign in 2010, 19 states have enacted legislation based all or in part on our AMA TIA legislation.
- Physician-led, team-based care campaign advances: In Nebraska, LB 916 was vetoed. The bill would have eliminated the requirement that nurse practitioners enter into an integrated practice agreement with a licensed physician and would have allowed independent practice after 2,000 hours of supervised practice. Other bills in conflict with the physician-led team model of care were also defeated in Florida, Iowa, Kansas, Massachusetts, Mississippi, Missouri, and Utah.
- Support for graduate medical education funding: With our AMA’s support, California added to the state budget over \$7 million in new funds for primary care residency slots. This critical funding will help California meet increasing demand for medical services.

To provide a further update to the HOD on health insurance exchanges, as of August 2014, 36 states declined to establish ACA exchanges of their own and have relied instead on the federally run exchange. In recent decisions in the Fourth Circuit (*King v. Burwell*) and the D.C. Circuit (*Halbig v. Burwell*), the federal courts have split over the question of whether individuals in these states are eligible for federal subsidies for the purchase of coverage through federally run exchanges. The Obama administration has requested a rehearing of *Halbig* case before the full panel in the D.C. Circuit. If this request is declined, or if the full court affirms the original decision, it is likely that the eligibility question will come before the Supreme Court in its next session. This case could have major implications for individuals in states that did not establish exchanges, and states may be forced to act. Our AMA will continue to monitor and engage on this topic as events warrant.

For more information on our AMA's state advocacy activities, please visit the [Advocacy Resource Center website](#).

2014 AMPAC ACTIVITIES

AMPAC's mission is to provide member physicians with the opportunity to support candidates to federal office who will help advance our AMA's legislative goals and to assist physicians and their families in carrying out their civic responsibilities in democratic government. AMPAC activities involve more than making direct contributions to candidates for the US House of Representatives and Senate. AMPAC also has a long history of engaging in independent expenditures and partisan communications, and providing political education programs such as its Campaign School, Candidate Workshop, and Regional Political and Grassroots Seminars.

In the 2014 election cycle, AMPAC was focused on providing support to candidates who could advance our AMA's legislative agenda and to involve members of organized medicine in the political process. Working closely with our state medical society political action committee (PAC) partners, AMPAC check presentations to candidates provided hundreds of opportunities for local physicians and AMA lobbyists to engage with Members of Congress and other supportive candidates to discuss our AMA's top federal priorities.

Participation in AMPAC's political education programs continues to grow and draws rave reviews from participants. Graduates are currently serving in the US Senate and House of Representatives as well as winning seats in dozens of state legislative and other local races. This year AMPAC also co-hosted with state medical societies eight regional campaign and grassroots seminars in Colorado, Kentucky, Nebraska, Nevada, New York, North Carolina, Ohio and Oregon.

AMPAC fundraising has been increasing steadily each year since 2010. Our Capitol Club major donor program is chiefly responsible for this growth, but AMPAC must continue to grow in order to compete in an election environment that has seen the influx of substantial new sources of money. Single-issue Super PACs and individual wealthy donors now often spend more on individual races than the candidates themselves. AMPAC's fundraising success begins, first and foremost, with the leaders of organized medicine—members of the AMA House of Delegates. We need your contributions and your help promoting AMPAC membership with your colleagues back home at state and county medical societies.

Additional information about AMPAC activities is included in the report of the AMPAC Board of Directors distributed to the HOD at each Annual and Interim Meeting.

2014 GRASSROOTS/GRASSTOPS ACTIVITIES

Our AMA continues to operate robust grassroots and grasstops efforts. Our Very Influential Physicians (VIP) program enlists physicians who have good relationships with key members of Congress to serve as trusted resources on health care legislation. The Physicians' Grassroots Network (PGN) helps physicians to take action on timely issues important to physicians and patients. Finally, our Patient Action Network (PAN) topped over 1 million patient advocates that we educate on key health care topics and mobilize at critical points in the legislative process.

Our AMA has hosted two interactive grassroots training webinars so far this year with over 125 physician activists taking part. The first was in February as SGR repeal efforts were reaching a fevered pitch. The second was held in advance of Congress' August Recess and featured Rep. Ami Bera (D-CA) who provided a congressional insider's view on SGR's latest state of play. These events are part of the VIP key contact program and impart valuable tactics

and communication best practices to assist these elite physician activists in lobbying their elected officials one-on-one.

Our collective grassroots push on the SGR during the 113th Congress has been very successful to date. The FixMedicareNow.org website received over 180,000 views. We had close to 2 million physician and patient Facebook impressions. Our Facebook physician and patient reach tallied over 1 million. We had close to 300,000 views of our SGR YouTube videos. Our email and phone activity has also been very heavy in this Congress. There have been over 900,000 patient emails and over 44,000 physician emails to Congress urging them to solve the SGR problem, and we generated nearly 30,000 calls to Congress.

FixMedicareNow.org has been very impactful and is being recognized by industry observers. In 2014, it was selected as a Webby Honoree in the Webby Awards Activism category. Established in 1996, the Webby Awards are presented by the International Academy of Digital Arts and Sciences and recognize the best work on the Internet from across the globe. The FixMedicareNow.org website shared honoree status this year with nine other advocacy websites, including Greenpeace, CNN and MSNBC.com. The website was also honored by the Academy of Interactive & Visual Arts' Communicator Awards, receiving a Silver Award of Distinction in three separate categories. The Communicator Awards this year also recognized major organizations such as Adobe, the Coca-Cola Co., Cisco Corp., GlaxoSmithKlein, Intel Corp. and the Weather Channel, among others.

NEW ADVOCACY RESOURCES

The Advocacy Group produces new tools and resources for physicians to assist them in adapting to the changing health care environment.

- Our AMA, in collaboration with the Medical Group Management Association, developed a checklist for medical practices that provides practical advice for addressing issues that might arise with patients who purchased coverage through the new exchange health plans. The checklist is available on our [ACA website](#).
- Our AMA created additional resources, including fact sheets and frequently asked questions, on our ACA page for physicians and practice managers/front office staff to answer questions from patients on the ACA and to direct them to additional resources at healthcare.gov, as well as a tool kit on issues related to the grace period under the new exchange health plans.
- Our [AMA Innovators Committee](#) created a new resource titled “Where do I Fit in? Dividing the Pie in New Payment Models,” providing guidance to practicing physicians on how to make sure new payment models translate into fair reimbursements down to the individual provider. Webinars highlighting how payments flow are available on our AMA website to further educate physicians on these critical issues.
- Our AMA produced policy briefs on telemedicine as well as payment for mental health and substance abuse services. “Coverage of and payment for telemedicine” describes categories of telemedicine technologies, summarizes current health plan coverage of and payment for telemedicine services, and presents AMA principles for ensuring the appropriate coverage of and payment for telemedicine services. “Improving mental health care in the United States” highlights AMA advocacy to improve payment for and access to mental health and substance abuse services, including significant increases in Medicare payment that resulted from the work of the CPT® Editorial Panel and the RUC. These documents are available on the [Council on Medical Service website](#).
- A new [AMA resource](#) details the effects that virtual credit cards—an increasingly used form of electronic payment—can have on physician practices. Using a virtual credit card, a payer will send a physician practice (via fax, mail, or email) information that needs to be punched into a credit card point-of-service system in order to receive contractual payments. This payment method, which is often implemented by health insurers without provider notification or choice, can result in lost revenue and administrative burden for physician practices. “The effect of health plan virtual credit card payments on physician practices” details potential concerns regarding virtual credit cards and provides recommendations and useful information about the benefits of standardized electronic funds transfer (EFT) using the Automated Clearinghouse Network. The issue of virtual credit cards and related AMA resources were also highlighted in AMA testimony presented twice in 2014 before the National Committee on Vital and Health Statistics (NCVHS).
- New AMA toolkits help physicians take advantage of [EFT](#) and electronic remittance advice ([ERA](#)). With operating rules for EFT and ERA in effect as of Jan. 1, physicians have the opportunity to reduce administrative hassles. Most notably, health insurers are required to make claims payments using the newly designated EFT

standard transaction to all physician practices requesting this payment method. Our AMA has developed EFT and ERA toolkits with step-by-step guidance to help physicians take advantage of these electronic transactions.

- Our AMA's new Health Workforce Mapper, launched in collaboration with the American Academy of Family Physicians and the Scope of Practice Partnership, is a dynamic interactive mapping tool that illustrates to policymakers the geographic distribution of the health care workforce by specialty, state, county, or census tracts, to assist them in making appropriate, evidence-based decisions. The AMA Health Workforce Mapper allows the user to build a rich display of factors relevant to the health care workforce. For example, users can layer geographic and health policy data such as hospital locations or health professional shortage areas, population indicators, landmarks and other topographical features. The user can also display the ratio of physician or non-physician clinicians to population in any given region or nationally. The AMA Health Workforce Mapper can be used to distinguish possible areas of both deficiency and overlap, and to identify high-priority areas for workforce expansion.
- New AMA web-resources provide guidance on how to complete the cumbersome Open Payments registration process, to review their data, and to dispute potential reporting errors before the public release on September 30. The resources include user-friendly step-by-step instructions on how to register and review data in addition to a printer-friendly and downloadable toolkit that provides a broad overview of the Sunshine Act and offers practical information on how to prepare for the public release. Additionally, the web-resources include key reporting deadlines and a compendium of AMA advocacy efforts that urge changes to Open Payments implementation.
- Our AMA has produced the first of multiple toolkits addressing the complexities in MU Stage 2. The first [toolkit](#) examines the view, download, and transmit patient engagement MU objective. It was designed to clearly state what is required by the physician and how the measure is calculated. The toolkit identifies seven tips that provide physicians the ability to meet this measure through patient engagement with the least amount of workflow disruption. Forthcoming toolkits will help physicians utilize health information service providers (HISPs) for direct exchange and a plain English explanation of the protected patient health information MU core requirement.
- Our AMA, in partnership with the Healthcare Information and Management Systems Society (HIMSS), co-developed three audio podcast learning sessions tailored for physicians and their medical staff. The [first podcast](#) identified what is required by the Health Insurance Portability and Accountability Act (HIPAA) to protect electronic patient health information and the steps necessary to conduct a security risk assessment. Combined with supportive written material, the first podcast was awarded AMA PRA Category 1 Credit™. The [second podcast](#) explains the basics of health information exchange (HIE) participation, meaningful use requirements, the role of public health departments and clinical decision support. The [third](#) addresses medication reconciliation, registries, health information service providers and the business case to engage with HIEs.
- In conjunction with the Physician Consortium for Performance Improvement, our AMA developed resources to assist physicians with participating in the Physician Quality Reporting System (PQRS). The [AMA website](#) has a searchable and downloadable database of all PQRS measure specifications. It also outlines the various reporting options.

NEW ADVOCACY RESEARCH

Our AMA also conducts research on topics important to physicians that will help to shape our advocacy efforts.

- [AMA Economic Impact Study: \\$1.6 trillion, 10 million jobs](#): Each physician in the US supports close to 14 jobs on average and contributes \$2.2 million in economic output, underscoring how physicians influence the health of both their patients and the economy, according to our AMA's Economic Impact Study. Nationally, these physicians support \$1.6 trillion in total economic output and 10 million jobs. Visit the [Economic Impact Study Web page](#) to access an interactive map and see a specific breakdown of economic contributions for each state.
- [Physician Practice Benchmark Survey](#): In the fall of 2014, our AMA is fielding the "Physician Practice Benchmark Survey" which collects the most recent data on physician practice arrangements and physician compensation methods. The 2012 edition of the survey found that although there has been a shift toward hospital employment, 53 percent of physicians were self-employed and 60 percent of physicians worked in practices that were wholly-owned by physicians. Results from the most recent survey should be available in early 2015.
- [ACA Impact Survey](#): In August 2014, our AMA fielded its "ACA Impact Survey" to better assess how the implementation of the ACA has affected physician practices. Topics addressed in the survey include changes in

patient and payer mix, changes in provider networks, and cash flow issues in practices of all sizes and across all specialties.

COLLABORATION WITH THE FEDERATION

The Federation of Medicine is at its strongest and most effective when it advocates with a unified voice on a focused agenda. This was reinforced at a session with former White House Press Secretaries at the 2014 NAC. Dana Perino, Press Secretary during President George W. Bush's Administration, stated "You're a very powerful group if you're speaking collectively with one voice about an issue that you can drive home." We must work to ensure that our members are fully engaged and energized in order to bring about a successful result on our top issues. If policymakers see disparate messages from the Federation rather than a unified message, we hinder our chances for success significantly.

Our AMA is committed to the continuous improvement of our advocacy activities. Help is needed at the local level to move our collective national agenda forward. Our AMA needs assistance with increasing physician grassroots involvement; higher attendance at the NAC; more physicians donating to AMPAC at major donor levels; more in-district meetings with policymakers; and most importantly, we need to work together to hold members of Congress accountable for the votes that they take (or do not take) on key issues for physicians and patients.

Our AMA stands ready to work with the Federation on these goals, and we welcome all parties' commitment to enhancing our collective advocacy work. To enhance that work, we all must prioritize the issues that impact physicians nationwide and remain focused with our advocacy agenda. The volume and subject matter of resolutions coming to the HOD can present our AMA with an advocacy agenda that is very wide and can limit deployment of resources to accomplish our top goals. This is an issue that was broached in the review of the Advocacy Group. Since the 2012 Interim Meeting, the HOD has adopted over 175 reports and resolutions on various advocacy topics, including over 60 directives from the 2014 Annual Meeting alone. Many of these directives focus on topics that affect all of medicine, but others are more limited in scope and can divert resources from our top priorities. Further, as resolutions become more prescriptive on tactics and timelines, our AMA's ability to negotiate the best possible outcome for physicians and patients is limited.

We are not discouraging the HOD from tackling tough or diverse issues. We are asking that state and national medical specialty societies take a hard look at the resolutions that they decide to transmit to the HOD for consideration and review how they affect our AMA's overall advocacy agenda. We want to be responsive to the HOD and impactful on the directives that they adopt.

DISCUSSION

Your Board of Trustees appreciates the opportunity to report our advocacy work. We have used various tactics to report our work to the HOD previously, and this report affords us a chance to lay out our work in a more comprehensive fashion. This report is a good showcase for our federal, state, political and research efforts.

Your Board of Trustees is also committed to increasing and improving our communications on advocacy topics with the HOD. Our AMA sends a biweekly Advocacy Update to key Federation leaders, including the HOD. Since its retooling and relaunch in June of this year, the open rate has hovered just above 30 percent. While this is a very strong number for an email vehicle, we would encourage HOD members who are not reviewing this email to do so in order to read about our AMA's various advocacy and litigation efforts in a near real-time format. Our AMA has also revamped Morning Rounds, and the updated vehicle also includes advocacy news on a near daily basis. Our Federation Relations staff also sends out email blasts to the HOD and other Federation leaders when breaking news occurs. Your Speakers also send information periodically to the HOD on pertinent matters. Our AMA website also contains a significant library of advocacy information, provides updates and advocacy tools for Federation members to use and remains a vital tool for them. We also conduct conference calls with the Federation on a regular basis, and besides the Annual and Interim Meetings, we host the NAC, the State Legislative Strategy Conference, the AMPAC Federation meeting, political education programs, and other in-person events to collect feedback, refine our strategy, and to marshal our resources as we pursue our advocacy agenda.

Regarding advocacy sessions at the Annual and Interim Meetings, your Board is cognizant of the HOD's desire for more information and opportunities for discussion. At the last Interim Meeting, we held an open forum on SGR, and

we will hold another one at this year's Interim Meeting. We will consider hosting similar open forums whether on SGR or other advocacy topics at future HOD meetings. The Council on Legislation also hosts a session at Interim Meetings. While these Council sessions have been successful to date, we will discuss with the Council ways to redesign the format and increase attendance to ensure that these sessions are having maximum effect. Our AMPAC Capitol Club lunch is another opportunity to bring in informative and influential policymakers and thought leaders to interact with Capitol Club members. We will continue to have this venue at Annual and Interim Meetings and the NAC.

CONCLUSION

Once again, your Board of Trustees appreciates the opportunity to provide an update on our advocacy efforts in a comprehensive fashion to the HOD. Advocacy is a key component of the AMA Equation, and we are committed to successfully advancing remedies and solutions to the challenging issues facing our nation's physicians and their patients. Our AMA is committed to ongoing, continual improvement across all of our business units, and we will continue to seek ways to improve the effectiveness of our advocacy efforts and to increase our communication to the HOD, and the Federation more broadly, on these efforts.

9. 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 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 2014 American Medical Association (AMA) Interim Meeting in compliance with the five-year review process established by the House of Delegates in Policy G-600.020 and AMA Bylaw 8.5.

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

The following organizations were reviewed for the 2014 Interim Meeting:

- American College of Cardiology
- American College of Chest Physicians
- American College of Emergency Physicians
- American College of Gastroenterology
- American College of Nuclear Medicine
- American Medical Group Association
- National Association of Medical Examiners

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 American College of Chest Physicians did not submit materials for review.

The materials submitted indicate that the: American College of Cardiology, American College of Emergency Medicine, American College of Gastroenterology, American College of Nuclear Medicine and the American

Medical Group Association 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 National Association of Medical Examiners does not meet the membership requirements for specialty organizations represented in the HOD, and therefore, is not in compliance with the five-year review requirements.

The American College of Chest Physicians' failure to submit data and information is a violation of the Responsibilities of National Medical Specialty Organizations (Bylaw 8.2 – Exhibit C) and in accordance with Bylaw 8.51 (Exhibit D) allows for the Specialty and Service Society (SSS) to make a recommendation through the BOT to the HOD that may call for the termination of an organization's representation in the HOD or may take such other action as deemed appropriate. The SSS recommends, and the Board deems appropriate, allowing the American College of Chest Physicians six months to submit materials for review.

The Society of Medical Consultants to the Armed Forces having fulfilled their mission and sunset as an organization should be removed from the list of organizations in the House of Delegates and Specialty and Service Society per the request of the organization.

RECOMMENDATIONS

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

1. That American College of Cardiology, American College of Emergency Physicians, American College of Gastroenterology, American College of Nuclear Medicine and the American Medical Group Association retain representation in the American Medical Association House of Delegates.
2. That the National Association of Medical Examiners 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.
3. That American College of Chest Physicians be given six months to submit materials for consideration for continued representation in the American Medical Association House of Delegates or risk loss of representation in the House of Delegates.
4. That the Society of Medical Consultants to the Armed Forces representation in the American Medical Association House of Delegates be terminated per the organization's request.

APPENDIX

Exhibit A - Summary Membership Information

Organization	AMA Membership of Organization's Total Eligible Membership
American College of Cardiology	5,504 of 30,063 (18%)
American College of Chest Physicians	data not submitted
American College of Emergency Physicians	5,200 of 29,202 (18%)
American College of Gastroenterology	1,292 of 7,622 (17%)
American College of Nuclear Medicine	87 of 294 (30%)
American Medical Group Association	2,425 of 18,946 (13%)
National Association of Medical Examiners	114 of 624 (18%)

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.
2. 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
 - (c) 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.
4. 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.
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.

Exhibit C - Responsibilities of National Medical Specialty Organizations (Bylaw 8.2)

- 8.2.1 To cooperate with the AMA in increasing its AMA membership.
- 8.2.2 To keep its delegate to the House of Delegates fully informed on the policy positions of the organization so that the delegate can properly represent the organization in the House of Delegates.
- 8.2.3 To require its delegate to report to the organization 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

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 8.20. 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 8.20.

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 8.20, 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 8.20 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 8.20, 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 8.20, 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 8.531.

8.5.3.2.2 The House of Delegates may terminate the representation of the specialty society or the professional interest medical association in the House of Delegates. The specialty society or the professional interest medical association shall remain a member of the SSS, pursuant to the provisions of the Standing Rules of the SSS. The specialty society or the professional interest medical association may apply for reinstatement in the House of Delegates, through the SSS, when it believes it can comply with all of the current guidelines for representation in the House of Delegates.

SPEAKERS' REPORTS

The following reports, 1–2, were presented by Andrew W. Gurman, MD, Speaker, and Susan R. Bailey, MD, Vice Speaker:

1. RULES FOR CAMPAIGN PARTIES

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

HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

See Policy [G-610.020](#).

Prior to the 2014 Annual Meeting, paragraph 6 of Policy G-610.020, Election Campaigns, read as follows:

AMA policy on election campaigns includes the following: ... (6) A coalition or a state or specialty delegation may finance only one big party at the Annual Meeting irrespective of the number of candidates from the society or coalition. This rule limits a candidate to only one big party at the Annual Meeting whether financed by a coalition or a state or specialty delegation. This rule also limits a state or specialty society or coalition to one big party irrespective of the number of candidates from that society or coalition. At these events, alcohol may be served only on a cash or no-host bar basis;

Resolution 602-A-14 proposed an addition to the existing policy that would allow societies to sponsor multiple parties, so long as any particular candidate was featured at only one party. Following its open hearing, Reference Committee F proffered an amendment to the policy by substitution, which was adopted. The language of Policy G-610.020(6) now reads (the full policy can be found in [Appendix A](#)):

A state, specialty society, caucus, coalition, etc. may contribute to more than one party. However, a candidate may be featured at only one party, which includes: (a) standing in a receiving line, (b) appearing by name or in a picture on a poster or notice in or outside of the party venue, or (c) distributing stickers, buttons, etc. with the candidate's name on them.

The amendment by substitution effectively rescinded the language dealing with alcohol. The rescission appears to have been inadvertent, however, because testimony in the reference committee addressed concerns about party sponsorship. No comments related to the serving of alcohol were heard, and in fact, the language of Resolution 602 as originally proposed had retained the restrictions on alcohol service. The item was not debated on the floor of the House, having been adopted on the consent calendar.

The limits on serving alcohol had been adopted at the 1997 Annual Meeting based on a [recommendation](#) from the Special Committee on Campaigns and Elections ([Appendix B](#)), which had been formed to address concerns about the expense of AMA campaigns. The committee concluded that members of the House appreciated the collegiality of social functions and the opportunity to become better acquainted and discuss business with fellow delegates and alternate delegates, but that there was “much concern expressed about the cost of these social events, especially the cost of serving alcoholic beverages.... The Special Committee now believes that given the political and financial climate, a firm rule must be established that is easily enforced and applies to everyone equally.”

The rule that eventuated was simple and easily implemented, and it served our AMA well for over 15 years. Moreover, the challenges of election campaigns are not dissimilar to those from 1997. Your Speakers believe that the removal of language relating to alcohol at campaign parties should be reinstated and therefore propose the following recommendation. As an aside, we would note that the rule applies only to election parties and not to other traditional activities that are not campaign-related.

RECOMMENDATION

Your Speakers recommend that Policy G-610.020, paragraph 6, be amended by addition to read as follows:

A state, specialty society, caucus, coalition, etc. may contribute to more than one party. However, a candidate may be featured at only one party, which includes: (a) standing in a receiving line, (b) appearing by name or in a picture on a poster or notice in or outside of the party venue, or (c) distributing stickers, buttons, etc. with the candidate's name on them. At these events, alcohol may be served only on a cash or no-host bar basis;

and that the remainder of this report be filed.

APPENDIX A - Policy G-610.020, Election Campaigns

AMA policy on election campaigns includes the following:

(1) Active campaigning for AMA elective office may not begin until the Board of Trustees, after its April meeting, announces the nominees for council seats. Active campaigning includes mass outreach activities directed to all or a significant portion of the members of the House of Delegates and communicated by or on behalf of the candidate. If in the judgment of the Speaker of the House of Delegates circumstances warrant an earlier date by which campaigns may formally begin, the Speaker shall communicate the earlier date to all known candidates; (2) A campaign manual containing information on all candidates for election shall continue to be developed and distributed; (3) Campaign expenditures and activities should be limited to prudent and reasonable levels necessary for adequate candidate exposure to the delegates. The Speaker of the House should meet with all announced candidates and campaign managers at each meeting of the House of Delegates to agree on general campaign procedures; (4) At the Interim Meeting, campaign-related expenditures and activities shall be discouraged, and there shall be no large campaign receptions, luncheons, or other formal campaign activities. This rule does not preclude distribution of a declaration of candidacy on the last day of the Annual Meeting, last day of the Interim Meeting, or one announcement of candidacy by a mailing prior to the Interim Meeting. An announcement of candidacy includes only the candidate's name, photograph, email address, URL, the office sought and a list of endorsing societies. This rule prohibits campaign parties at the Interim Meeting and the distribution of campaign literature and gifts at the Interim Meeting. It is permissible at the Interim Meeting for candidates seeking election at the next Annual Meeting to engage in individual outreach, such as small group meetings, including informal dinners, meant to familiarize others with a candidate's opinions and positions on issues; (5) The AMA believes that: (a) specialty society candidates for AMA House of Delegates elected offices should be listed in the pre-election materials sent to the House and on the ballot as the representative of that society and not by the state in which the candidate resides; (b) elected specialty society members should be identified in that capacity while serving their term of office; and (c) nothing in the above recommendations should preclude formal co-endorsement by any state delegation of the national specialty society candidate, if that state delegation should so choose; (6) A state, specialty society, caucus, coalition, etc. may contribute to more than one party. However, a candidate may be featured at only one party, which includes: (a) standing in a receiving line, (b) appearing by name or in a picture on a poster or notice in or outside of the party venue, or (c) distributing stickers, buttons, etc. with the candidate's name on them; (7) Displays of campaign posters, signs, and literature in public areas of the hotel in which Annual Meetings are held are prohibited. Displays of campaign posters, signs, and literature in public areas of hotels in which Annual Meetings are held detract from the dignity of the position being sought and are unsightly. Campaign posters may be displayed at campaign parties and campaign literature may be distributed in the non-official business folder for members of the House of Delegates. No campaign literature shall be distributed and no mass outreach electronic messages shall be transmitted after the opening session of the House of Delegates; (8) A reduction in the volume of telephone calls from candidates, and literature and letters by or on behalf of candidates is encouraged. The use of electronic messages to contact electors should be minimized, and if used must allow recipients to opt out of receiving future messages. The Election Manual serves as a mechanism to reduce the number of telephone calls, mailings and other messages members of the House of Delegates receive from or on behalf of candidates. The Election Manual provides an equal opportunity for each candidate to present the material he or she considers important to bring before the members of the House of Delegates and should relieve the need for the additional expenditures incurred in making non-scheduled telephone calls and duplicative mailings; (9) Campaign gifts can be distributed only at the Annual Meeting in the non-official business folder and at one campaign party. Campaign gifts should only be distributed during the Annual Meeting and not mailed to Delegates and Alternate Delegates in advance of the meeting. Campaign memorabilia are limited to either a button, pin, sticker, or other low-cost item, the maximum cost of which shall be determined by the Speaker of the House. No other campaign memorabilia shall be distributed at any time; (10) The Speaker's office will coordinate the scheduling of candidate interviews for general officer positions (Trustees, President-Elect, Speaker and Vice Speaker); (11) Candidates for AMA office should not attend meetings of state medical societies unless officially invited and could accept reimbursement of travel expenses by the state society in accordance with the policies of the society; (12) Every state and specialty society delegation is encouraged to participate in a regional caucus, for the purposes of candidate review activities; and (13) Our AMA (a) requires completion of Disclosure of Affiliation forms by all candidates for election to our AMA Board of Trustees and Councils prior to their election; and (b) will expand accessibility to completed Disclosure of Affiliation information by posting such information on the "Members Only" section of the AMA website before election by the House of Delegates. (CLRPD Rep. E, I-80; Res. 22, I-81; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: CLRPD Rep. F, I-91; CCRC Special Report, I-92; CCRC Special Report I-93; Special Committee on Campaign and Elections and Reaffirmed Special Committee Report on Campaigns and Elections, I-96; Special Committee on Campaigns and Elections, A-97; CLRPD Rep. E, I-80; Res. 22, I-81; A-

82; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: CLRPD Rep. F, I-91; CCRC Special Report, I-92; CCRC Special Report I-93; Special Committee on Campaign and Elections and Reaffirmed Special Committee Report on Campaigns and Elections, I-96; Special Committee on Campaigns and Elections, A-97; Reaffirmed: Sunset Report, I-00; Consolidated: CLRPD Rep. 3, I-01; CCB Rep. 3, I-08; Modified: Rules and Credentials Rep. 1, A-11; Modified: Rules and Credentials Rep. 1, I-13; Appended: BOT Rep. 5, I-13; Modified: Res. 602, A-14)

APPENDIX B - Report of the Special Committee on Campaigns and Elections, from the Proceedings for the 1997 Annual Meeting

The following report was presented by Joseph T. Ostroski, MD, Chair:

CAMPAIGN-RELATED SOCIAL FUNCTIONS

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

At the 1996 Interim Meeting, the House of Delegates revised certain rules pertaining to the conduct of campaigns for AMA office. The House acted upon recommendations of a special committee appointed by the Speaker to observe the campaign process and solicit suggestions from the delegates for making revisions. In addition the Speaker asked the special committee to sit as Reference Committee I and conduct an open hearing and prepare a report for House of Delegates consideration. Members of the Special Committee on Campaigns and Elections are:

Joseph T. Ostroski, MD, Florida, Chair
 Cathy O. Blight, MD, Michigan
 Jimmie A. Gleason, MD, Kansas
 Charles D. Hollis, MD, Georgia
 Jack P. Strong, MD, US and Canadian Academy of Pathology, Inc.

While modifying several campaign rules, the House of Delegates was uncertain about the best course of action to take regarding campaign related social functions. The House voted to continue the special committee for the sole purpose of considering this issue and referred the Special Committee's Recommendation 5 back to the committee for a report at the 1997 Annual Meeting. This action had the effect of keeping unchanged the rule on campaign parties adopted in 1992. The Special Committee's Recommendation 5 states:

"Social functions at AMA Annual and Interim Meetings may be continued without bands, entertainment, lavish decorations and formal reception lines. Adoption of one or more of the following options may be considered by sponsors of social functions seeking to limit expenditures: utilizing a cash or no-host bar; limiting alcoholic beverages to beer and wine; eliminating all alcoholic beverages."

The Special Committee believes that there is overwhelming sentiment to continue both campaign and noncampaign social functions at meetings of the House of Delegates. Members of the House of Delegates appreciate the opportunities to enjoy collegiality, become better acquainted with delegates and alternate delegates, to discuss issues on the House agenda, and to share experiences. The Special Committee also heard much concern expressed about the cost of these social events, especially the cost of serving alcoholic beverages. The discussion only involved the cost of these beverages and did not include any moral issues about the appropriateness of having alcohol available at social events. Various suggestions were offered to control these costs without eliminating social functions altogether.

The Special Committee now believes that given the political and financial climate, a firm rule must be established that is easily enforced and applies to everyone equally. The Committee wants the candidates' sponsoring societies to have a large measure of flexibility in determining what kind, if any, social activities are arranged on behalf of their candidates. One candidate may prefer to spend a large share of the available budget on food, another on entertainment, and another on decorations. The Committee believes, however, costs can be curtailed by requiring all campaign social events that plan to serve alcohol to do so only on the basis of a cash or no-host bar. This new rule would apply only to campaign related social events and would not apply to any receptions, dinners, or parties of a non-campaign nature organized by the AMA or units in the Federation. Also, this rule would apply to social functions held in public meeting rooms of the hotel and would not apply to social functions held in the hotel suites, commonly called "Open Hospitality."

RECOMMENDATION:

The Special Committee on Campaigns and Elections recommends:

That the following rule on campaign related social functions be adopted to become effective at the 1998 Annual Meeting of the House of Delegates:

There will be only one big party at the Annual Meeting financed by a coalition or a state or specialty delegation irrespective of the number of candidates from that society or coalition. At these events, alcohol may be served only on a cash or no-host bar basis.

That the rule on Campaign Related Social Functions be reviewed in two years and modified as necessary.

2. RECOMMENDATIONS FOR POLICY RECONCILIATION

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

Recommended actions accomplished.

In accord with American Medical Association (AMA) Policy G-600.111, your Speakers present this report dealing with obsolete policies.

RECOMMENDED RECONCILIATIONS

In reviewing actions taken at recent House of Delegates meetings, we uncovered a handful of anomalies in AMA policy that warrant attention. While none of these is critical, each presents an opportunity to neaten or clarify AMA policy statements. The changes outlined below will be made.

Policies to be Rescinded in Part

1. At the 2013 Annual Meeting, G-625.020, AMA Strategic Planning, was amended by the addition of paragraph 8, in which “Our AMA Board of Trustees will be asked to consider whether our American Medical Association’s strategic plan adequately addresses public health and primary prevention and report back to the House of Delegates at the 2013 Interim Meeting.” An informational report ([BOT Report 9-1-13](#)) was delivered to the House at the 2013 Interim Meeting as requested, making paragraph 8 obsolete. That paragraph will be rescinded.
2. Policy H-165.877, Increasing Coverage for Children, includes a reference to “the AMA standard benefit package,” which is no longer policy. Prior to supporting a system of individually selected and owned health insurance, our AMA had policy in support of standard benefits packages in the context of its previous support for an employer mandate. Support for an employer mandate and the minimum and standard benefits packages were rescinded. Consequently, the reference in Policy H-165.877 will be stricken.

H-165.877, Increasing Coverage for Children

Our AMA: (1) supports appropriate legislation that will provide health coverage for the greatest number of children, adolescents, and pregnant women; (2) recognizes incremental levels of coverage for different groups of the uninsured, consistent with finite resources, as a necessary interim step toward universal access; (3) places particular emphasis on advocating policies and proposals designed to expand the extent of health expense coverage protection for presently uninsured children and recommends that the funding for this coverage should preferably be used to allow these children, by their parents or legal guardians, to select private insurance rather than being placed in Medicaid programs; (4) supports, and encourages state medical associations to support, a requirement by all states that all insurers in that jurisdiction make available for purchase individual and group health expense coverage solely for children up to age 18; (5) encourages state medical associations to support study by their states of the need to extend coverage under such children’s policies to the age of 23; (6) seeks to have introduced or support federal legislation prohibiting employers from conditioning their provision of group coverage including children on the availability of individual coverage for this age group for direct purchase by families; (7) advocates that, in order to be eligible for any federal or state premium subsidies or assistance, the private children’s coverage offered in each state should be no less than the benefits provided under Medicaid in that state and allow states flexibility in the basic benefits package; (8) advocates that state and/or federal legislative proposals to provide premium assistance for private children’s coverage provide for an appropriately graduated subsidy of premium costs for insurance benefits that meet the standards of the AMA standard benefit package; (9) supports an increase in the federal and/or state sales tax on tobacco products, with the increased revenue earmarked for an income-related premium subsidy for purchase of private children’s coverage;

(10) advocates consideration by Congress, and encourage consideration by states, of other sources of financing premium subsidies for children's private coverage; (11) supports and encourages state medical associations and local medical societies to support, the use of school districts as one possible risk pooling mechanism for purchase of children's health insurance coverage, with inclusion of children from birth through school age in the insured group; (12) supports and encourages state medical associations to support, study by states of the actuarial feasibility of requiring pure community rating in the geographic areas or insurance markets in which policies are made available for children; and (13) encourages state medical associations, county medical societies, hospitals, emergency departments, clinics and individual physicians to assist in identifying and encouraging enrollment in Medicaid of the estimated three million children currently eligible for but not covered under this program. (Sub. Res. 208, A-97; CMS Rep. 7, A-97; Reaffirmation A-99; Reaffirmed: CMS Rep. 5, I-99; Reaffirmed: Res. 238 and Reaffirmation A-00; Reaffirmation A-02; Reaffirmation A-05; Consolidated: CMS Rep. 7, I-05; Reaffirmation A-07; Reaffirmation A-08)

Suggested Language Update

As we have experimented with the virtual reference committees, one change that has been made is to refer to them as "online member forums." In fact, the forums are open to any AMA member and are promoted as such. In this vein, references to "virtual reference committee(s)" in Policy G-600.045, Virtual Reference Committees in the House of Delegates, will be changed to "online member forums," including the title. The word "should" will also be inserted as an editorial correction in the first line.

~~Virtual reference committees~~ Online member forums should be incorporated into every House of Delegates policymaking meeting, using the following parameters: a. Each reference committee should participate in the online member forum ~~virtual reference committee~~ process; b. Each online member forum ~~virtual reference committee~~ should cover as many items of business as possible, including, at minimum, those items that appear in the initial compilation of the Delegate Handbook; c. Comments submitted to an online member forum ~~virtual reference committee~~ should be used to prepare a summary report that reflects the comments received up to that point; d. Full, free and complete testimony should be allowed in the onsite hearings; and e. The Speakers should experiment with alternative procedures to enhance and improve the overall online member forum ~~virtual reference committee~~ process. (BOT Rep. 8, A-13; Modified: CCB Rep. 1, I-13)

Possible Change to Bylaws

Your Speakers are ex officio members of the Council on Constitution and Bylaws, and in reviewing the newly renumbered bylaws, the following provision was noted:

1.1.1.4 Rights and Privileges. Active members are entitled to receive the *Journal of the American Medical Association*, *American Medical News* and such other publications as the Board of Trustees may authorize.

Insofar as *American Medical News* is no longer published, the Council on Constitution and Bylaws should consider preparing a report to correct this outdated language.

The changes outlined herein will be implemented when this report is filed.