

## REPORTS OF THE BOARD OF TRUSTEES

The following reports, 1–31, were presented by David O. Barbe, MD, MHA, Chair:

### 1. INCREASING AWARENESS OF NUTRITION INFORMATION IN SCHOOLS (RESOLUTION 914-I-11)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS  
IN LIEU OF RESOLUTION 914-I-11 AND  
REMAINDER OF REPORT FILED**  
*See Policy [H-150.948](#).*

Resolution 914-I-11 “Increasing Awareness of Nutrition Information in Schools”, submitted by the Medical Student Section, asked that our American Medical Association (AMA) support the adoption of federal regulations requiring that all school and work cafeterias have nutritional information for menu items available for public viewing.

Testimony on this resolution raised questions about the effectiveness of a federal mandate, as well as concern for unintended consequences. The reference committee concluded that more information was needed and therefore recommended referral, to which the House of Delegates (HOD) agreed. This report reviews pertinent federal action which has been enacted since 2010 and directly addresses this resolution, as well as related AMA policy and efforts.

#### INTRODUCTION

The consumption of healthy foods and beverages is influenced by multiple factors including awareness, education, behavior, policy, and social determinants (such as access to grocery stores, transportation, employment, income, language). For children, the ability to address these factors is limited given that decisions about foods and beverages are often made for them by adults. Over 31 million children receive meals through the school lunch program; many students receive most of their meals at school.<sup>1</sup> With one out of every three children in the United States considered overweight or obese, schools are well positioned to improve children’s health.<sup>1</sup>

In schools, the primary sources of foods and beverages include school meal programs, school cafeterias, and vending machines. There is concern that those sources have not always provided items of optimal nutritional value, and that when given a choice, children do not always pick the healthiest items. The influence of industry to promote unhealthy items has complicated the issue of foods and beverages in schools; however, federal policy in recent years has been enacted with the intent of improving the health of all children in the United States.

#### NATIONAL POLICY AND EFFORTS

In December 2010, Congress passed the Healthy, Hunger-Free Kids Act.<sup>2</sup> This comprehensive bill addresses many aspects of school nutrition including:

- improvements in nutrition quality of preK-12 school food and beverages;
- enhancements to school-based meal programs to increase access;
- creation of demonstration projects to determine best practices;
- increase in farm-to-school programs to encourage the use of produce and whole foods; and
- expansion of access to drinking water.<sup>1,3</sup>

Of particular relevance to Resolution 914, this Act:

- requires schools to make information about the nutritional quality of meals more readily available<sup>1,3</sup>;
- gives the USDA the authority to set nutritional standards for all foods regularly sold in schools and requires school districts to be audited every three years to see if they have met nutrition standards; and
- strengthens local school wellness policies while requiring transparency and opportunities for public input.

The Act does not specify how information about the nutritional quality of meals shall be made available; such discretion will be determined at the local level. Many of the requirements of the Act are set to start in the 2014-2015 school year.<sup>4</sup>

The 2010 Patient Protection and Affordable Care Act (ACA) established national labeling requirements for chain restaurants, retail food establishments, and chain vending machine operators;<sup>5,6</sup> however, it does not address schools.

Organizations such as the School Nutrition Association; the Center for Science in the Public Interest (CSPI); the Food, Research, and Action Center (FRAC); the Alliance for a Healthier Generation; and the First Lady's "Let's Move" initiative are very active in the arena of school nutrition and continue to monitor progress.

#### AMA POLICY AND EFFORTS

The AMA is committed to improving health outcomes, particularly those with cardiovascular disease and/or type 2 diabetes, and continues to develop its population health agenda around prevention of these chronic diseases. Proper nutrition can have a significant positive impact in the prevention of these conditions. Furthermore, there is value in addressing nutrition at a young age so as to cultivate healthy behaviors early in the life-span. Current AMA policy is supportive of both nutrition education and labeling, especially regarding children and schools (see Appendix). Upon review of relevant policies, it became apparent that Policies D-60.990 and D-150.988 have been accomplished and are therefore recommended for rescission. In Policy D-60.990, the first clause is addressed in the Healthy, Hunger-Free Kids Act of 2010, and the second clause was addressed by the AMA's Weigh What Matters campaign (2011-2012). Regarding Policy D-150.988, it was accomplished by a letter from the AMA to the FDA in 2005.

#### CONCLUSION

The Healthy, Hunger-Free Kids Act of 2010 contains a multi-factorial set of regulations to improve nutrition in schools in order to benefit the health of all children. The Act requires schools to make information about the nutritional quality of meals more readily available, therefore addressing the main issue raised in Resolution 914-I-11 as well as reinforcing current AMA policy.

While the federal mandate is comprehensive, its full implementation remains to be seen. Study of the implementation of the regulations in different school settings would be informative, particularly as it relates to the availability of nutrition information to students, parents, caregivers, and decision-makers. School districts should consider assessing student understanding of nutrition information, particularly young children; advocating for improved nutrition education; and engaging adult stakeholders such as parents, caregivers, educators, and the medical community. Further areas of study include possible unintended consequences such as the impact on eating disorders, as well as the potential burden put upon small school districts.

#### RECOMMENDATIONS

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 914-I-11 and the remainder of this report be filed:

1. That Policy H-150.948 be amended by addition and deletion to read as follows:

##### ~~CUSTOMER~~ INCREASING CUSTOMER AWARENESS OF NUTRITION INFORMATION AND INGREDIENTS LISTS IN RESTAURANTS

Our AMA supports ~~and seeks~~ federal legislation or rules requiring ~~(1) restaurants, retail food establishments and vending machine operators~~ that have menu items common to multiple locations ~~to provide standard nutrition labels for all applicable items, available for public viewing; and (2) as well as all school and workplace cafeterias, especially those located in health care facilities, and restaurants~~ to have available for public viewing ingredient lists, nutritional information and standard nutrition labels for all menu items, ~~available for public viewing.~~

2. That Policies D-60.990 and D-150.988 be rescinded.

## REFERENCES

1. White House. Child Nutrition Reauthorization: Healthy Hunger-Free Kids Act of 2010. [whitehouse.gov/sites/default/files/Child\\_Nutrition\\_Fact\\_Sheet\\_12\\_10\\_10.pdf](http://whitehouse.gov/sites/default/files/Child_Nutrition_Fact_Sheet_12_10_10.pdf). Accessed January 15, 2014.
2. Govtrack.us. House bill S.3307. [govtrack.us/congress/bills/111/s3307/text](http://govtrack.us/congress/bills/111/s3307/text). Enacted December 13, 2010.
3. Food, Research and Action Center (FRAC). Highlights: Healthy Hunger Free Kids Act of 2010. [frac.org/highlights-healthy-hunger-free-kids-act-of-2010/](http://frac.org/highlights-healthy-hunger-free-kids-act-of-2010/). Accessed Jan 15, 2014.
4. Strom, S. U.S. Standards for School Snacks Move Beyond Cafeteria to Fight Obesity. *The New York Times*. June 27, 2013. [nytimes.com/2013/06/28/business/us-takes-aim-on-snacks-offered-for-sale-in-schools.html?\\_r=0](http://nytimes.com/2013/06/28/business/us-takes-aim-on-snacks-offered-for-sale-in-schools.html?_r=0)
5. Centers for Disease Control and Prevention. Menu Labeling. [cdc.gov/phlp/winnable/menu\\_labeling.html](http://cdc.gov/phlp/winnable/menu_labeling.html). Accessed January 17, 2014.
6. Food and Drug Administration. Guidance for Industry: Questions and Answers Regarding the Effect of Section 4205 of the Patient Protection and Affordable Care Act of 2010 on State and Local Menu and Vending Machine Labeling Laws. [fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm223408.htm](http://fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm223408.htm). Accessed January 17, 2014.

## APPENDIX

*Relevant AMA Policies*

## H-150.948 Increasing Customer Awareness of Nutrition Information and Ingredient Lists in Restaurants

Our AMA supports and seeks federal legislation or rules requiring (1) restaurants that have menu items common to multiple locations to provide standard nutrition labels for all applicable items, available for public viewing; and (2) all school and work cafeterias and restaurants to have ingredient lists for all menu items, available for public viewing. (Sub. Res. 411, A-04; Reaffirmation A-07; Reaffirmed in lieu of Res. 413, A-09, Res. 416, A-09 and Res. 418, A-09)

## D-60.990 Exercise and Healthy Eating for Children

Our AMA shall: (1) seek legislation that would require the development and implementation of evidence-based nutrition standards for all food served in K-12 schools irrespective of food vendor or provider; and (2) work with the US Public Health Service and other federal agencies, the Federation, and others in a coordinated campaign to educate the public on the epidemic of childhood obesity and enhance the K-12 curriculum by addressing the benefits of exercise, physical fitness, and healthful diets for children. (Res. 423, A-02; Reaffirmation A-04; Reaffirmation A-07; Reaffirmation I-07; Reaffirmed: Res. 408, A-11)

## D-150.988 Revision of Nutrition Labels

Our AMA will ask the appropriate federal agency or body to require that the nutritional labels on all products sold in the United States have both the absolute amount (in appropriate units) and the percent daily values listed for the nutrients in the product. (Res. 428, A-05)

## H-150.971 Food Labeling and Advertising

Our AMA believes that there is a need for clear, concise and uniform labeling on food products and supports the following aspects of food labeling: (1) Required nutrition labeling for all food products that includes a declaration of carbohydrates, protein, total fat, total saturated and polyunsaturated fatty acids, cholesterol, sodium and potassium content, and number of calories per serving. (2) Use of and/or ingredient labeling to declare the source of fats and oils. Knowledge of the degree of saturation is more important than knowing the source of oils in food products. It is not uncommon for manufacturers to use blends of different oils or to hydrogenate oils to achieve specific functional effects in foods. For example, vegetable oils that are primarily unsaturated may be modified by hydrogenation to more saturated forms that bring about desired taste, texture, or baking characteristics. This recommendation is therefore contingent upon nutrition labeling with saturated fat content. (3) The FDA's proposed rule on food labeling that requires quantitative information be provided on both fatty acid and cholesterol content if either one is declared on the label, as an interim step. (4) Warning statements on food labels are not appropriate for ingredients that have been established as safe for the general population. Moreover, the FDA has not defined descriptors for foods that are relatively higher in calories, sodium, fat, cholesterol, or sugar than other foods because there are no established scientific data indicating the level at which any of these substances or calories would become harmful in an individual food. (5) Our AMA commends the FTC for its past and current efforts and encourages the Commission to monitor misleading food advertising claims more closely, particularly those related to low sodium or cholesterol, and health claims. (6) Our AMA supports the timely approval of the Food and Drug Administration's proposed amendment of its regulations on nutrition labeling to require that the amount of trans fatty acids present in a food be included in the amount and percent daily value, and that definitions for "trans fat free" and "reduced trans fat" be set. (BOT Rep. C, A-90; Reaffirmed: Sunset Report, I-00; Appended: Res. 501, A-02; Reaffirmation A-04; Reaffirmed in lieu of Res. 407, A-04)

## H-150.939 Accurate Reporting of Fats on Nutritional Labels

Our AMA urges the Food and Drug Administration to require the use of more precise processes to measure the fat content in foods, particularly trans fats and saturated fats, and to require that the most accurate fat content information based on these processes be included on food labels. (Res. 412, A-10)

## 2. AMERICAN BOARD OF MEDICAL SPECIALTIES: OFFICIAL OBSERVER STATUS IN THE HOUSE OF DELEGATES

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

### HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED

*See Policy [G-600.025](#).*

#### INTRODUCTION

The American Board of Medical Specialties (ABMS) has requested official observer status in the American Medical Association (AMA) House of Delegates (HOD). The AMA and the ABMS share many goals when it comes to ensuring high standards in medical education and improving health care outcomes. The following report: (1) outlines AMA Bylaws and Policy that address requests and establish guidelines for official observer status; (2) provides background on the ABMS and discusses how the ABMS meets the official observer guidelines; and (3) recommends that the ABMS be granted official observer status.

#### AMA BYLAWS AND POLICY

Our AMA Bylaws state the following regarding official observers:

2.20 Official Observer. National organizations may apply to the Board of Trustees for official observer status in the House of Delegates. Applicants must demonstrate compliance with guidelines for official observers adopted by the House of Delegates, and the Board of Trustees shall make a recommendation to the House of Delegates concerning the application. The House of Delegates will make the final determination on the conferring of official observer status.

2.201 Rights and Privileges. Organizations with official observer status are invited to send one representative to observe the actions of the House of Delegates at all meetings of the House of Delegates. Official observers have the right to speak and debate on the floor of the House of Delegates upon invitation from the Speaker. Official observers do not have the right to introduce business, introduce an amendment, make a motion, or vote.

Policy G-600.025 establishes the following criteria for selection of and attendance by official observers in our AMA HOD:

1. Applications for official observer status will be reviewed using the following guidelines:
  - a. The organization and the AMA should already have established an informal relationship and have worked together for the mutual benefit of both.
  - b. The organization should be national in scope and have similar goals and concerns about health care issues.
  - c. The organization is expected to add a unique perspective or bring expertise to the deliberations of the House of Delegates.
  - d. The organization does not represent narrow religious, social, cultural, economic, or regional interests so that formal ties with the AMA would be welcomed universally by AMA members.
2. An organization granted official observer status in the House shall automatically lose that status if no representative of the organization appears at six consecutive House of Delegates meetings.

A full list of official observers in the House of Delegates is available in the Appendix.

#### DISCUSSION

The ABMS is a 501(c)(6) not-for-profit organization consisting of 24 Member Boards that certify the competency of physicians in 150 medical specialties and subspecialties. More than 800,000 licensed physicians are certified by one or more of the 24 Boards, and more than half of these medical specialists participate in the ABMS Maintenance of Certification (MOC). The mission of the ABMS Member Boards is to improve the quality of care provided to

patients and to facilitate continuous professional development of certified medical specialists. The ABMS does not represent religious, social, cultural, or economic interests.

The AMA and the ABMS share a long history of commitment to high standards in the education, training and practice of physicians. The AMA and the ABMS have had a collegial and productive working relationship on issues related to physician certification and MOC. The AMA has official status as one of nine Associate Members of the ABMS. Appointed AMA staff liaisons regularly attend meetings and workshops hosted by the ABMS. The AMA nominates members to eight of the 24 ABMS Member Boards of Directors. Currently, an AMA staff appointee sits on the ABMS Committee on Certification, which develops policies, procedures and standards for the initial certification of physician specialists by one of the ABMS Member Boards. A sitting member of the AMA Council on Medical Education was recently appointed to the ABMS Committee on Continuous Certification (CCC). The CCC will develop and monitor standards for MOC.

The HOD and the Council on Medical Education have a strong interest in MOC, particularly ensuring its cost-effectiveness, practice relevancy and alignment (versus redundancy) with other physician accountability requirements. Selected AMA policy about MOC is listed below. ABMS leadership has maintained a productive relationship with the Council on Medical Education and is responsive to questions and concerns raised by the Council. The ABMS CEO attends Council meetings when requested, and at the 2013 Interim Meeting met with the AMA Young Physicians Section assembly and spoke at an education session co-sponsored by the Organized Medical Staff and Young Physicians Sections. Lastly, informal observation of HOD deliberations on MOC-related resolutions was instrumental in helping ABMS senior staff understand participating physicians' concerns with the current MOC program requirements.

#### AMA POLICY REGARDING MOC

The AMA has provided strong input and developed extensive policy to support ABMS specialty board certification and MOC as well as policy calling for us to work with the ABMS.

#### RECOMMENDATION

In summary, there is a cooperative and productive relationship between our AMA and the ABMS. This productive relationship has and will continue to facilitate our efforts to influence the ABMS and its Member Boards to ensure that MOC is cost-effective, practice relevant and not redundant with other physician accountability requirements. The opportunity for ABMS to observe HOD deliberations on board certification and MOC issues will allow ABMS leadership to gather perspective from physicians regarding their concerns and experiences with MOC. In addition, observer status will facilitate joint efforts of the ABMS and AMA to continue to enhance medical education across the continuum of medical training and to improve health care in our country. Lastly, the ABMS observer can provide information and respond directly to HOD questions and concerns as they arise.

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

That our American Medical Association grant the American Board of Medical Specialties official observer status in the House of Delegates.

#### APPENDIX - Official Observers to the House of Delegates

Organization	Year Admitted
1. Accreditation Association for Ambulatory Health Care	1993
2. Alliance for Continuing Medical Education	1999
3. Ambulatory Surgery Center Association	2005**
4. American Academy of Physician Assistants	1994
5. American Association of Medical Assistants	1994
6. American Dental Association	1982
7. American Health Quality Association	1987*
8. American Hospital Association	1992
9. American Nurses Association	1998
10. American Public Health Association	1990

11. Association of periOperative Registered Nurses	2000
12. Association of State and Territorial Health Officials	1990
13. Commission on Graduates of Foreign Nursing Schools	1999
14. Council of Medical Specialty Societies	2008
15. Educational Commission for Foreign Medical Graduates	2011
16. Federation of State Medical Boards	2000
17. Federation of State Physician Health Programs	2006
18. Medical Group Management Association	1988
19. National Association of County and City Health Officials	1990
20. National Commission on Correctional Health Care	2000
21. National Council of State Boards of Nursing	2000
22. National Indian Health Board	2013
23. PIAA (Physician Insurers Association of America)	2013
24. Society for Academic Continuing Medical Education	2003
25. US Pharmacopeia	1998

\*- Admitted in 1987 as the American Medical Peer Review Association

\*\*-. Admitted in 2005 as the Federated Ambulatory Surgery Association. In 2008 merged with American Association of Ambulatory Surgery Centers to become Ambulatory Surgery Center Association.

### 3. NEW SPECIALTY ORGANIZATIONS REPRESENTATION IN THE HOUSE OF DELEGATES

*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 and the Specialty and Service Society (SSS) considered the applications of the American Society of Metabolic and Bariatric Surgery and the International Society for the Advancement of Spine Surgery for national medical specialty organization representation in the American Medical Association (AMA) House of Delegates (HOD). The applications were first reviewed by the AMA SSS Rules Committee and presented to the SSS Assembly for consideration.

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

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

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

Before a society is eligible for admission to the House of Delegates, it must participate in the SSS for three years. The American Society of Metabolic and Bariatric Surgery was admitted to the SSS in 1995, and the International Society for the Advancement of Spine Surgery was admitted to the SSS in 2009. Both organizations have been members in good standing since they were admitted.

Review of the materials and discussion during the SSS meeting at the 2013 Interim Meeting indicated that American Society of Metabolic and Bariatric Surgery and the International Society for the Advancement of Spine Surgery meet the criteria for representation in the House of Delegates.

## RECOMMENDATIONS

The Board of Trustees recommends that the American Society of Metabolic and Bariatric Surgery and the International Society for the Advancement of Spine Surgery be granted representation in the AMA House of Delegates and the remainder of this report be filed.

Exhibit A - Guidelines for Representation in and Admission to the House of Delegates:

### National Specialty Societies

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

### Responsibilities of National Medical Specialty Organizations

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

### Exhibit B - Summary Membership Information

Organization	AMA Membership of Organization's Total Eligible Membership	
American Society of Metabolic and Bariatric Surgery	258 of 1,279	20%
International Society for the Advancement of Spine Surgery	123 of 486	25%

## 4. AUDITOR'S REPORT

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

### HOUSE ACTION: FILED

The Consolidated Financial Statements for the years ended December 31, 2013 and 2012 and the Independent Auditor's report have been included in a separate booklet, titled "2013 Annual Report." This booklet is included in the Handbook mailing to members of the House of Delegates and will be discussed at the Reference Committee F hearing.

## 5. ANNUAL UPDATE ON ACTIVITIES AND PROGRESS IN TOBACCO CONTROL: MARCH 2013 THROUGH FEBRUARY 2014

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

### HOUSE ACTION: FILED

This report summarizes American Medical Association (AMA) activities and progress in tobacco control from March 2013 through February 2014 and is written in response to AMA Policy D-490.983 “Annual Tobacco Report.”

### TOBACCO USE IN THE UNITED STATES

#### *Surgeon General Releases 34<sup>th</sup> Report on Tobacco*

January 11, 2014 marked the 50<sup>th</sup> anniversary of the first Surgeon General’s Report on Smoking and Health. The 1964 landmark report was the first federal government report linking smoking and diseases, including lung cancer and heart disease. In recognition of the 50<sup>th</sup> anniversary, the Office of the Surgeon General released its 34<sup>th</sup> report on tobacco: The Health Consequences of Smoking – 50 Years of Progress. Despite tremendous progress in reducing the health consequences associated with tobacco use, it still remains the leading preventable cause of death in the United States. It is responsible for about one in five deaths annually. Smoking prevalence among adults has declined from 42% in 1965 to 18% in 2012; however, more than 42 million Americans still smoke. Tobacco has killed more than 20 million people prematurely since the first Surgeon General’s report in 1964. The findings in this report show that the decline in the prevalence of smoking has slowed in recent years and that the burden of smoking-attributable mortality is expected to remain at high for decades to come unless urgent policy and programmatic actions are taken (i.e., about 443,000 deaths per year, and an estimated 49,000 of these smoking-related deaths are the result of secondhand smoke exposure). The estimated economic costs attributable to smoking and exposure to tobacco smoke continue to increase and now approach \$300 billion annually, with direct medical costs of at least \$130 billion and productivity losses of more than \$150 billion a year.

Since the report in 1964, which highlighted lung cancer in males, subsequent reports have provided evidence that links smoking to diseases in nearly every organ in the body. The 2014 report finds that active smoking is now causally associated with major diseases including diabetes and liver cancer. It also concludes that secondhand smoke exposure causes strokes in nonsmokers.

#### *Major Pharmacy Chain Quits Tobacco*

On February 5, 2014, CVS Caremark, the country’s largest drugstore chain in overall sales, announced its plan to stop selling cigarettes and other tobacco products by October 2014. Citing pressure from groups such as the AMA, CVS agreed that it could no longer promote better health and still sell tobacco products. In its public statement, the AMA noted that reducing access to tobacco products is one part of a multi-pronged approach to lowering smoking rates in the United States.

#### *Chicago First in Nation to Address Menthol Sales*

The Chicago City Council voted in January 2014 to eliminate the sales of all menthol and flavored tobacco products within 500 feet of Chicago schools-five times the existing radius. This distance is the largest buffer zone in the country and one step towards an overall ban on these products which primarily appeal to youth and are heavily marketed in minority communities. According to the Food and Drug Administration (FDA) 40 percent of all youth smokers report smoking menthol cigarettes. In July 2013, the FDA released a 153-page report regarding the health impact of menthol cigarettes and asked for public comment.

#### *Big Tobacco Moves into Electronic Cigarettes (E-Cigarettes)*

E-cigarettes are battery-powered devices that provide nicotine and other chemicals via an aerosol and are being heavily marketed as a safer alternative to cigarettes and a way to “smoke” where laws prohibit cigarette smoking. These marketing tactics lead to a high level of dual users according to a paper released in November 2013 by the World Health Organization Tobacco Free Initiative. The marketing of e-cigarettes will soon mirror the aggressive marketing tactics of the past when the world’s largest tobacco manufacturer, Philip Morris International, enters the



market in late-2014. The company announced in February that its reduced risk division will launch a new range of products. They join Lorillard which owns Blu, the market leader.

#### *CDC Morbidity and Mortality Weekly Reports (MMWR)*

The Centers for Disease Control and Prevention (CDC) released 10 MMWRs in 2013-14 related to tobacco use. Among the topics were smoking rates, quit line usage, effect of global antismoking messages and electronic cigarettes (e-cigarettes).

#### *Antismoking Messages and Intent to Quit*

According to the May 31, 2013 MMWR issue, approximately 6 million tobacco-related deaths occur each year worldwide, including 600,000 from secondhand smoke. The report, released in recognition of World No Tobacco Day, focused on antismoking messages and the relationship with smokers' intent to quit. The CDC analyzed data from 17 foreign countries that participated in the Global Adult Tobacco Survey. The data supported the results of similar studies: mass media can reduce tobacco use by encouraging smokers to contemplate quitting and that messages in multiple media channels might be even more effective.

#### *Alarming Trends Identified in Youth Tobacco Use*

The CDC tracks youth tobacco usage by collecting self-reported data from youth in grades 6-12. The November 15, 2013 MMWR reported on data from the 2012 National Youth Tobacco Survey (NYTS). According to the analyses, e-cigarette use increased significantly from 2011 among middle school (0.6% to 1.1%) and high school students (1.5% to 2.8%). These devices are offered in a variety of youth-friendly flavors such as bubble gum and cherry with virtually no restrictions on sales to minors in most states. What is particularly disturbing about this trend is that among youth e-cigarette users, 9.3% reported never using a conventional cigarette. The implication is that youths who were not attracted to cigarettes have found another nicotine delivery system to which they are attracted.

#### *Maternal Smoking – A 10-Year Review*

The November 8, 2013 MMWR provided data on trends in smoking among pregnant women. The Pregnancy Risk Assessment Monitoring System (PRAMS) was initiated by the CDC in 1987, and it is the most extensive source of data on smoking before, during and after pregnancy in the United States. According to the report only three states saw decreases in smoking among women before, during and after pregnancy (Minnesota, New York and Utah); however, overall efforts to decrease smoking before pregnancy have not been effective. The report authors conclude that tobacco control activities in most states might be insufficient. They outline intervention recommendations to assist states in reaching the national goal of reducing smoking during pregnancy to 1.7%.

#### *CDC Updates State Guidelines*

In January 2014, CDC's Office on Smoking and Health released its third edition of Best Practices for Comprehensive Tobacco Control Programs—2014. This update provides states with new programmatic and funding recommendations to effectively plan and implement comprehensive and sustainable tobacco prevention and control programs. It draws upon best practices, as informed by state experiences in tobacco control program implementation, new scientific evidence and changes in the tobacco control landscape since the Best Practices—2007 release.

## AMA TOBACCO CONTROL ACTIVITIES

#### *The Litigation Center of the American Medical Association and State Medical Societies*

The Family Smoking Prevention and Tobacco Control Act of 2009 granted the Food and Drug Administration (FDA) the power to regulate tobacco companies. Since that law's passage, however, the tobacco industry has filed several lawsuits to dismantle or limit FDA's authority. The Litigation Center has filed numerous amicus curiae briefs to support the law and the FDA. In April 2013, the Supreme Court let stand a ruling of the United States Court of Appeals, which upheld the law's constitutionality. (*American Snuff Co., LLC v. United States*, 185 L.Ed.2d 865)

The AMA also filed an amicus curiae brief in *Evans v. Lorillard Tobacco Company*, in which Lorillard Tobacco Company was found liable for selling mentholated cigarettes, targeted toward African-American children. The trial court had awarded \$25 million in compensatory damages and \$81 million in punitive damages to the Estate of Marie Evans. It also awarded her son \$10 million. In June 2013, the Massachusetts Supreme Judicial Court reversed on a number of issues and remanded the case for a new determination on one of the claims and a redetermination of damages.

### *Collaborations*

The AMA is a member of a national tobacco control partnership that includes public health and advocacy organizations, as well as medical specialty societies. Among the activities this partnership engaged in during 2013 was support for the 50<sup>th</sup> Anniversary of the first Surgeon General's report on tobacco. The AMA was one of the signatories on a letter to President Obama highlighting the effect this report had on reducing the toll of tobacco use in the United States. In addition, the AMA and others urged the President to use the anniversary as an opportunity to continue to reduce the health and economic consequences associated with tobacco use.

In 2010, the AMA founded the Smokefree Clinical Practice and Policy Collaborative (Collaborative) which includes the American Academy of Pediatrics, American Academy of Family Physicians, American College of Physicians and American Congress of Obstetricians and Gynecologists. In April 2013, the Collaborative sponsored an advocacy workshop focused on clinical and public health policies to reduce tobacco use and secondhand smoke exposure. The day and a half workshop, Protecting Children and Families from Tobacco: Leadership Advocacy Training, featured a keynote address by Tim McAfee, MD, MPH, Director, CDC Office on Smoking and Health, on the intersection of clinical practice and community advocacy. Dr. Thomas Houston, former AMA Director of Science and Public Health Advocacy, led a breakout sessions on increasing access to tobacco cessation and pharmacotherapy coverage, and another on e-cigarettes in clinical practice.

### *CDC Partners with AMA and Federation Members to Re-Launch Media Campaign*

CDC's Office on Smoking and Health re-launched its successful Tips From Former Smokers (Tips) tobacco education media campaign in May 2013. The 2012 "Tips" campaign profiled people who are living with significant, adverse health effects due to smoking and proved effective in increasing calls to state quit lines. The 2013 campaign included a Talk with Your Doctor component, and the AMA partnered with CDC in this initiative along with the other four members of the Collaborative. A full-page ad appeared in *JAMA* alerting doctors to the campaign and the availability of clinical practice resources. To coincide with this campaign the AMA worked with the National Cancer Institute to develop an insert for *AMNews* that had a tear-off card illustrating the "5 As" used to counsel patients about tobacco use: Ask, Advise, Assess, Assist and Arrange.

### *AMA Highlights History of Tobacco Control*

In recognition of the 50<sup>th</sup> anniversary of the first Surgeon General's report on tobacco, AMA President-elect Dr. Robert Wah attended a press conference in Washington, DC with Health and Human Services Secretary Kathleen Sebelius, Acting Surgeon General Dr. Boris Lushniak, and other government officials and public health groups. AMA's website featured a chronology of AMA's involvement in reducing the toll of tobacco on Americans including support for an increase in the federal cigarette excise tax and adopting a resolution calling for restrictions on tobacco advertising targeting children.

The AMA's efforts coincided with the January 8, 2014 *JAMA* issue whose theme was "50 Years of Tobacco Control" which included essays from individuals who have played key roles in advancing tobacco control research and advocacy efforts.

### *Smoking in the Movies Entice Youth*

The AMA continued its support for limiting youth exposure to smoking shown in movies. The AMA was one of several public health organizations including the American Academy of Pediatrics, American Heart Association, American Lung Association and others featured in a full-page ad in the movie industry trade publication *Variety*. The AMA and others in the Smokefree Movies coalition have been calling on the industry to put an R rating on movies showing tobacco use. The 2012 Surgeon General's report, Preventing Tobacco Use Among Youth and

Young Adults, included studies that supported a causal relationship between depictions of smoking in movies with youth tobacco uptake. It also called for actions that would eliminate tobacco use depicted in movies. The 2014 Surgeon General's report released in January 2014 reiterated this finding and the need for regulatory actions.

## 6. AMA 2015 DUES

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

### **HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED**

*See Policy [G-635.130](#).*

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

### RECOMMENDATION

#### 2015 Membership Year

The Board of Trustees recommends no change to the dues levels for 2015, that the following be adopted and that the remainder of this report be filed:

Regular Members	\$420
Physicians in Their Second Year of Practice	\$315
Physicians in Military Service	\$280
Physicians in Their First Year of Practice	\$210
Semi-Retired Physicians	\$210
Fully Retired Physicians	\$84
Physicians in Residency Training	\$45
Medical Students	\$20

## 7. DEMOGRAPHIC REPORT OF THE HOUSE OF DELEGATES AND AMA MEMBERSHIP

*Informational report; no reference committee hearing.*

### **HOUSE ACTION: FILED**

#### INTRODUCTION

This informational report, "Demographic Report of the House of Delegates and AMA Membership," is prepared pursuant to Policy G-600.035, "House of Delegates Demographic Report," which states:

A report on the demographics of our AMA House of Delegates will be issued annually and include information regarding age, gender, race/ethnicity, education, life stage, present employment, and self-designated specialty.

In addition, this report includes information pursuant to Policy G-635.125, "AMA Membership Demographics," which states:

Stratified demographics of our AMA membership will be reported annually and include information regarding age, gender, race/ethnicity, education, life stage, present employment, and self-designated specialty.

This document compares the House of Delegates (HOD) with the entire AMA membership and with the overall United States physician and medical student population. Medical students are included in all references to the total

physician population throughout this report to remain consistent with the bi-annual Council on Long Range Planning and Development report. In addition, residents and fellows endorsed by their states to serve as sectional delegates and alternate delegates are included in the appropriate comparisons for the state and specialty societies. For the purposes of this report, AMA-HOD includes both delegates and alternate delegates.

## DATA SOURCES

Lists of delegates and alternate delegates are maintained in the Office of House of Delegates Affairs and are based on official rosters provided by the relevant society. The lists used in this report reflect 2013 year-end delegation rosters.

Data on individual demographic characteristics are taken from the AMA Physician Masterfile, which provides comprehensive demographic, medical education, and other information on all United States and international medical graduates (IMGs) who have undertaken residency training in the United States. Data on AMA membership and the total physician and medical student population are taken from the Masterfile and are based on 2013 year-end information.

Some key considerations must be kept in mind regarding the information captured in this report. Vacancies in delegation rosters mean that the total number of delegates is less than the 527 allotted at the 2013 Interim Meeting, and the number of alternate delegates is nearly always less than the full allotment. As such, the total number of delegates and alternate delegates is 945 rather than the 1054 allotted. Race and ethnicity information, which is provided directly by physicians, is missing for approximately 15% of AMA members and approximately 21% of the total United States physician and medical student population, limiting the ability to draw firm conclusions. Efforts to improve AMA data on race and ethnicity are part of AMA policy (see Policy [D-630.972](#)). Improvements have been made in collecting data on race and ethnicity, resulting in a decline in reporting race/ethnicity as unknown in the HOD and the overall AMA membership.

## CHARACTERISTICS OF AMA MEMBERSHIP AND DELEGATES

Table 1 presents basic demographic characteristics of AMA membership and delegates along with corresponding figures for the entire physician and medical student population.

Data on physicians' and students' current activities appear in Table 2. This includes life stage as well as present employment and self-designated specialty.

Table 1. Basic Demographic Characteristics of AMA Members & Delegates, December 2013

2013	AMA Members	All Physicians & Medical Students	AMA Delegates & Alternate Delegates <sup>1,2</sup>
Total	227,874	1,211,733	945
Mean age (years) <sup>3</sup>	48.5	51.0	55.5
<b>Age distribution (percent)</b>			
Under age 40	44.53%	29.99%	16.19%
40-49 years	11.52%	19.63%	13.23%
50-59 years	13.56%	19.82%	23.81%
60-69 years	11.33%	15.71%	31.32%
70 or more	19.05%	14.85%	15.45%
<b>Gender (percent)</b>			
Male	68.01%	67.47%	76.30%
Female	31.99%	32.53%	23.70%
<b>Race/Ethnicity (percent)</b>			
White non-Hispanic	60.62%	53.49%	73.33%
Black non-Hispanic	4.33%	4.04%	3.60%
Hispanic	4.29%	4.99%	2.86%
Asian/Asian American	13.99%	14.73%	6.88%
Native American	0.32%	0.23%	0.32%
Other <sup>4</sup>	1.37%	1.77%	1.38%
Unknown	15.07%	20.75%	11.64%

<b>Education (percent)</b>			
US or Canada	83.69%	77.03%	92.06%
IMG	16.31%	22.97%	7.94%
1. There were 109 vacancies as of year's end, most of which are unfilled alternate delegate slots. 2. Numbers include medical students and residents endorsed by their states for delegate and alternate delegate positions. 3. Age as of December 31. Mean age is the arithmetic average. 4. Includes other self-reported racial and ethnic groups.			

Table 2. Life Stage, Present Employment and Self-Designated Specialty,<sup>5</sup> December 2013

2013	AMA Members	All Physicians & Medical Students	AMA Delegates & Alternate Delegates
<b>Life Stage (percent)</b>			
Student <sup>6</sup>	22.73%	8.01%	6.24%
Resident <sup>6</sup>	17.04%	10.02%	6.46%
Young (under 40 or first 8 years in practice)	8.46%	16.67%	4.87%
Established (40-64)	27.88%	43.59%	54.29%
Senior (65+)	23.89%	21.71%	28.15%
<b>Present Employment (percent)</b>			
Self-employed solo practice	10.34%	10.13%	15.77%
Two physician practice	2.13%	2.09%	3.39%
Group practice	29.87%	44.37%	41.48%
HMO	0.14%	0.22%	0.53%
Medical school	1.66%	1.88%	6.46%
Non-government hospital	16.12%	11.36%	9.21%
State or local government hospital	4.03%	5.41%	6.77%
US government	1.35%	2.29%	3.70%
Locum Tenens	0.23%	0.22%	0.21%
Retired/Inactive	9.70%	9.69%	5.19%
Other/Unknown	1.70%	4.32%	1.06%
Student	22.73%	8.01%	6.24%
<b>Specialty (percent)</b>			
Family Medicine	9.39%	12.03%	11.75%
Internal Medicine	18.73%	22.92%	19.37%
Surgery	14.76%	13.78%	23.28%
Pediatrics	4.87%	8.63%	3.70%
OB/GYN	5.92%	4.84%	6.24%
Radiology	3.88%	4.56%	4.97%
Psychiatry	3.79%	5.41%	4.97%
Anesthesiology	3.86%	4.78%	4.23%
Pathology	1.87%	2.30%	2.12%
Other specialty	10.19%	12.74%	13.12%
Students	22.73%	8.01%	6.24%
5. See Appendix for a listing of specialty classifications.			
6. Students and residents are categorized without regard to age.			

## APPENDIX - Specialty classification using physician's self-designated specialties.

Major Specialty Classification	AMA Physician Masterfile Classification
Family Practice	General Practice, Family Practice
Internal Medicine	Internal Medicine, Allergy, Allergy and Immunology, Cardiovascular Diseases, Diabetes, Diagnostic Laboratory Immunology, Endocrinology, Gastroenterology, Geriatrics, Hematology, Immunology, Infectious Diseases, Nephrology, Nutrition, Medical Oncology, Pulmonary Disease, Rheumatology

Surgery	General Surgery, Otolaryngology, Ophthalmology, Neurological Surgery, Orthopedic Surgery, Plastic Surgery, Colon and Rectal Surgery, Thoracic Surgery, Urological Surgery
Pediatrics	Pediatrics, Pediatric Allergy, Pediatric Cardiology
Obstetrics/Gynecology	Obstetrics and Gynecology
Radiology	Diagnostic Radiology, Radiology, Radiation Oncology
Psychiatry	Psychiatry, Child Psychiatry
Anesthesiology	Anesthesiology
Pathology	Forensic Pathology, Pathology
Other Specialty	Aerospace Medicine, Dermatology, Emergency Medicine, General Preventive Medicine, Neurology, Nuclear Medicine, Occupational Medicine, Physical Medicine and Rehabilitation, Public Health, Other Specialty, Unspecified

## 8. 2013 GRANTS AND DONATIONS

*Informational report; no reference committee hearing.*

### HOUSE ACTION: FILED

This informational financial report details all grants or donations received by the American Medical Association during 2013.

American Medical Association  
Grants & Donations  
For the Year Ended December 31, 2013  
Amounts in thousands

Funding Institution	Project	Amount Received
Agency for Healthcare Research and Quality	Patient Safety Organization Privacy Protection Center	\$ 190
Centers for Medicare & Medicaid Services (via YMCA)	Diabetes Prevention Program	15
Centers for Disease Control	Health Information Security Card	78
Centers for Medicare & Medicaid Services (via Brandeis University)	Episode Grouper for Medicare Project	29
Centers for Medicare & Medicaid Services (via Mathematica Policy Research, Inc.)	ARRA HITECH Eligible Professional Clinical Quality Measures	195
National Highway Transportation Safety Administration	Engage Physicians in Addressing Older Driver Safety	42
National Institute on Drug Abuse (via Booz Allen Hamilton)	Substance Use Screen and Brief Counseling Composite Electronic Clinical Quality Measure Development	50
Office of the National Coordinator for Health Information Technology (via Booz Allen Hamilton)	Hospital and Ambulatory Electronic Clinical Quality Measures	92
Substance Abuse & Mental Health Services Administration (via American Academy of Addiction Psychiatry)	Prescribers' Clinical Support System for Opioid Use	47
Government Funding		<u>738</u>
AMA Foundation	Accelerating Change in Medical Education Initiative	143
American College of Cardiology Foundation	Quality Measures for Peripheral Arterial Disease and Cardiac Rehabilitation	2

American College of Emergency Physicians	Quality Measures to Enhance Emergency Care	14
American College of Rheumatology	Quality Measures for Rheumatoid Arthritis	7
Massachusetts Medical Society	International Congress On Peer Review and Biomedical Publication	10
NonProfit Contributors		<u>176</u>
Stanford University	International Congress On Peer Review and Biomedical Publication	10
University Funding		<u>10</u>
Wolters Kluwer Health, Inc.	International Congress On Peer Review and Biomedical Publication	25
Pharma Funding		<u>25</u>
BMJ Publishing Group LTD	Evidence Based Medicine Oral History Project	15
Elsevier Science	International Congress On Peer Review and Biomedical Publication	25
Global Advances in Health and Medicine	International Congress On Peer Review and Biomedical Publication	5
McGraw-Hill Education LLC	International Congress On Peer Review and Biomedical Publication	10
Precision Computer Works, Inc.	International Congress On Peer Review and Biomedical Publication	10
Silverchair Science+Communications, LLC	International Congress On Peer Review and Biomedical Publication	10
John Wiley & Sons Limited	International Congress On Peer Review and Biomedical Publication	10
Contributions less than \$5,000	International Medical Graduates Section Reception	9
Other Contributors		<u>94</u>
Total Grants and Donations		<u>\$ 1,043</u>

### 9. INJURIES IN CHEERLEADING (RESOLUTION 411-A-13)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS  
IN LIEU OF RESOLUTION 411-A-13 AND  
REMAINDER OF REPORT FILED  
WITH A CHANGE IN TITLE**

*See Policies [H-470.956](#), [H-470.959](#) and [H-470.971](#).*

Resolution 411-A-13, "Cheerleading as a Sport," introduced by the Illinois Delegation and referred by the House of Delegates, asked:

That our American Medical Association support (1) the designation of cheerleading as a sport; and (2) the requirement that cheerleading coaches undergo training on reducing risk associated with potentially dangerous cheerleading activities.

The designation of cheerleading as "sport" would likely subject it to formal safety requirements and injury reporting. Referral was based on the concern that school districts may face hardships due to the burdens of implementing such requirements and reporting. Additionally, the designation of cheerleading as a sport has implications under Title IX, which introduces complexity into the decision. This report briefly reviews cheerleading participation and injuries, recommendations for increased safety and the question of whether cheerleading should be designated as a sport.

#### BACKGROUND ON CHEERLEADING

Cheerleading became a common activity more than a century ago to support athletic teams from the sidelines by leading spectators in cheers. Cheerleading routines consisted primarily of clapping, with some minor physical stunts

such as toe-touch jumps and the splits. In the 1980s, cheerleading began to evolve into a more rigorous athletic activity, and today involves the incorporation of individual gymnastics and tumbling stunts, and team stunts such as human pyramids, lifts, catches, and tosses.<sup>1,2</sup> Safely performing these technical stunts requires strength, stamina, balance, and specialized training in dance, tumbling, and gymnastics.

More than three million individuals aged 6 years and older participate in cheerleading activities; this number reflects an approximate 18% increase in participation over the last 25 years. The majority of today's cheerleaders are part of "sideline" squads, i.e., those whose primary function is to support athletic teams at events. These squads are usually formed within a school setting such as high school or college, but include professional cheerleaders as well. "Competitive" or "all-star" squads are those that compete by performing a routine consisting of stunts. These competitions take place apart from the traditional athletic support role played by sideline squads, but both sideline and competitive squads perform stunts, and some sideline squads may participate in competitive events. Likewise, individual cheerleaders may participate on both sideline and competitive squads.

The vast majority (more than 96%) of cheerleading participants at the high school and lower levels are female.<sup>2</sup> At the collegiate level, the percentage of male participation is higher, likely nearing 50%; the collegiate number is more difficult to estimate since squad composition is different at each school.

### INJURIES IN CHEERLEADING

The number of reported cheerleading-related injuries has steadily increased over the last several decades. In 1980, nearly 5,000 cheerleading injuries were treated in emergency departments; by 2007, that number had climbed to nearly 27,000.<sup>3</sup> The increase has been attributed to the growing incorporation of technical stunts into cheerleading routines.<sup>2</sup> The most common injuries caused by cheerleading are ankle sprains/strains, knee abrasions/contusions/hematomas, lower back lacerations/punctures, concussions/closed head injuries, and in some cases neck fractures.<sup>4</sup> However, the vast majority of injured cheerleaders (98%) are treated and released.<sup>3</sup> Among cheerleading injuries in participants aged 18 years or younger, 97% occur in females.<sup>1</sup>

The rate of overall cheerleading injury is approximately 1 per 1,000 athletic exposures (AE; "athletic exposures" is defined as one athlete participating in one practice or competition session).<sup>2</sup> When compared with existing high school girls' sports, the rate of overall cheerleading injuries is lower than that for gymnastics (8.5 per 1,000 AE), soccer (5.3 per 1,000 AE), basketball (4.4 per 1,000 AE), field hockey (3.7 per 1,000 AE), and softball (3.5 per 1,000 AE).<sup>2</sup> However, catastrophic injury rates are higher in cheerleading compared with these sports. Catastrophic injuries are those that result in fatality, permanent severe functional disability, or severe impairment (such as cervical spinal or skull fractures and closed-head injuries).<sup>5</sup> Cheerleading's catastrophic injury rate is 0.50-1.62 per 100,000 AE, compared to 0.44, 0.03, 0.03, 0.02, and 0.0 per 100,000 AE for gymnastics, soccer, basketball, softball, and field hockey, respectively.<sup>6</sup> College-level cheerleaders' overall and catastrophic injury rates are higher than those of high schoolers' at 2.4 per 1,000 AE and 2.0 per 100,000 AE, respectively, presumably due to the more technically difficult routines often performed at the collegiate level.<sup>5,6</sup>

### INCREASING THE SAFETY OF CHEERLEADING

Several groups have studied the issue of cheerleading safety and developed recommendations aimed at reducing the risk of cheerleading injuries. These groups include the American Academy of Pediatrics (AAP) and the American Academy of Orthopaedic Surgeons (AAOS); the National Center for Catastrophic Sports Injury Research (NCCSIR), a research center focusing on sports injury reporting and prevention; the American Association of Cheerleading Coaches and Administrators (AACCA), an educational association for cheerleading coaches at all levels; the National Federation of State High School Associations (NFHS), the body that writes the rules of competition for most high school sports and activities in the United States; the National Cheer Safety Foundation (NCSF), a cheerleading safety advocacy group; and the USA Federation for Sport Cheering (USA Cheer), the national governing body for club and school-based cheer programs.

Recommendations for improving the safety of cheerleading generally include training for coaches and participants, implementation of rules for the execution of technical stunts, avoidance of hard surfaces and preparedness for injury management. These are based on evidence suggesting that injury risk is increased when coaches are inadequately trained and when stunts are performed improperly and on surfaces that are hard or otherwise inappropriate.<sup>7,8</sup> Proposed recommendations that have broad-based support among the groups noted above include:



- Designate cheerleading as a sport under the National Collegiate Athletic Association (NCAA) and the NFHS.<sup>5,6,9,11</sup>
- Pre-participation physical examinations should be required and access to appropriate strength and conditioning programs available.<sup>5,6,11</sup>
- Cheerleading coaches should be trained and certified in proper cheerleading techniques, safety measures and basic injury management.<sup>5,6,11-15</sup>
- Cheerleaders should be trained in proper cheerleading techniques and should attempt stunts only after demonstrating appropriate skills and proficiency.<sup>5,6,12-15</sup>
- Coaches should be present during all practice and competition events.<sup>5,12-15</sup>
- Technical stunts should not be performed on hard, wet, or uneven surfaces, or on surfaces with obstructions; cheer events should not take place on surfaces composed of dirt, vinyl, concrete or asphalt. Stunts should instead take place on a spring floor or on a traditional foam floor or grass/turf with a landing mat.<sup>6,12,13,15</sup>
- Coaches should follow rules for the execution of technical skills set forth in the most recent version of the NFHS Spirit Rules Handbook.<sup>6,15</sup>
- Coaches, parents and athletes should have access to a written emergency plan, designed in conjunction with a physician and/or certified athletic trainer. When possible, a physician or certified athletic trainer should be present at practices and competitions.<sup>5,6,11-14</sup>
- Any cheerleader showing signs of a head injury should be removed from practice or competition and not allowed to return until he or she has received written clearance from a physician or qualified health care provider. All coaches and parents should be knowledgeable on the cause, prevention, signs of and response to concussion.<sup>5,6,11,14,15</sup>
- Surveillance of cheerleading injuries and research on safety should continue, with all catastrophic injuries reported to the NCCSIR.<sup>5,6,11</sup>

#### THE DESIGNATION OF CHEERLEADING AS A SPORT

Several groups, including the AAP, have promoted the idea that the designation of cheerleading as a sport under the NCAA and the NFHS would make it safer. NCAA- and NFHS-designated sports are subject to rules regarding practice length, practice facilities, coach training/certification, availability of certified athletic trainers, access to medical care and injury surveillance/reporting.<sup>6</sup> Despite the athleticism required of cheerleading participants and the competition-based atmosphere of the activity, only a minority of states consider it a sport under NFHS, and the NCAA does not consider it a sport. To be considered an NCAA-designated sport, several standards must be met, including regularly scheduled team and/or individual head-to-head competitions (at least five) within a defined competitive season and standardized rules with rating/scoring systems ratified by official regulatory agencies and governing bodies.<sup>16</sup> At present, cheerleading competitions are held by several different organizations, each with different rules, meaning that it does not yet meet NCAA-sport criteria.

In 2012, the US Court of Appeals for the 2<sup>nd</sup> District upheld a lower court ruling that Quinnipiac University could not consider cheerleading as a sport for Title IX purposes.<sup>17</sup> Quinnipiac University had discontinued its women's volleyball program and established a competitive cheerleading team. Members of the volleyball team subsequently sued the university, alleging that it was denying women equal athletic opportunities in violation of Title IX, which protects against sex discrimination in federally funded educational programs. The court found that Quinnipiac's competitive cheer program diverged from other sports for several reasons including the fact that cheerleading has not been recognized as a sport by the NCAA.<sup>17</sup> NCAA recognition is not a requirement for Title IX eligibility, but it usually weighs heavily in eligibility decisions. NFHS has stated that it believes competitive cheer should be counted as a Title IX-eligible sport.<sup>18</sup>

In response to the court decision, both USA Cheer and USA Gymnastics (the sole governing body for the sport of gymnastics in the United States) submitted proposals to the NCAA Committee on Women's Athletics requesting that forms of competitive cheerleading (called "STUNT" by USA Cheer and "Acrobatics and Tumbling" by USA Gymnastics) be placed on the NCAA Emerging Sports for Women list.<sup>19</sup> Placement on the list is often a precursor to recognition as an NCAA sport. The NCAA Committee on Women's Athletics has requested that USA Cheer and USA Gymnastics jointly develop a single proposal, rather than proposals for two similar, competing concepts.<sup>19</sup>

## CONCLUSIONS

Cheerleading results in more catastrophic injuries than any other sport activity engaged in by females. Medical specialty societies, research institutes, and cheerleading advocacy organizations have developed recommendations aimed at reducing injury rates. Some of these recommendations are supported by AMA policy: medical examinations prior to athletic participation (Policy H-470.971) and authorization by a physician before returning to athletic activity after sustaining a concussion (Policy H- 470.959).

The designation of cheerleading as a sport under NCAA and NFHS is supported by several groups, both as a means for improving its safety and for improving its credibility as a sport on equal footing with other NCAA-sanctioned sports. However, the NCAA does not believe that cheerleading meets the requirements for such a designation at this time, and it has not yet been placed on the Emerging Sports for Women list. Similarly, courts have recently ruled that it cannot be considered a sport for Title IX purposes. Although the NFHS has stated that it supports the designation of cheerleading as a sport, only a minority of states consider it as such. Given these findings, it does not appear that cheerleading will be designated as a sport in the near future. Since ensuring the health and safety of cheerleaders is immediately important, it seems most effective to advocate for consistent adoption and implementation of recommendations aimed at improving cheerleading safety now, rather than to advocate for a designation that may or may not ever occur. Most of the suggested recommendations above enjoy broad support among medical professionals and cheerleading groups alike.

## RECOMMENDATIONS

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 411-A-13 and that the remainder of this report be filed.

1. That our American Medical Association support the designation of cheerleading as a sport.
2. That our AMA recognizes the potential dangers of cheerleading, including the potential for concussion and catastrophic injury and supports the implementation of recommendations designed to improve its safety equivalent to those that apply to other athletic activities formally recognized as “sports” by appropriate accrediting bodies. These include proper training of coaches, avoidance of inappropriate surfaces when performing stunts and adherence to rules for the proper execution of stunts.
3. That Policy H-470.959, which supports the requirement that athletes suspected of sustaining a concussion be allowed to return to play only after approval by a physician, be reaffirmed.
4. That Policy H-470.971, which supports medical examinations for youth before participation in athletic activities, be reaffirmed.

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## 10. PROVIDING PHYSICAL FITNESS GUIDELINES (RESOLUTION 427-A-12)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED  
IN LIEU OF RESOLUTION 427-A-12 AND  
REMAINDER OF REPORT FILED**  
*See Policies [H-60.979](#) and [H-470.997](#).*

Resolution 427-A-12 “Providing Physical Fitness Guidelines,” submitted by the Pennsylvania Delegation, asked that our American Medical Association (AMA): (1) coordinate with the appropriate national specialty societies to seek the development of a jointly endorsed checklist designed to help identify underlying risk factors in patients interested in beginning or resuming physical fitness activities; (2) offer non-legal guidance regarding the liability associated with signing releases for patients’ participation in physical fitness activities; and (3) maintain a current resource for its members as data becomes available regarding evidence-based recommendations that would be appropriate for their patients.

The reference committee noted that physical activity is important, but there are challenges when physicians are asked to sign releases, and further, that this work may be duplicative and out of the scope of the AMA. Therefore, the reference committee recommended that Resolution 427-A-12 be not adopted; however, due to mixed testimony on the floor of the House of Delegates (HOD), the resolution was referred.

This report will review the initiatives of national organizations and specialty societies that are involved in the establishment of physical activity guidelines for patients, as well as related legislation and current policy efforts of the AMA.

### INTRODUCTION

Scientific evidence has proven that regular physical activity is one of the most important steps a person can take to improve and maintain his or her own health. It can reduce one’s risk of cardiovascular disease, type 2 diabetes and some cancers, as well as help to maintain or lose weight. Physical activity can also strengthen bones and muscles, improve mental health, mood and capacity for daily activity, prevent falls, and increase longevity.<sup>1</sup> Despite the benefits, most adults and youth in the United States do not meet current physical activity recommendations.<sup>2</sup> The medical community plays an important role in promoting healthy lifestyles to their patients, including encouraging participation in physical activity. Given the various ages, health conditions and socioeconomic constraints of patients, physical activity counseling can be a challenge for physicians.

## NATIONAL GUIDELINES

In 2008, the US Department of Health and Human Services (HHS) issued the *Physical Activity Guidelines for Americans* (“Guidelines”), which provide guidance on the importance of being physically active to promote good health and reduce the risk of chronic diseases.<sup>3</sup> These Guidelines, which target health care professionals and policymakers, are designed to provide information and guidance on the significant health benefits of physical activity for people aged 6 and over. They also address women during pregnancy and postpartum, adults with disabilities and people with chronic medical conditions.

The Guidelines are supported by the Community Preventive Services Task Force, which was established by HHS in 1996 to identify population health interventions that are scientifically proven to save lives, increase lifespans and improve quality of life.<sup>2</sup> Likewise, the Guidelines are referenced by the US Preventive Services Task Force (USPSTF), an independent panel of non-Federal primary care provider experts in prevention and evidence-based medicine.<sup>4</sup> Also, the Institute of Medicine cited the Guidelines in its 2013 report, “Educating the Student Body: Taking Physical Activity and Physical Education to School.”<sup>5</sup>

Various medical specialty societies also produce guidelines, recommendations and policy statements for physicians pertaining to physical activity for specific subpopulations, including the American Congress of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the American College of Cardiology (ACC).<sup>6</sup> Further, the American College of Sports Medicine (ACSM) is particularly invested in this field given that its mission is to “advance and integrate scientific research to provide educational and practical applications of exercise science and sports medicine.”<sup>7</sup> Web links to these guidelines and recommendations are provided in the References.

## PENDING NATIONAL LEGISLATION

House bill [H.R. 2179](#), “The Physical Activity Guidelines for Americans Act,” was introduced in May 2013 and would require the secretary of HHS to publish physical activity guidelines every ten years based on the latest scientific evidence and include guidelines for identified population subgroups.<sup>8</sup> Every five years, the secretary would be required to issue a mid-course report that summarizes best practices as well as emerging issues regarding physical activity. This bill was endorsed by ACSM.

## AMA POLICY AND EFFORTS

The AMA is committed to improving health outcomes, specifically by focusing on prevention and treatment of cardiovascular disease and type 2 diabetes. Physical activity can have a significant, positive impact on these conditions. The AMA is currently working to expand physician awareness of and patient referral to the Diabetes Prevention Program (DPP) located at various YMCAs and other community-based sites across the country. The DPP is an evidence-based lifestyle education program which addresses the importance of physical activity. The AMA Healthier Life Steps® program (2008-2012) provided a toolkit to physicians that addressed four areas of health behaviors: healthy eating, physical activity, tobacco cessation and risky drinking. The toolkit provided physicians with resources and tools to improve physical activity counseling within clinical practice. The AMA is a member of the coordinating committee of the National Physical Activity Plan, which makes recommendations for specific policies that promote physical activity in various societal sectors; the AMA co-chairs the Health Care Sector Committee, which supports physician counseling of patients based on the Guidelines.<sup>9</sup> Existing AMA policy addresses physical activity and fitness for all ages in various settings (see Appendix).

A review of AMA policy indicates that Policies D-470.991, D-90.993 and D-470.990 have been accomplished and are therefore recommended for rescission. Policy D-470.991, “Adoption of a Universal Exercise Database and Prescription protocols for Obesity Reduction,” has been addressed by the Physical Guidelines for Americans, and Policy H-60.979. AMA Policy D-90.993, “Fitness and Athletics Equity for Students with Disabilities,” was accomplished in 2008 by the AMA’s Advocacy Resource Center, which communicated with all state and specialty societies. Policy D-470.990, “Exercise Information on the American Medical Association Web Site,” was accomplished by way of the AMA Healthier Life Steps® program webpage which provided information and web links regarding physical activity from 2008-2012. This webpage was removed in 2013 during the AMA website revision due to the strategic reorganization.

## DISCUSSION

The first resolve of Resolution 427-A-12 asks for coordination of appropriate national specialties in order to produce a single “jointly endorsed checklist designed to help identify underlying risk factors in patients” who wish to begin/resume exercise. The identification of underlying risk factors denotes a screening or more thorough examination. The HHS Guidelines advisory committee did an extensive literature review through 2007 that did not locate any evidence supporting examinations in healthy people or people with chronic illness as a mechanism to reduce exercise-related adverse events.<sup>10</sup> Additionally, the creation of the proposed checklist would require significant effort and cost to the AMA. Existing Policy H-470.971, “Athletic Preparticipation Examinations for Adolescents,” addresses this issue, recommending that the most current guidelines established by the AAP, ACC, ACSM, and other appropriate medical specialty societies be used to determine eligibility for sports participation.

The second resolve asks for non-legal guidance regarding liability pertaining to release forms for patient participation in physical fitness activities. The interpretation and effect of release forms is a matter of state law. Since there is likely to be variability among states, a comprehensive examination of such relevant statutes and case law in all 50 states would require significant staff and financial resources.

The third resolve asks for a database of “evidence-based recommendations that would be appropriate for their patients,” although it does not specify what is meant by “recommendations.” The USPSTF provides recommendations regarding screening and counseling to promote physical activity and a healthful diet to prevent cardiovascular disease.<sup>11</sup> The Guidelines website provides a wealth of resources for health care professionals, including the [Guidelines Advisory Committee Report](#) describing the scientific background and rationale for the guidelines and Web links to other resources that provide information for professionals and patients alike.<sup>12</sup> The specialty societies listed earlier also provide recommendations and guidelines for subpopulations on their websites.

## CONCLUSION

The federal government as well as several national organizations and specialty societies are active in the field of physical activity. The actions requested in Resolution 427-A-12 are duplicative and would require the AMA to involve itself in matters in which it does not have requisite expertise or resources. Also, the request goes beyond the scope of the AMA’s current strategic focus.

## RECOMMENDATIONS

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 427-A-12 and the remainder of this report be filed:

1. That Policy H-470.997, which encourages physicians to promote physical activity, be reaffirmed.
2. That Policy H-60.979 be amended by addition and deletion to read as follows:

### PHYSICAL ACTIVITY GUIDELINES

### ~~PHYSICIAN-BASED PHYSICAL ACTIVITY AND EXERCISE COUNSELING PROTOCOLS FOR YOUTH AND ADOLESCENTS~~

The AMA supports the continued expert review and development of national guidelines regarding physical activity for all ages and the dissemination of such guidelines to physicians. ~~It is the policy of the AMA, in collaboration with appropriate agencies, to assist in the development of physician-based physical activity assessment and counseling protocols for youth and adolescents, including the development of training materials to instruct physicians in the use of these protocols.~~

3. That Policies D-470.991, D-90.993, and D-470.990 be rescinded.

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#### APPENDIX - Relevant AMA Policies:

##### H-470.997 Exercise and Physical Fitness

The AMA encourages all physicians to utilize the health potentialities of exercise for their patients as a most important part of health promotion and rehabilitation, and urges state and local medical societies to emphasize through all available channels the need for physical activity for all age groups and both sexes. The AMA encourages other organizations and agencies to join with the Association in promoting physical fitness through all appropriate means. (BOT Rep. K, A-66; Reaffirmed: CLRPD Rep. C, A-88; Reaffirmed: Sunset Report, I-98; Modified and Reaffirmed: CSAPH Rep. 2, A-08)

##### H-60.979 Physician-Based Physical Activity and Exercise Counseling Protocols for Youth and Adolescents

It is the policy of the AMA, in collaboration with appropriate agencies, to assist in the development of physician-based physical activity assessment and counseling protocols for youth and adolescents, including the development of training materials to instruct physicians in the use of these protocols. (Res. 186, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: CSAPH Rep. 1, A-10)

##### D-470.991 Adoption of a Universal Exercise Database and Prescription protocols for Obesity Reduction

Our AMA: (1) will collaborate with appropriate federal agencies and professional health organizations to develop an independent meta-database of evidence-based exercise guidelines to assist physicians and other health professionals in making exercise prescriptions; and (2) supports longitudinal research on exercise prescription outcomes in order to further refine prescription-based exercise protocols. (Res. 415, A-10)

##### D-90.993 Fitness and Athletics Equity for Students with Disabilities

Our AMA will work with state medical associations and specialty societies to encourage individual state legislatures to enact laws which ensure that students with disabilities have an equal opportunity to participate in mainstream physical education programs and try out for and, if selected, participate in mainstream athletic programs, except when the inclusion of the student presents an objective safety risk to the student or to others, or fundamentally alters the nature of the school's mainstream physical education or mainstream athletic program. (Res. 202, A-08)

##### D-470.990 Exercise Information on the American Medical Association Web Site

Our AMA will work with appropriate agencies and organizations to improve means of disseminating information to patients and physicians regarding safe and effective options for healthy exercise on its public web site with the goal of increasing the number of patients who participate in regular physical activity. (Res. 425, A-10)

##### H-470.971 Athletic Preparticipation Examinations for Adolescents

To promote the health and safety of adolescents, our AMA recommends that state medical societies work with appropriate state and local agencies to promote the following: (1) The development of standards for preparticipation athletic examinations that are consistent with consensus recommendations of the American Academy of Family Physicians, American Academy of Pediatrics, American Medical Society for Sports Medicine, American Orthopedic Society for Sports Medicine, and the American Osteopathic Academy of Sports Medicine. (2) Only licensed MDs, DOs, and licensed physician extenders practicing under the supervision of licensed MDs and DOs perform preparticipation examinations. (3) The decision of whether or not an adolescent is healthy and physically mature enough to participate in a particular sport is made by a qualified physician. (4) The decision of when an injured athlete resumes participation is made by a qualified physician. (5) The most current guidelines established by the American Academy of Pediatrics, American College of Cardiology, American College of Sports Medicine, and other appropriate medical specialty societies are used to determine eligibility for sports participation. (BOT Rep. R, A-90; Amended: CSA Rep. 5, I-99; Reaffirmed: CSAPH Rep. 1, A-09)

**H-470.991 Promotion of Exercise**

1. Our AMA: (A) supports the promotion of exercise, particularly exercise of significant cardiovascular benefit; and (B) encourages physicians to prescribe exercise to their patients and to shape programs to meet each patient's capabilities and level of interest. 2. Our AMA supports National Bike to Work Day and encourages active transportation whenever possible. (Res. 83, parts 1 and 2, I-77; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Appended: Res. 604, A-11)

**H-470.990 Promotion of Exercise Within Medicine and Society**

Our AMA supports (1) education of the profession on exercise, including instruction on the role of exercise prescription in medical practice in its continuing education courses and conferences, whenever feasible and appropriate; (2) medical student instruction on the prescription of exercise; (3) physical education instruction in the school system; and (4) education of the public on the benefits of exercise, through its public relations program. (Res. 56, I-78; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmation I-98; Reaffirmation A-07; Reaffirmed: BOT Rep. 21, A-12)

**H-25.995 Exercise Programs for the Elderly**

The AMA recommends that physicians: (1) stress the importance of exercise for older patients and explain its physiological and psychological benefits; (2) obtain a complete medical history and perform a physical examination that includes exercise testing for quantification of cardiovascular and physical fitness as appropriate, prior to the specific exercise prescription; (3) provide appropriate follow-up of patients' exercise programs; and (4) encourage all patients to establish a lifetime commitment to an exercise program. (CSA Rep. C, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CSA Rep. 8, A-05)

**H-440.917 Increased Physical Activity for Most US Adults**

The AMA endorses, in principle, the movement calling for every adult to accumulate in the course of each day 30 or more minutes of physical activity of moderate intensity; and urges physicians to review the consensus statement of the Centers for Disease Control and Prevention and the American College of Sports Medicine which extends the traditional concept of physical fitness to include intermittent cumulative physical activity and the scientific evidence on which this advice rests. (Res. 408, A-95; Reaffirmed: CSA Rep. 8, A-05)

**H-440.859 American's Health**

Our AMA will: (1) make improving health through increased activity and proper diet a priority; (2) propose legislation calling on the federal government and state governments to develop new and innovative programs in partnership with the private sector that encourage personal responsibility for proper dietary habits and physical activity of individual Americans; and (3) continue to work in conjunction with the American College of Sports Medicine, American Heart Association, US Department of Health and Human Services and any other concerned organizations to provide educational materials that encourage a healthier America through increased physical activity and improved dietary habits. (Res. 201, A-09; Reaffirmation A-12)

**H-425.972 Healthy Lifestyles**

Our AMA: (1) recognizes the 15 competencies of lifestyle medicine as defined by a blue ribbon panel of experts convened in 2009 whose consensus statement was published in the Journal of the American Medical Association in 2010; (2) will urge physicians to acquire and apply the 15 clinical competencies of lifestyle medicine, and offer evidence-based lifestyle interventions as the first and primary mode of preventing and, when appropriate, treating chronic disease within clinical medicine; and (3) will work with appropriate federal agencies, medical specialty societies, and public health organizations to educate and assist physicians to routinely address physical activity and nutrition, tobacco cessation and other lifestyle factors with their patients as the primary strategy for chronic disease prevention and management. (Res. 423, A-12)

**H-440.866 The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity**

Our AMA supports: (1) greater emphasis in physician educational programs on the risk differences among ethnic and age groups at varying levels of BMI and the importance of monitoring waist circumference in individuals with BMIs below 35 kg/m<sup>2</sup>; (2) additional research on the efficacy of screening for overweight and obesity, using different indicators, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain; and (3) more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks. (CSAPH Rep. 1, A-08; Reaffirmed: CSAPH Rep. 3, A-13)

**H-425.993 Health Promotion and Disease Prevention**

The AMA (1) reaffirms its current policy pertaining to the health hazards of tobacco, alcohol, accidental injuries, unhealthy lifestyles, and all forms of preventable illness; (2) advocates intensified leadership to promote better health through prevention; (3) believes that preventable illness is a major deterrent to good health and accounts for a major portion of our country's total health care expenditures; (4) actively supports appropriate scientific, educational and legislative activities that have as their goals: (a) prevention of smoking and its associated health hazards; (b) avoidance of alcohol abuse, particularly that which leads to accidental injury and death; (c) reduction of death and injury from vehicular and other accidents; and (d) encouragement of healthful lifestyles and personal living habits; and (5) strongly emphasizes the important opportunity for savings in health care

expenditures through prevention. (Presidential Address, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: BOT Rep. 8, I-06)

## **11. MEDICATION NON-ADHERENCE AND ERRORS (RESOLUTION 115-A-13)**

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

### **HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 115-A-13 AND REMAINDER OF REPORT FILED**

*See Policy [D-115.988](#).*

Resolution 115-A-13, “Medication Non-Adherence and Errors,” introduced by the Michigan Delegation and referred by the House of Delegates asked:

That our American Medical Association work with the Centers for Medicare & Medicaid Services to seek federal legislation to require Medicare to provide the option of prescribing, according to patient need, timed calendar blister packs to be filled locally with pharmacist counseling with no or minimal extra cost to the patient.

### **MEDICARE REQUIREMENTS**

Under 42 CFR §483.60(a), Medicare requires long term care (LTC) facilities to have in place “procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biological ... to meet the needs of each resident.”<sup>1</sup> Thus, Medicare regulated LTC facilities must be able to meet the prescription drug needs of each resident. Additionally, it is CMS’ expectation...”that Part D plans provide coverage of dosage forms of drugs that are widely utilized in the LTC setting...”<sup>2</sup> Blister packs are considered a standard operating procedure in the long-term care industry to ensure accuracy, accountability and adherence. Accordingly, Medicare Part D is expected to cover the use of blister packs in LTC facilities; the facility, not the patient, chooses the pharmacy to supply the blister packs and other Part D drugs. Medicare Part D is not currently required to cover blister packs outside the LTC setting.

### **BACKGROUND**

#### *Patterns of Disease and Medication Use*

Men and women aged 65 years and older are the biggest consumers of medication. Three quarters of such individuals use two or more prescription drugs weekly, approximately 40% take five or more, and 20% in this age group take at least ten different medications in a given week.<sup>3,4</sup>

Medication adherence is defined as the extent to which patients take medications as prescribed, but can be difficult to measure. Poor medication adherence is common and contributes to poor outcomes and increases healthcare system costs. It is estimated that between 20-30% of patients fail to fill prescriptions, and at least 50% of medications prescribed for chronic diseases are not taken as prescribed. These percentages may be even higher in elderly patients with chronic conditions who are taking multiple medications on a daily basis (typically from more than one prescriber), which also puts them at higher risk for drug interactions, adverse events and medication errors.<sup>5-8</sup> Adherence typically decreases as the number of daily medications increases.<sup>9</sup>

Two-thirds of Medicare beneficiaries are undergoing treatment for two or more chronic illnesses; nearly one in seven are burdened with six or more chronic conditions.<sup>10</sup> Non-adherence is more common when the disease being treated is asymptomatic (e.g., hypertension, hypercholesterolemia). In 2012, more than half of Medicare beneficiaries were being treated concurrently for these two conditions.<sup>11</sup> Multiple chronic conditions are even more likely to be present among dual eligible beneficiaries.<sup>11</sup> Of interest, a 2012 report from the Congressional Budget Office (CBO) concluded that greater enrollment in, and use of, Medicare Part D drug plans had contributed to reduced health care costs. Medical service costs decreased 0.2% for every 1% increase in prescriptions filled by Medicare beneficiaries.<sup>12</sup>



### *Poor Medication Adherence*

In addition to non-adherence resulting from never filling a prescription (or failure to fill on time), unintentional non-adherence occurs when a patient forgets to take medication or otherwise misses a scheduled dose. Some non-adherence is intentional, particularly if it is cost-related, a factor which may be common in elderly patients who are prescribed multiple medications and living on a fixed income.

Macro factors that either foster medication adherence or contribute to non-adherence include health policies (e.g., access to care; insurance), the health system (e.g., communication systems for interdisciplinary care; transitions in care), and prescriber and patient factors.<sup>11,13</sup> The costs of poor medication adherence are staggering. In addition to causing approximately 125,000 deaths and contributing to at least 10% of hospital admissions annually, the estimated annual healthcare expenditures attributable to non-adherence range from \$105-290 billion.<sup>14,15</sup>

### USE OF BLISTER PACKS TO PROMOTE ADHERENCE

#### *Efficacy of Blister Packs for Promoting Adherence and Improving Outcomes*

Resolution 115-A-13 addresses one intervention that may improve medication adherence, namely the preparation of timed calendar blister packs that consolidate daily doses, enabling patients and caregivers to readily identify and quantify daily medication use. While it seems intuitive that such an approach would improve medication adherence, clinical trials examining the concept are limited.

A study of military health care beneficiaries aged 65 years or older who were taking at least 4 medications daily for chronic disease, combined a pharmacy care program (including patient education) with medication supplied in custom-packaged blister packs.<sup>16</sup> After six months, adherence increased from a baseline of 61% to 97% in the intervention group versus 69% for the usual care group. Increases in medication adherence led to clinically meaningful reductions in systolic blood pressure but not LDL-cholesterol for those patients suffering from hypertension and hypercholesterolemia, respectively. Another trial compared daily dose blister packaging of one blood pressure medication (lisinopril) with medication packaged in bottles for use in elderly outpatients. Those who receive their medication in the blister pack refilled their prescriptions on time more often and attained lower diastolic blood pressure.<sup>17</sup>

One systematic review examined the effects of calendar packaging (either blister packs or pill organizers) versus conventional bottles on patient adherence and outcomes in community dwelling adult outpatients with a variety of chronic diseases (hypertension, Type 2 diabetes, epilepsy, depression). Trial quality was rated very poor to fair. Six out of eight evaluable trials improved adherence. Only one trial demonstrated improved outcomes, but most were small and not adequately powered to do so.<sup>18</sup> None of these trials involved predominately Medicare patients.

### CONCLUSION

Based on initial study by the CBO, improved access and use of prescription medications may lower costs related to medical services in Medicare beneficiaries. Certain residents of LTC facilities may have their daily medications supplied in blister packs to promote medication adherence. However, no cost/benefit analysis of providing medications in timed calendar blister packs to Medicare beneficiaries in the outpatient arena is available. Moreover, although blister packs may be commonly used as packaging for oral drug products in LTC facilities, utilization problems among older adults with pharmaceutical packaging are well known from investigation of multi-use dose containers. Similarly, blister pack design, including the force required for opening and opening mechanisms, can have significant impact on usability in older patients.<sup>19</sup>

### RECOMMENDATION

The Board of Trustees recommends that the following statement be adopted in lieu of Resolution 115-A-13 and the remainder of the report filed.

That our American Medical Association recommend the Centers for Medicare and Medicaid Services conduct a cost/benefit analysis and an analysis of the ability of seniors and people with disabilities to use blister packs in

order to determine the feasibility of expanding coverage for timed calendar blister packs for prescription medications beyond residents of long term care facilities.

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## 12. MENTAL HEALTH SERVICES FOR SCHOOL-AGED CHILDREN (RESOLUTION 708-A-13)

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED  
IN LIEU OF RESOLUTION 708-A-13 AND  
REMAINDER OF REPORT FILED  
See Policy [H-345.977](#).**

Resolution 708-A-13, “Mental Health Services for School-Aged Children,” submitted by the American Academy of Pediatrics (AAP) and the American Academy of Child and Adolescent Psychiatry (AACAP) and referred by the House of Delegates asked:

That our American Medical Association work with child psychiatrists, primary care physicians, the public schools, multiple groups of mental health professionals, and other organizations to develop school-based programs that assure at-risk children/adolescents access to appropriate mental health screening and treatment services.

This resolution seeks to have our AMA take a leadership role in working with other relevant stakeholders to address a fundamental public health imperative, namely to develop and make available credible and appropriate school-

based programs for screening and treatment of children and adolescents at-risk for mental health disorders. Current Policy H-60.991 identifies several minimum standards for the operation of school-based health services. Policy D-60.984 supports the concept of “adequately equipped and staffed School-Based or School-Linked Health Centers (SBHCs) for the comprehensive management of conditions of childhood and adolescence,” as well as AMA participation in a broad-based public-private approach for “the creation, funding and sustaining of SBHCs throughout the country.”

## BACKGROUND

Educational systems and individual schools are critical partners aligned with the broader healthcare system for addressing the medical needs of children and adolescents. The importance of providing mental health services for school-aged children has long been recognized.<sup>1,2</sup> School-based mental health services are important settings for recognizing and addressing mental health problems at early stages, particularly in otherwise underserved areas.

### *Psychiatric Disorders in Children and Adolescents*

Psychiatric disorders are prevalent in children and adolescents. Approximately 1 in 5 children and adolescents ages 9 to 17 have diagnosable psychiatric disorders, and the prevalence of certain severe disorders (e.g., bipolar, attention deficit hyperactivity and autism spectrum disorders) has increased.<sup>1,3</sup> The lifetime prevalence of mental disorders that cause severe impairment and/or distress in adolescents is ~22%.<sup>4</sup> The median age of onset for anxiety disorders may be as early as 6 years, 11 years for behavioral/conduct disorders, 13 years for mood disorders and 15 years for substance use disorders. Nearly half of adults in the United States with mental health disorders had identifiable symptoms by the age of 14.

### *Workforce*

Currently, about 7,000 child and adolescent psychiatrists are practicing in the United States; children in rural areas and those burdened by low socioeconomic status have significantly reduced access.<sup>5</sup> Given the limited number of specialists, and existing barriers for access to child and adolescent psychiatrists, additional burdens are placed on pediatricians, family physicians, and other health care providers and mental health care professionals to identify and manage children and adolescents in need of treatment for mental health disorders, and to work in a collaborative fashion. Only 20% of children who need treatment for mental health and substance use disorders receive it, despite the availability of effective, evidence-based treatments.<sup>1,6</sup>

### *Promoting Collaborative Care for Mental Health Disorders in Children and Adolescents*

The mission of AACAP is, in part, “to promote the healthy development of children, adolescents, and families.” AAP formed a Task Force on Mental Health in 2004 to “assist pediatricians and other primary care clinicians<sup>1</sup> in enhancing the mental health care that they provide to children and adolescents.”<sup>8</sup> This was to be accomplished by: 1) facilitating system changes; 2) articulating competencies needed by primary care clinicians to address mental health problems prevalent among children and adolescents in the United States; and 3) building capacity for practice enhancements in mental health.<sup>9-11</sup> In 2011, AAP formed a Mental Health Leadership Work Group to help integrate the work of the Task Force (which was sunsetted) into mainstream pediatric practices.<sup>5</sup>

Accordingly several clinical resources and important policies, including some developed in a collaborative fashion, have emanated from both AACAP and AAP. These are intended to address competencies for diagnosing and treating mental health disorders in children and adolescents, enhance cooperation between child and adolescent psychiatrists and pediatricians, and strengthen the clinical interface with schools.<sup>12-22</sup>

## SCHOOL BASED MENTAL HEALTH

A 2004 report from AAP’s Committee on School Health articulated a comprehensive, multifaceted, and integrated approach to address barriers and promote healthy development of school-aged children with a focus on school-based mental health services.<sup>7</sup> This report recommended a tiered approach to school-based mental health services comprising: 1) an array of preventive mental health programs and services targeting all children; 2) targeted mental

<sup>1</sup>The term “primary care clinicians” is intended to encompass pediatricians, family physicians, nurse practitioners and physician assistants who provide primary care to infants, children and adolescents.

health services designed to assist students who have one or more identified mental health needs but who are otherwise engaging successfully in many social and academic activities; and 3) addressing the needs of students with more severe mental health diagnoses and symptoms by providing access to a multidisciplinary team of professionals.

A rich array of institutional programs, resources, curricula and pilot programs have evolved over the past 20 years to promote expanded school-based mental health programs and services including the:

- UCLA Center for Mental Health in Schools<sup>23</sup>
- Center for School Mental Health at the University of Maryland<sup>24</sup>
- National Technical Assistance Center for Children’s Mental Health at Georgetown University’s Center for Child and Human Development<sup>25</sup>
- Center for School Based Mental Health Programs at Miami University (OH)<sup>26</sup>
- American Psychiatric Association Foundation’s “Typical or Troubled?”<sup>TM</sup> curriculum<sup>27</sup>

Information on some local programs designed to enhance school-based mental health services is available through the AAP website.<sup>28</sup>

### *Legislation*

Implementing successful school-based mental health programs requires resources and funding. The Mental Health in Schools Act of 2013 (H.R. 628, S. 195) is based on the premise that “if a school is going to respond to the mental health needs of its students, it must have access to resources that provide family-centered, culturally and linguistically appropriate supports and service.”<sup>29</sup> This act, supported by AACAP, would expand the scope of the Safe School-Health Students program by funding local educational agencies to increase collaborative efforts using a public health-based approach, while providing culturally and linguistically appropriate in-service training to school personnel.

### CONCLUSION

Almost 20% of children and adolescents have a mental health disorder, with at least half suffering from a serious emotional or behavioral disorder that causes substantial impairment in functioning at home, school or in the community. Our AMA recognizes the importance of this issue and commends AACAP and AAP for their leadership in developing resources, clinical practice tools and policies designed to improve the recognition and treatment of mental disorders in children and adolescents and promoting appropriate school-based mental health programs. AACAP and AAP are best positioned to move this issue forward. If a need exists to develop further science or public health-based policy, our AMA could play a contributory role. Otherwise, our AMA would seek to lend expertise in a supportive fashion where available.

### RECOMMENDATION

The Board of Trustees recommends that the following statement be adopted in lieu of Resolution 708-A-13 and the remainder of the report filed.

That our American Medical Association recognizes the importance of developing and implementing school-based mental health programs that ensure at-risk children/adolescents access to appropriate mental health screening and treatment services and supports efforts to accomplish these objectives.

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### 13. PHARMACIST ADMINISTRATION OF IMMUNIZATIONS

*Informational report; no reference committee hearing.*

#### HOUSE ACTION: FILED

Board of Trustees Report 1-I-13, "Pharmacist Administration of Immunizations," was referred by the House of Delegates (HOD) for report back at the 2014 Annual meeting. The report was generated in response to Resolution 212-I-12, "Pharmacist Administration of Vaccines," submitted by the Louisiana delegation and referred by the HOD.

In referring Board of Trustees Report 1-I-13 back for further study, the HOD identified several issues in need of clarification including pharmacists vaccinating at-risk populations, questions surrounding patient safety especially in the pediatric population, managing adverse events, communicating with the patient's treating physician and parity in reporting requirements for immunization registries. Given the broad public health and clinical implications of these issues, the BOT believes that the issue of pharmacist administration of vaccines could benefit from a contemporary, collaborative review by relevant councils of our AMA. The Council on Science and Public Health has agreed to take the lead in this process and will engage the Council on Medical Service, Council on Legislation, and the Council on Long Range Planning and Development, as well as the AMA's Advocacy Resource Center, to develop a comprehensive report that is responsive to the public health imperative to immunize and protect patients from dangerous infectious diseases, and reflects best practices for patient selection, management, and follow-up.

It is anticipated that this joint council effort will result in a report being developed and submitted to the HOD for deliberation at the 2014 Interim Meeting.

#### **14. ALLIANCE FOR REGENERATIVE MEDICINE: OFFICIAL OBSERVER STATUS IN THE HOUSE OF DELEGATES**

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

#### **HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED**

*See Policy [G-600.025](#).*

#### **INTRODUCTION**

The Alliance for Regenerative Medicine (ARM) has requested official observer status in the House of Delegates (HOD). The American Medical Association (AMA) and the ARM share similar goals concerning the importance of science and technology in improving patient care. This report: (1) discusses AMA Bylaws and Policy that address requests and establish guidelines for official observer status; (2) provides background on the ARM and discusses how the ARM meets the official observer guidelines; and (3) recommends that the ARM be granted official observer status.

#### **AMA BYLAWS AND POLICY**

Our AMA Bylaws 2.20 and 2.201 state the following regarding official observers:

2.20 Official Observer. National organizations may apply to the Board of Trustees for official observer status in the House of Delegates. Applicants must demonstrate compliance with guidelines for official observers adopted by the House of Delegates, and the Board of Trustees shall make a recommendation to the House of Delegates concerning the application. The House of Delegates will make the final determination on the conferring of official observer status.

2.201 Rights and Privileges. Organizations with official observer status are invited to send one representative to observe the actions of the House of Delegates at all meetings of the House of Delegates. Official observers have the right to speak and debate on the floor of the House of Delegates upon invitation from the Speaker. Official observers do not have the right to introduce business, introduce an amendment, make a motion, or vote.

Governance Policy G-600.025 establishes the following criteria for selection of and attendance by official observers in our AMA House of Delegates:

1. Applications for official observer status will be reviewed using the following guidelines:
  - a. The organization and the AMA should already have established an informal relationship and have worked together for the mutual benefit of both.
  - b. The organization should be national in scope and have similar goals and concerns about health care issues.

- c. The organization is expected to add a unique perspective or bring expertise to the deliberations of the House of Delegates.
  - d. The organization does not represent narrow religious, social, cultural, economic, or regional interests so that formal ties with the AMA would be welcomed universally by AMA members.
2. An organization granted official observer status in the House shall automatically lose that status if no representative of the organization appears at six consecutive House of Delegates meetings.

A full list of official observers to the House of Delegates is available in the Appendix.

## DISCUSSION

The term “regenerative medicine” refers to the process of creating living, functional tissues—often through the use of stem cells—to repair or replace tissue or organ function lost due to age, disease, damage or congenital defects. The ARM is a non-profit advocacy organization that promotes legislative, regulatory, reimbursement, investment and technical initiatives to accelerate the development of safe and effective regenerative medicine technologies. ARM also works to increase public understanding of the field and its potential to transform human health care.

The ARM is seeking official observer status as a mechanism to improve awareness among the physician community about regenerative medicine as a source of current and future health care solutions. Also, it seeks to become aware of our AMA’s positions on regenerative medicine and to establish a working relationship with the AMA, with the goal of developing educational programs and other resources on clinical regenerative medicine for physicians.

The ARM was launched in 2009 by a coalition of approximately 25 universities, life sciences companies, health care investors and patient advocates with the common goal of advancing cell-based therapies. Today, its members include nearly 140 companies, patient advocacy groups and research institutes. Over the last five years, the ARM has worked to pass legislation that would provide for a national strategy on regenerative medicine by setting priorities for research and development, establishing grants for research, increasing funding opportunities for companies developing regenerative medicine products, funding for the FDA to perform regulatory research and a study of federal research activities. This legislation would promote timely translation of regenerative medicine research advances into the clinical setting, thereby enhancing patient care. The ARM also holds several meetings each year for stakeholders, including Clinical Outlooks for Regenerative Medicine, State of the Industry Briefings, Regenerative Medicine Investor Days and Regenerative Medicine Partnering Forums focused on stem cell research.

The AMA and the ARM share common interests and goals concerning science and technology in medicine. For example, AMA policy supports research on multipotent and pluripotent stem cells, and funding for such research, with the goal of improving patient care (Policies H-460.915 and D-460.993). Additionally, the AMA is a strong supporter of federal funding for biomedical, translational, and clinical research (Policy H-460.926) and is committed to supporting such research through advocacy and education (Policy H-460.941). Both the AMA and the ARM have advocated for the maintenance of federal funding for medical research. Although collaborative work between the AMA and the ARM has been limited to date, the increasing translation of research-derived cell therapies into the clinic signifies the need for more physician involvement and awareness on the topic of regenerative medicine. It is anticipated that the AMA and the ARM together could meet such a need more effectively than could either organization on its own.

As stated above, the ARM membership consists of a wide array of companies, research institutions and patient advocacy groups, so its reach is national in scope. Additionally, it advocates for research and application of therapies that are applicable to many medical specialties, so it is not bound by narrow interests. Further, it is expected that the House of Delegates would welcome the expertise that the ARM brings on regenerative medicine.

## SUMMARY AND RECOMMENDATION

In summary, the AMA and the ARM share similar goals regarding science and technology in medicine, and could benefit from a joint relationship based on observer status for ARM. The Board of Trustees believes the ARM would bring a unique perspective, and would be a welcome addition, to the deliberations of the AMA House of Delegates.

The Board of Trustees therefore recommends that our American Medical Association grant the Alliance for Regenerative Medicine official observer status in the House of Delegates and that the remainder of this report be filed.

APPENDIX -- Official Observers to the House of Delegates

Organization	Year Admitted
1. Accreditation Association for Ambulatory Health Care	1993
2. Alliance for Continuing Medical Education	1999
3. Ambulatory Surgery Center Association	2005**
4. American Academy of Physician Assistants	1994
5. American Association of Medical Assistants	1994
6. American Dental Association	1982
7. American Health Quality Association	1987*
8. American Hospital Association	1992
9. American Nurses Association	1998
10. American Public Health Association	1990
11. Association of periOperative Registered Nurses	2000
12. Association of State and Territorial Health Officials	1990
13. Commission on Graduates of Foreign Nursing Schools	1999
14. Council of Medical Specialty Societies	2008
15. Educational Commission for Foreign Medical Graduates	2011
16. Federation of State Medical Boards	2000
17. Federation of State Physician Health Programs	2006
18. Medical Group Management Association	1988
19. National Association of County and City Health Officials	1990
20. National Commission on Correctional Health Care	2000
21. National Council of State Boards of Nursing	2000
22. National Indian Health Board	2013
23. PIAA (Physician Insurers Association of America)	2013
24. Society for Academic Continuing Medical Education	2003
25. US Pharmacopeia	1998

\*- Admitted in 1987 as the American Medical Peer Review Association

\*\*-. Admitted in 2005 as the Federated Ambulatory Surgery Association. In 2008 merged with American Association of Ambulatory Surgery Centers to become Ambulatory Surgery Center Association.

## 15. EVALUATION OF ICD-11 AS A NEW DIAGNOSTIC CODING SYSTEM

*Informational report; no reference committee hearing.*

### HOUSE ACTION: FILED

#### INTRODUCTION

At its 2012 Annual Meeting, the House of Delegates adopted Policy D-70.952 “Stop the Implementation of ICD-10.” It asks that our American Medical Association (AMA) evaluate the feasibility of moving from ICD-9 to ICD-11 as an alternative to moving to ICD-10 and report back to the House of Delegates. Board of Trustees Report 25-A-13, titled “Evaluation of ICD-11 as a New Diagnostic Coding System,” was presented to the House of Delegates at its 2013 Annual Meeting and was referred.

This Board of Trustees (BOT) report will address the question of feasibility of remaining on ICD-9, not implementing ICD-10, and waiting for ICD-11. The report will provide an overview of the development of ICD-11, a comparison of the implementation of ICD-10 versus ICD-11 and advantages and disadvantages of moving directly from ICD-9 to ICD-11.

It is important to note that on March 27, 2014, the House of Representatives passed H.R. 4302 “Protecting Access to Medicare Act of 2014,” which was primarily addressing a patch for the Medicare Sustainable Growth Rate deadline.



The bill included a section stating that the Secretary of the Department of Health and Human Services (HHS) may not, prior to October 1, 2015, adopt ICD-10. This same bill passed in the Senate on March 31 and was signed by the President on April 1. The full implication of this one-year delay has not yet been assessed by the industry. Many questions remain at this date as to the process going forward to establish a new compliance date.

## ADVOCACY

The AMA has worked vigorously to stop the implementation of ICD-10 since the passage of Policy D-70.952 in November 2011. In 2012 following letters the AMA sent to Congress and the Secretary of HHS, HHS initiated a regulatory change to delay the ICD-10 implementation date until October 1, 2014. This delay followed years of previously successful advocacy resulting in the Centers for Medicare and Medicaid Services (CMS) holding back on the implementation of ICD-10 for over a decade.

Most recently, the AMA published in February 2014 a study it funded on the updated costs for physician practices to implement ICD-10. The findings show that in some cases, costs are nearly three times what had been predicted in the 2008 study. Using this updated data, the AMA sent another letter to HHS expressing its concerns with the implementation of ICD-10 and the likely disastrous financial implications of it on physicians.

The AMA has also supported two Congressional bills, H.R. 1701 and S. 972, introduced in spring 2013 calling to stop the implementation of ICD-10 and require the Government Accountability Office to recommend a less disruptive replacement for ICD-9.

The implementation of ICD-10 is a divisive issue for the industry. While many physicians have concerns about the costs and burden of ICD-10, there are many other stakeholders, including government agencies, researchers, large payers, large health system providers and public health entities, that support the conversion. Stakeholders have already invested millions towards the adoption of ICD-10. Several physician state and specialty societies supported the one-year delay in 2012 as a good compromise. The AMA has continued to engage HHS on a wide variety of ICD-10 implementation issues, including reducing the burden on physician practices and the need for more appropriate testing and education.

## DEVELOPMENT OF ICD-11

ICD-11 is currently being developed by the World Health Organization (WHO). To develop ICD-11, the WHO is using a collaborative process calling on experts and users to participate in the revision process through a Web-based platform. The anticipated outcome will be a classification that is based on user input and needs.

The WHO development work has included the development of an Alpha Browser that was available in 2011 for public viewing and comment. In May 2012, the Beta Browser was made available to the public. During the Beta period, the WHO is encouraging stakeholders to participate in the ICD-11 revision process. Individuals are able to make comments, make proposals to change ICD categories, participate in field trials and assist in translating.

Initially, ICD-11 was scheduled to be brought to the World Health Assembly, the decision-making body of the WHO, for consideration in May 2015. This date has now been delayed until May 2017. Once approved by the WHO, the United States would presumably need to develop its clinical modification of the code set; just as it has done for ICD-9 and ICD-10.

The WHO has been questioned about the prematurity of planning to move to ICD-11 when some countries have not implemented ICD-10. Specifically, 57 out of 194 countries continue to use ICD-9 for mortality reporting, which the United States converted to ICD-10 use in 1999.

There has been speculation that the health care industry will have to wait many years to have a US version of ICD-11 implemented, based on the experience of when the WHO ICD-10 version was available and the final implementation date for ICD-10. This point has been used to underscore the need to implement ICD-10. The implementation of ICD-11, however, could occur sooner if there is a strong commitment by the industry, along with adequate resources. There is no accurate way to predict or anticipate a timeframe for the implantation of ICD-11. No matter, it is expected to take at least several years.

## FEATURES OF ICD-11

Although ICD-11 is not yet finalized, the WHO has provided some information on expected features. In ICD-11, each disease category will have definitions, a standard definition template, and further features in what will be a “Content Model.” The Content Model will allow for more computerization, with links to the Systemized Nomenclature of Medicine–Clinical Terms (SNOMED CT) and other terminologies. ICD-11 will have a multi-axial framework with linkages among the diagnostic concepts, which is in contrast to the hierarchical structure of ICD-10.

## COMPARING ICD-10 AND ICD-11

Since ICD-11 is not yet complete, a comparison of ICD-10 to ICD-11 is limited. From a code structure standpoint, ICD-10 differs from ICD-9 by having more characters and being alphanumeric. These changes will require updates to computer systems currently programmed for ICD-9. A large difficulty with implementing ICD-10 involves the use of outdated practice management and other electronic systems that cannot accommodate the ICD-10 structure change and need to be updated or replaced. ICD-11 will have other terminology underpinnings, e.g., SNOMED CT, that do not exist in ICD-10 and will require more computerization to support it. The result is that the practice system changes for implementing both ICD-10 and ICD-11 will be significant.

Training to understand and code using ICD-10 will be substantial due to the changes in coding concepts and coding guidelines and the fact that the majority of coders today have only known ICD-9 and have never made a transition to a newer version. Training will also go beyond the traditional billing staff, since ICD-10 will have a greater impact on clinical work, quality measurement, disease management and public health reporting. While it is too early to understand what the needs for training will be for ICD-11, it can be anticipated that most staff, as with ICD-10, will be using ICD-11 and will need training. It is likely that training for ICD-11 will require similar levels of resources and result in disruptions in productivity as expected with ICD-10.

The act of coding in ICD-10 will remain largely consistent with ICD-9, in that coding can be done manually using code books or electronically using code selection software. ICD-11 is expected to allow for both manual coding and computerized coding, but more computerization may be necessary for the coding. The multi-axial structure of ICD-11 will allow for more linkages of code concepts, which will require greater electronic collection and storage of the codes. ICD-11 is also expected to support better natural language coding and data exchange.

The costs to implement ICD-10 will be significant based on the nature of how and where ICD-10 will be used, the need for widespread system changes and the need for training of clinical and administrative staff. With ICD-11, these same costs will exist in its implementation. In addition, the development of the Content Model for ICD-11, the multi-axial format and need for more computerization have the potential to add to its implementation costs.

## DISCUSSION

This report is an evaluation of ICD-11 and an assessment of the feasibility of moving from ICD-9 to ICD-11 without implementing ICD-10. The assessment of feasibility is based on the advantages and disadvantages of moving directly from ICD-9 to ICD-11.

The following are advantages for moving directly from ICD-9 to ICD-11 (skipping ICD-10):

- Implementation efforts for ICD-11 will be significant and costly regardless of whether or not ICD-10 is implemented.
- Waiting to implement ICD-11 will give physicians and the health care industry more time to implement electronic health records (EHRs) and develop the electronic systems infrastructure for health information exchange, since resources will not be stretched between the two major implementation activities of ICD-10 and EHRs.
- Physicians will only have to go through one implementation period, instead of two to go from ICD-9 to ICD-10 to ICD-11.
- Physicians and practices will have more time to prepare for and train staff on transitioning to a new code set if ICD-10 is not implemented.

The following are disadvantages of moving directly from ICD-9 to ICD-11 (skipping ICD-10):

- ICD-9 is outdated today and continuing to use the outdated codes limits the ability for diagnosis codes to advance the understanding of diseases and treatments, identify quality care, drive better treatments for populations of patients, and develop new payment delivery models.
- The market will miss out on the improvements in the ICD-10 codes that align with today's diagnosis coding needs, including the addition of laterality, updated medical terminology, greater specificity of the information in a single code, and flexibility to add more codes.
- Skipping ICD-10 will impede the ability of the industry to build on their knowledge and experience of ICD-10, which is expected to be needed for ICD-11. Learning the medical concepts, training efforts, and overall implementation efforts for ICD-11 will be more challenging if ICD-10 is not implemented first.
- Focusing solely on moving from ICD-9 to ICD-11 risks missing the opportunity to educate physicians and leaving them unprepared for the anticipated transition to ICD-10, which could result in significant cash flow disruptions.
- Implementing ICD-10 is expected to reduce payers' reliance on requesting additional information, known as "attachments," which could reduce burdens on physicians, but this opportunity will be delayed until ICD-11 is implemented.

## CONCLUSION

The AMA has worked vigorously to stop the implementation of ICD-10 since the passage of Policy D-70.952 in November 2011 by actively communicating the significant burden of this transition to Congress and the Secretary of HHS, and by supporting Congressional bills H.R. 1701 and S. 972 in 2013. While the most recent legislation provides a welcome relief of a minimum one-year delay of ICD-10 beyond October 1, 2014, we remain committed to relieving physicians of the crushing administrative burdens and practice disruptions that are anticipated during the scheduled transition to ICD-10.

In addition, the AMA will continue to advocate that CMS adopt a policy for Medicare that provides a two-year 'implementation' period during which Medicare will not be allowed to deny payment based on the specificity of the ICD-10 code, will provide feedback to the physician on any coding concerns and will not be allowed to recoup payment due to a lack of ICD-10 specificity.

Given that physicians cannot rely on additional delays to the implementation of ICD-10, or moving directly from ICD-9 to ICD-11, the BOT believes the AMA should continue to prepare physicians for the conversion to ICD-10, as well as advocate for additional remedies such as a two-year ICD-10 implementation period.

Our AMA will continue to advocate for physicians per AMA policy on this issue, monitor the situation and provide updates as new information becomes available.

## 16. PEDIATRIC MEDICAL ORDERS BETWEEN STATES (RESOLUTION 707-A-13)

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

### **HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 707-A-13 AND REMAINDER OF REPORT FILED**

*See Policy [H-275.918](#).*

Resolution 707-A-13, "Pediatric Medical Orders Between States," introduced by the American Academy of Pediatrics and referred to the Board of Trustees, asked that our American Medical Association (AMA) advocate so that board-certified physicians currently licensed and registered to practice medicine can duly execute conventional medical orders for their patients who are moving out of state, for a transitional period of no more than sixty days. This would allow a child with special health care needs to attend early child care, daycare, nursery, preschool, and school safely in their new location while the family secures a new medical home, health insurance, and, when indicated, subspecialty care.

Testimony heard during Reference Committee G stressed that physicians should facilitate the transition of care for their patients before their patients move out of state. It was also noted that the resolution could be construed as support for national licensure of physicians, which is counter to AMA policy. The item was therefore referred for report.

## BACKGROUND

Ideally, medical care for children with special health care needs should be transferred between pediatricians before a child moves from one state to another; however, this is not always possible and might not always occur before the move. Therefore, many families bring medical orders from their former pediatrician with them, anticipating in good faith that their child with special needs can attend school under temporary orders from their former out-of-state pediatrician while they find a new medical home and secure health insurance in the new locale.

Some states do not allow out-of-state physician medical orders to be honored by the school nurse, creating a situation of exclusion for some children, based solely on the fact that they have special medical health care needs while lacking regionally accepted medical orders. Examples of children affected by this issue have included: a diabetic child who went to school with endocrine orders for insulin and glucagon, a child with active seizure disorder with rescue medications, and a child with an unstable heart condition. In cases such as these, the school could not accept an out-of-state medical order for their care. Consequently, these children were put on home tutoring or schooling and were otherwise delayed until the parents could schedule an appointment with a physician. Their resultant exclusion from school and placement on home instruction might last weeks or months, and it may take more time for the family to secure local health care and insurance. School nurses are reporting a six-to eight-month waiting list to get an appointment with a neurodevelopmental and behavioral pediatric or mental health clinic in Rochester, NY for a physical and medication order. Seeking temporary medical orders from an emergency room or urgent care center from an in-state physician has been an alternative option for some patients.

## STATE REGULATIONS

Each state has the authority to license physicians and regulate the practice of medicine. Allowing US licensed physicians to execute conventional medical orders for their patients who are moving out of their state and into another state, for use in any of the United States for a transitional period, would not be construed national licensure. The primary responsibility of each medical licensing board is to protect the public through the regulation of physicians and other health care providers. Within the United States, the organization and activities of each state medical board are determined by a unique state statute (medical practice act). The differences among these statutes are related to the general administrative structure of each jurisdiction and to the needs of the public as they are perceived by each responsible legislative body.<sup>1</sup>

## AMA POLICY

Policy H-60.974, "Children and Youth with Disabilities," encourages physicians to provide schools with medical information to ensure that children and youth with disabilities receive appropriate school health services.

Policy H-275.973, "State Control of Qualifications for Medical Licensure," states that the AMA firmly opposes the imposition of federally mandated restrictions on the ability of individual states to determine the qualifications of physician candidates for licensure by endorsement, and actively opposes the enactment of any legislation introduced in Congress that promotes these objectives.

## RECOMMENDATIONS

Optimal health care for children with special health care needs includes provision of health maintenance and acute care as well as referral to, and coordination of, care with other physicians. As a result, primary care pediatricians and pediatric medical subspecialists are coordinating care services, counseling families, and advocating for their patients with insurers, schools and other community agencies. Laws currently exist in certain states, such as states bordering the state of New York, that allow for a temporary honoring of medical orders by an out-of-state physician, as long as the physician is registered and licensed to practice in New York. These policies have been implemented without consequence. Your Board believes it is reasonable for other states to consider similar legislation or regulation.

Therefore, the Board of Trustees recommends that the following be adopted in lieu of Resolution 707-A-13 and the remainder of this report be filed:

1. That our American Medical Association support legislation or regulation that allows physicians currently licensed and registered to practice medicine in any of the United States to duly execute conventional medical orders for their patients who are moving out of their state and into another state for use in any of the United States, for a transitional period of no more than sixty days. This would allow a child with special health care needs to attend early child care, daycare, nursery, preschool, and school safely in their new location while the family secures a new medical home, health insurance, and, when indicated, subspecialty care.
2. That our AMA will work with interested states and specialties on legislation or regulations to allow temporary honoring of medical orders by an out-of-state physician, as long as the physician is registered and licensed to practice medicine in the United States.

#### REFERENCE

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### 17. TUBAL LIGATION AND VASECTOMY CONSENTS

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

#### HOUSE ACTION: FILED

#### INTRODUCTION

At the 2013 Interim Meeting, the House of Delegates (HOD) adopted Policy D-75.994, Tubal Ligation and Vasectomy Consents. The policy calls on our American Medical Association (AMA) to: work closely with the American Congress of Obstetricians and Gynecologists, the American Urological Association, and any other interested organizations, to advocate to Congress for the legislative or regulatory elimination of the required 30-day interval between informed consent and a permanent sterilization procedure; and work with the Centers for Medicare & Medicaid Services to eliminate the time restrictions on informed consent for permanent sterilization procedures. In addition, Policy D-75.994 calls on our AMA to “study the current ramifications of the existing regulations mandating a waiting period for informed consents for Medicaid patients undergoing tubal ligations and vasectomies, specifically noting potential financial costs regarding bureaucratic enforcement, unintended pregnancies, public health and ethical considerations and concomitant health care inequity/disparity issues and report back to the AMA HOD at the 2014 Annual Meeting.” This informational report responds to the request for a study and provides support and background for the action items described above which are now AMA policy.

#### BACKGROUND

Female sterilization is the second most commonly used contraceptive method in the United States, with approximately one-quarter of American women relying on such sterilization for contraception.<sup>1</sup> Postpartum sterilization, usually done through tubal ligation, is one of the safest and most effective methods of contraception.<sup>2</sup> The immediate postpartum period following vaginal delivery or at the time of cesarean delivery is the ideal time to perform sterilization, according to American College of Obstetricians and Gynecologists (ACOG), because of technical ease and convenience for the patient and physician.<sup>3</sup> Sterilization procedures are more common among underserved women, including those with lower incomes and lower levels of education, public health insurance or no health insurance, and those who are African American or Hispanic.<sup>4</sup> Women who rely on Medicaid may face barriers to obtaining a desired sterilization procedure, especially post-partum, as a result of current Medicaid policy.<sup>5</sup>

#### *Medicaid Sterilization Policy*

Prior to the 1960s, the main reasons for sterilization in the United States were to prevent pregnancies with potentially severe medical consequences for the mother or to promote the eugenics movement.<sup>6</sup> During the early 20<sup>th</sup>

century, more than 30 states passed compulsory sterilization laws to advance eugenics principles. It is estimated that these laws led to more than 60,000 forced sterilizations of disabled individuals, primarily women who were “mentally retarded” or considered “feeble-minded.”<sup>7</sup> Some states continued to sterilize residents into the 1970s.

During the 1960s and 1970s, the use of tubal ligation as a contraceptive method increased significantly as a result of the legalization of contraception, improved and safer laparoscopic techniques, and the creation of federally-funded family planning programs that provided subsidies for the costs of sterilization.<sup>8</sup> However, reports of coercive and nonconsensual sterilizations of poor and minority women resulted in a public uproar in which the federal government was accused of racism and classism in its implementation of family planning programs. This public outcry resulted in the promulgation, in 1976, by the US Department of Health, Education, and Welfare of strict regulations and a consent form for all federally-funded sterilizations. Under these regulations, sterilization was prohibited for persons younger than 21 years of age or who were mentally incompetent or institutionalized. The regulations also required a 72-hour waiting period after written informed consent before sterilization could occur.<sup>9</sup> The waiting period was extended to 30 days (with some exceptions) in 1978.<sup>10</sup> Under additional regulations developed in the 1970s, women who opt for sterilization must complete the detailed Consent to Sterilization section of the Medicaid Title XIX form at least 30 days and no more than 180 days before the procedure. A signed copy of the consent form must be available at the time of the procedure.<sup>11</sup> These regulations remain in effect today.

The 30-day waiting period policy applies to both men and women, but female sterilization is significantly more common than male sterilization within low-income populations. Since women often desire sterilization at a specific time, i.e., after a delivery, the extended mandatory waiting period is particularly problematic for them.<sup>12</sup>

#### *Ramifications of Medicaid Sterilization Policy*

Medicaid is the largest payer of publicly funded family planning services, accounting for 75 percent of all public expenditures.<sup>13</sup> In addition, Medicaid pays for the vast majority of publicly funded sterilizations.<sup>14</sup> According to the National Hospital Discharge Survey, 136,853 Medicaid-funded postpartum sterilizations were performed in 2010.<sup>15</sup> Given these numbers, Medicaid’s sterilization waiting period policy clearly can have a significant impact on low-income and minority women.

#### The Cost of Unintended Pregnancies

Unintended pregnancy continues to be a serious problem in the United States that is associated with health risks and social and economic costs for a woman, her family, and society. One half of pregnancies in the United States are unintended and disproportionately occur in minority and low-income populations. Women continuing with unintended pregnancies are more likely to have poor health outcomes such as infant mortality, low birth weight infants, and maternal mortality and morbidity. In addition, children born as a result of unintended pregnancies have higher rates of developmental delay. Lack of access to effective family planning services is one of the key factors underlying the high rates of unintended pregnancies.<sup>16</sup>

Researchers have concluded that only 50 percent of women who request postpartum sterilization during prenatal contraception counseling actually have the procedure, and over half of those unfulfilled requests are due to the Medicaid policy-related barriers described above, e.g., the waiting period, the complex informed consent form and the requirement that the consent form must be presented at the time of the procedure.<sup>17</sup> Additional findings indicate that nearly one half of women whose sterilization requests were not achieved became pregnant within one year, twice the rate of women who did not request sterilization.<sup>18</sup> It is often difficult for lower-income women caring for newborns in the post-partum period to return to the outpatient office for other methods of contraception. In addition, because pregnancy-related Medicaid eligibility ends soon after delivery, Medicaid beneficiaries who do not undergo their desired sterilization during the immediate postpartum period may miss their limited window of opportunity.<sup>19</sup>

The inability to have a postpartum sterilization procedure creates a significant increase in cost both at the individual level and at the health system level. It has been estimated that the public cost to the health care system of births resulting from unintended pregnancies is billions of dollars; in 2006, the cost was \$11 billion.<sup>20</sup> A recent study done by researchers at the University of Pittsburgh School of Medicine concluded that a revised Medicaid sterilization policy that removes logistical barriers—i.e., the 30-day waiting period and the complex informed consent form—could potentially reduce over 29,000 unintended pregnancies annually and save \$215 million in taxpayer dollars each year.<sup>21</sup>

### Health Care Inequity/Disparity

The Medicaid 30-day waiting period has a disproportionate impact on low-income and minority women. Such women are most likely to request publicly funded sterilization and are at the highest risk for having an unintended pregnancy, resulting in higher rates of both unintended births and abortions.<sup>22</sup> Moreover, there are unfair differences in consent rules related to postpartum sterilization based on insurance. Women with private insurance are not subject to the same regulations and restrictions as women covered by Medicaid, and therefore may have more reproductive autonomy and better outcomes with regard to their contraceptive choices than lower-income women.<sup>23</sup> The Medicaid policy has created a two-tiered system of access to post-partum sterilization, resulting in discrimination against Medicaid beneficiaries based on their insurance coverage.

### CONCLUSION

Many experts in women's health, including ACOG and academic researchers, have concluded that Medicaid's sterilization waiting period policy, while originally well-intended in terms of ensuring informed consent, imposes significant barriers for lower-income women who have chosen sterilization as a permanent method of family planning. Based on the foregoing background information and discussion of the ramifications of the Medicaid sterilization waiting period policy, your Board concludes that there is ample evidence to support advocating for changing this policy, in accord with AMA policy.

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## 18. DATA TRANSITION COSTS WHEN SWITCHING ELECTRONIC MEDICAL RECORDS (RESOLUTION 728-A-13)

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

### **HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 728-A-13 AND REMAINDER OF REPORT FILED**

*See Policy [D-478.995](#).*

At the 2013 Annual Meeting, the House of Delegates (HOD) referred Resolution 728-A-13, “Data Transition Cost When Switching Electronic Medical Records”, for report back at the 2014 Annual Meeting. This resolution was introduced by the Texas Delegation and asked that our American Medical Association (AMA):

Work with the Office of the National Coordinator for Health Information Technology (ONC) and other interested parties to make EMR-to-EMR medical record data transition capabilities a requirement of ONC’s EMR product certification; and be it further

That if the ONC is unwilling or unable to make EMR medical record data transition a certification requirement, our AMA seek legislative action requiring this of EMR vendors.

This report provides background regarding the current obstacles and costs associated with transitioning data stored in electronic health records (EHRs) and outlines AMA advocacy efforts to improve data migration through the ONC certification process and other avenues.

### **BARRIERS TO EHR DATA MIGRATION**

One of the anticipated benefits of EHRs was that these systems would facilitate care coordination by improving data migration across care providers. Compared to paper-based systems, it was believed that EHRs would allow data to flow from one system to another without significant costs or other resources.<sup>1</sup> Yet, as more physicians have adopted EHRs, many have experienced “data lock-in,” where information is stored in one EHR system but cannot easily be moved or otherwise transferred to another system.<sup>2</sup> The following outlines the various barriers that currently inhibit EHR data migration.

#### *Technological Barriers*

Part of the problem with achieving data portability is the technical barriers that impair this process. Data stored within one EHR system may not be compatible with another vendor’s products, especially if systems are highly customized or a mismatch exists between the source EHR and the receiving system. For example, many first generation EHRs did not code all of the patient information stored in their systems, leaving data as free text. In this format, the data are not easily transferred from one EHR to another.<sup>3</sup>

Another technical challenge is the sheer scale of the data sets stored in EHRs. Even for small practices, moving patient records and all of the supporting documentation amounts to numerous files that require a significant amount of time and resources to transfer. As a result, physician practices are likely to experience disruptions in workflow or delays when trying to migrate data or switch EHR systems.<sup>4</sup>

Lastly the lack of interoperability—the ability for different EHR systems to not only migrate but also meaningfully incorporate data—is a significant obstacle to data migration. The technology to achieve interoperability is still in its very early stages of development and currently lacks clear standards and guidelines. Without a clear path forward, EHR vendors are hesitant to come to a consensus on how to transport the data since any agreement on data migration will also impact how interoperability is achieved. One study found that approximately 70 percent of surveyed clinicians cited a lack of interoperability and information exchange infrastructure as major barriers to electronic information sharing.<sup>5</sup> Effective data exchange therefore may be delayed until the market is also capable of achieving data interoperability.



### *Costs*

Where it is possible to overcome the existing technological barriers, the expense of migrating data across EHR systems is a further impediment for physicians. While some expenses may be justified, anecdotal evidence suggests that certain vendors may be using fees to prevent physician choice in purchasing or switching EHRs. Small physician practices have cited significant fees, of upwards of \$5000, to set up interfaces or otherwise migrate EHR data sets.<sup>6</sup> This is in addition to expenses incurred to purchase, train staff and implement EHR systems. Altogether these costs can greatly restrict provider choice and their ability to migrate data.

Not only are these costs substantial, but many providers are unaware of these fees. Contracts with some EHR vendors have failed to itemize these additional expenses, leading to a lack of transparency and confusion over what is or is not included in purchasing an EHR system.<sup>7</sup> In addition, fees to migrate data vary greatly due to a number of factors, including staff, number of office locations, as well as the unique circumstances of a provider's technical infrastructure. Some vendors, however, may take advantage of these varying costs and use prices to restrict data portability. ONC has attempted to address this lack of transparency in its 2014 EHR Certification Final Rule by requiring vendors to outline additional types of expenses (i.e., one-time, ongoing, or both) that affect a product's total cost of ownership.<sup>8</sup> However, the regulation only requires clarity in the type of costs that need to be disclosed, not the actual dollar amounts, leaving broad discretion to vendors.<sup>9</sup>

This lack of transparency is particularly concerning given that many physicians are considering switching EHR vendors, a process that requires a transfer of EHR data. A survey conducted by Black Book Rankings found that approximately one in six medical practices considered switching their EHR vendor in 2013.<sup>10</sup> While many providers are changing vendors due to dissatisfaction with existing products, others have little choice but to switch EHRs as vendors sunset certain products or decide not to seek Stage 2 certification.<sup>11</sup> Essentially this leaves physicians with a choice of incurring the cost to switch EHRs or incurring penalties under the Electronic Health Record Meaningful Use (MU) Program.

### *Lack of Certification Requirements*

An integral part of the EHR MU Program is the requirement that eligible providers use certified EHR technology (CEHRT). ONC is responsible for certifying EHRs nationwide through the adoption of standards, implementation specifications and criteria that EHR products must achieve. The intent of this certification process is to assure providers and other purchasers that an EHR system will offer the necessary technological capability, functionality and security to help them meet the MU program criteria.<sup>12</sup>

Despite this certification process, EHR products are held to few or no standards with respect to data migration. The certification requirements have initially focused on achieving specific MU measures (e.g., electronic prescribing and computerized physician order entry), leaving other aspects, such as usability, safety and data transfer, outside of the certification process. Consequently, EHR vendors are focusing first on achieving certification, which can be a time-consuming and demanding process that limits resources to adopt and improve other technology, such as data migration.

The lack of a certification requirement also means that vendors can place limits on or restrict data portability with few repercussions. They are not required to test their products or otherwise assure that data can be transferred. As noted by the Office of the Inspector General (OIG) of the Department of Health and Human Services, some vendors can gain a competitive edge by preventing data portability since "...the limited accessibility of the data makes it harder for the physician recipient to access and use it for clinical purposes. As a result, a physician recipient is more likely to utilize only the donor's services to make sure that necessary data are easily accessible."<sup>13</sup>

Normally, in a free market, consumer demand would mitigate such business practices since customers would simply choose to buy other products that allow for data migration. Yet, in this case, physicians are restricted to using certified EHRs since only these systems can be used to earn incentives and avoid financial penalties under the MU program. Furthermore, there are a limited number of products and vendors from which physicians can choose. One study found that only five vendors were used by 52.7 percent of physicians in ambulatory care settings who have received MU incentive payments in Stage 1.<sup>14</sup> In sum, the EHR market is distorted, focusing mainly on achieving MU criteria, while placing less emphasis on qualities like data portability.

## AMA STRATEGIC FOCUS, ADVOCACY, AND POLICY

The AMA strategic plan includes a focus on improving physician satisfaction, recognizing that a highly motivated physician workforce is more likely to provide high-quality care to patients. To determine specific factors that influence physician satisfaction, both positively and negatively, the AMA commissioned a study in conjunction with the RAND Corporation.<sup>15</sup> One of the key findings of this study was that the current state of EHR technology significantly worsened professional satisfaction in multiple ways.<sup>16</sup> In particular, the study found that the inability to exchange health information between EHR products was one of the sources of professional dissatisfaction, with several physicians describing systems that lacked data portability and required them to revert back to paper when receiving information from other EHR systems.<sup>17</sup>

Recognizing this significant problem for physicians, the AMA has actively engaged in efforts to reduce the barriers that currently inhibit data portability. The AMA has engaged with ONC to refine the certification process, urging ONC to place greater emphasis on data migration. AMA members have testified in front of relevant policy makers that vendors should be required to provide contractual, pre-defined specifications on data migration fees. The AMA also provided additional testimony on the issue of data lock-in to the Federal Trade Commission, highlighting factors which may be influencing the EHR market, including market consolidation and hurdles to data portability. The AMA has also called for an online list of vendors' data migration fees so that physicians can compare products and prices. The AMA has further recommended that ONC urge vendors to include independent (vs. vendor-employed) physicians during the EHR development and testing process to ensure that physician workflow needs are being met.

The AMA has directly engaged with the vendor community to promote greater data migration capabilities. As a result, the Electronic Health Record Association (EHRA) has included data migration issues in its EHR Developer Code of Conduct. This Code, although voluntary, outlines explicit goals for all EHR vendors. In terms of data portability the Code states that products should, "enable our customers to exchange clinical information with other parties, including those using other EHR systems, through standards-based technology, to the greatest extent possible" and "work with our customers to facilitate the export of patient data if a customer chooses to move from one EHR to another. We will enable, at a minimum, the export of one or more standards-based clinical summary formats such as CCD/CCDA (Continuity of Care Document/Clinical Document Architecture), or the then-current equivalent, for all patients."<sup>18</sup>

AMA policy also directs that steps be taken to improve data migration. Policy H-480.971 states that our AMA work to define the characteristics of an optimal medical record system, the goal being to define the content, format, and functionality of medical record systems, and aid physicians in evaluating systems for office practice computerization. Policy D-478.995 asks that our AMA seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community-based settings of care delivery. Policy D-478.976 seeks to improve transparency in the selection of EHR products by surveying physician use and issues with various open source and proprietary EHRs to create more transparency and support more informed decision making in the selection of EHRs. Similarly, Policy D-478.978 directs that AMA develop tools, accessible to all AMA members, that can help physicians in the selection and evaluation of electronic health records.

## DISCUSSION

Data lock-in impedes care coordination and the development of new delivery models, which diminishes any value associated with the use of an EHR. In addition, the inability to migrate data can present significant legal challenges for physicians since federal laws mandate that providers be able to access, furnish, and retain patient records for a number of years.<sup>19</sup> Further, loss of data or obstacles in accessing relevant information can lead to disruptions in billing for services or problems with quality measurement. All of these concerns suggest a need to remove the barriers to data migration.

Given the importance placed on EHR certification by both vendors and EHR users, incorporating data portability into the ONC certification process would help establish a common baseline for data migration. Establishing certification requirements would also move data migration from a voluntary requirement, which provides few guarantees to physicians, to one that must be incorporated by EHR products. This would provide less variability

among EHRs, engender physician choice in the marketplace and focus vendors on achieving interoperability, which is becoming more and more important as the industry increasingly moves towards an electronic record system.

A key concern, however, is that any certification criteria may be too prescriptive and will not be adaptable to different settings, provider/patient preferences, and documentation patterns. The EHRA has publicly urged ONC not to expand certification, stating that complex data migrations do not lend themselves to the uniformity imposed by product certification.<sup>20</sup> Likewise, given the existing state of technology, removing obstacles to data migration will also take time. Any established criteria must allow for the technology to properly develop so that requirements are achievable and systems are not pushed on physicians before physicians are ready.

To mitigate some of these concerns, one approach would be to first develop short-term, core data migration requirements that will establish a first step on the path towards improved data portability for patients and providers. This short-term goal would not only recognize the existing challenges and barriers facing data migration but would also begin moving the industry forward to improve EHR technology. ONC could then, over time, establish a long-term path to move the industry towards a practical data migration solution that is both cost effective and helps to improve patient care. The Health Information Technology Policy Committee has similarly recommended a two-stage approach, believing that this will outline a path for certification while allowing for revisions and flexibility.<sup>21</sup>

Currently, Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of clinical records to facilitate data exchange. While true interoperability is still developing, the EHR certification process could, at a minimum, seek to ensure that any vendor's EHR be able to export, import, and incorporate all CDA document, section, and entry templates into the correct patient's medical record. Furthermore, any clinical documents constructed in the CDA format should be completely consumable when exchanged between any two EHRs. Physicians should also have a basic guarantee from vendors that they can retain and access patient medical information in some format if they choose to switch EHR systems. This will ensure providers are able to comply with federal and state laws governing medical records and address some concerns about data lock-in.

While establishing ONC data migration certification requirements will remove one of the key barriers to data portability, cost and technology obstacles may remain intact. Some stakeholders have suggested amending the MU program statute to fully mandate that EHRs provide data portability. Legislation, however, can be cumbersome and lacks the flexibility and specificity that may be required in this context. This is especially true given that many of the obstacles are not stagnant but in flux and are likely to change over time. Instead, expanding the dialog with EHR vendors and other stakeholders may help explore other policy levers in addition to certification to address concerns with data migration. Working to establish best practices may help define solutions to existing gaps in technology. Similarly, efforts focusing on greater contract transparency and competition in the marketplace may mitigate cost concerns and ultimately improve EHR data portability.

## RECOMMENDATIONS

Based on the existing obstacles to data migration and the current EHR environment, the Board of Trustees recommends that the following policy should be adopted in lieu of Resolution 728-A-13 and the remainder of the report be filed:

1. That our American Medical Association seek to incorporate incremental steps to achieve electronic health record (EHR) data portability as part of the Office of the National Coordinator for Health Information Technology's (ONC) certification process.
2. That our AMA collaborate with EHR vendors and other stakeholders to enhance transparency and establish processes to achieve data portability.

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## APPENDIX - AMA Policy

### H-480.971 The Computer-Based Patient Record

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

### D-478.995 National Health Information Technology

1. Our AMA will closely coordinate with the newly formed Office of the National Health Information Technology Coordinator all efforts necessary to expedite the implementation of an interoperable health information technology infrastructure, while minimizing the financial burden to the physician and maintaining the art of medicine without compromising patient care.

2. Our AMA: (A) advocates for standardization of key elements of electronic health record (EHR) and computerized physician order entry (CPOE) user interface design during the ongoing development of this technology; (B) advocates that medical facilities and health systems work toward standardized login procedures and parameters to reduce user login fatigue; and (C)

advocates for continued research and physician education on EHR and CPOE user interface design specifically concerning key design principles and features that can improve the quality, safety, and efficiency of health care.; and (D) advocates for more research on EHR, CPOE and clinical decision support systems and vendor accountability for the efficacy, effectiveness, and safety of these systems.

3. Our AMA will request that the Centers for Medicare & Medicaid Services: (A) support an external, independent evaluation of the effect of Electronic Medical Record (EMR) implementation on patient safety and on the productivity and financial solvency of hospitals and physicians' practices; and (B) develop minimum standards to be applied to outcome-based initiatives measured during this rapid implementation phase of EMRs.

4. Our AMA will (A) seek legislation or regulation to require all EHR vendors to utilize standard and interoperable software technology components to enable cost efficient use of electronic health records across all health care delivery systems including institutional and community based settings of care delivery; and (B) work with CMS to incentivize hospitals and health systems to achieve interconnectivity and interoperability of electronic health records systems with independent physician practices to enable the efficient and cost effective use and sharing of electronic health records across all settings of care delivery. (Res. 730, I-04; Reaffirmed in lieu of Res. 818, I-07; Reaffirmed in lieu of Res. 726, A-08; Reaffirmation A-10; Reaffirmed: BOT Rep. 16, A-11; Modified: BOT Rep. 16, A-11; Modified: BOT Rep. 17, A-12; Reaffirmed in lieu of Res. 714, A-12; Reaffirmed in lieu of Res. 715, A-12; Reaffirmed: BOT Rep. 24, A-13; Reaffirmed in lieu of Res. 724, A-13; Appended: Res. 720, A-13; Appended: Sub. Res. 721, A-13; Reaffirmed: CMS Rep. 4, I-13; Reaffirmation I-13)

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

1. Our AMA will: (A) advocate for CMS and the Office of the National Coordinator (ONC) to support collaboration between and among proprietary and open-source EHR developers to help drive innovation in the marketplace; (B) continue to advocate for research and physician education on EHR adoption and design best practices specifically concerning key features that can improve the quality, safety, and efficiency of health care regardless of proprietary or open-source status; and (C) through its partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs--open source and proprietary--to create more transparency and support more informed decision making in the selection of EHRs.

2. Our AMA will, through partnership with AmericanEHR Partners, continue to survey physician use and issues with various EHRs--open source and proprietary--to create more transparency and formulate more formal decision making in the selection of EHRs.

3. Our AMA will work with AmericanEHR Partners to modify the current survey to better address the economics of EHR use by physicians including the impact of scribes.

4. Our AMA will make available the findings of the AmericanEHR Partners' survey and report back to the House of Delegates. (BOT Rep. 23, A-13; BOT Rep. 24, A-13)

D-478.978 Electronic Health Record "Lemon Law"

Our AMA will pursue possibilities, consistent with our strategic direction and existing guidelines for working with third parties, to develop tools, accessible to all AMA members, which can help physicians in the selection and evaluation of electronic health records. (BOT Rep. 9, A-12)

## 19. COUNCIL ON LEGISLATION SUNSET REVIEW OF 2004 HOUSE POLICIES

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

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

At its 1984 Interim Meeting, the House of Delegates established a sunset mechanism for House policies (Policy G-600.110). Under this mechanism, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to retain it.

The objective of the sunset mechanism is to help ensure that the AMA Policy Database is current, coherent and relevant. By eliminating outmoded, duplicative and inconsistent policies, the sunset mechanism contributes to the ability of the AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of House of Delegates deliberations.

At its 2002 Annual Meeting, the House modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following steps:

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

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

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

## RECOMMENDATION

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

## APPENDIX - Recommended Actions on 2004 House Policies

Policy Number	Title	Text	Recommendation
H-120.948	Positive Verification of Contact Lens Prescriptions	Our AMA will support positive prescription verification for contact lenses and recommend that the federal government monitor the effects of the Fairness to Contact Lens Consumers Act (FCLCA) on the accuracy of prescriptions. (Res. 225, A-04)	Retain – this policy remains relevant.
H-190.981	Required Timely Reimbursements by all Health Insurers	Our AMA will prepare and/or seek sponsorship of legislation calling for all health insurance entities and third party payers--inclusive of not-for-profit organizations and health maintenance organizations--to pay for "clean" claims when filed electronically within 14 days and paper claims within 30 days, with interest accruing thereafter. These time periods should be considered ceilings, not floors or fixed differentials between paper and electronic claims. (Sub. Res. 112, A-95; Modified: BOT Rep. 17, I-00; Reaffirmation A-02; Reaffirmed: Res. 815, I-02; Reaffirmation I-04)	Retain – this policy remains relevant.
H-245.979	Opposition to Proposed Budget Cuts in WIC and Head Start	The AMA opposes reductions in funding for WIC and Head Start and other programs that significantly impact child and infant health and education. (Res. 246, I-94; Reaffirmed: BOT Rep. 29, A-04)	Retain – this policy remains relevant.
H-250.987	Duty-Free Medical Equipment and Supplies Donated to Foreign Countries	Our AMA will seek, through the federal government, a process to allow for duty-free donations of medical equipment and supplies, which are intended to reach medically-underserved areas and not be used for profit, to foreign countries. (Res. 229, A-04)	Retain.
H-270.972	Protecting Raw Material Suppliers from Product Liability Litigation	The AMA supports legislation which protects raw material suppliers from product liability litigation so long as the materials they supply conform to medical device manufacturer specifications. (Res. 221, I-94; Reaffirmed: BOT Rep. 29, A-04)	Rescind – the intent of this policy has been achieved through enactment of the Biomaterials Access Assurance Act of 1998 (21 U.S.C. §§1601-1606)
H-270.992	Remedial Antitrust Legislation	Our AMA supports legislation that would require courts reviewing antitrust cases involving the sale or delivery of health services to consider whether the activities are directed, authorized or encouraged by the federal or state government, whether the activity is intended to maintain or improve the quality of health care in the public interest, and	Rescind – policy is outdated and no longer relevant.

		whether the activity is intended to control costs in the public interest. (BOT Rep. Q, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmation I-98; Reaffirmation A-00; Reaffirmation I-00; Reaffirmation A-04)	
H-365.980	OSHA Regulations Pertaining to Physicians' Offices and Hospitals	The AMA continues to review the data and rationale used to substantiate OSHA regulations pertaining to medical practice in physician offices and health care facilities. Where OSHA rules and regulations are found to be unnecessary or inappropriate, the AMA will work for their modification or repeal. (Sub. Res. 218, A-94; Reaffirmed: BOT Rep. 29, A-04)	Retain – this policy remains relevant.
H-415.998	Preferred Provider Organizations	The AMA: (1) opposes federal legislation that would preempt state regulation of PPOs; and (2) encourages state medical associations to support legislation that: (a) insures proper state regulation of PPOs, with particular attention to such practices as arbitrary determinations of medical necessity by carriers, "hold harmless" clauses, and predatory pricing concepts; and (b) requires independent, physician-directed peer review of the services provided by PPOs. (Sub. Res. 16, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmed: BOT Rep. 29, A-04)	Retain.
H-435.957	Uniform and Consistent Tort Reform	Our AMA will not pursue federal medical liability reform legislation that would divide or diminish the voice of the House of Medicine. (Sub. Res. 910, I-03; Reaffirmed in lieu of Res. 216, A-04)	Retain – this policy remains relevant.
H-435.963	Professional Liability Claims Reporting	The AMA opposes the need for reporting on medical staff and other non-licensing board applications, including insurance company credentialing applications, (excepting professional liability insurance applications) any threatened, pending, or closed professional liability claims where the claim did not result in payment on behalf of that physician. (Sub. Res. 818, A-95; Modified: BOT Rep. 18, A-03; Reaffirmed: Res. 806, I-03; Reaffirmation A-04)	Retain – this policy remains relevant.
H-435.968	Enterprise Liability	The AMA: (1) affirms its position that effective medical liability reform based on California's MICRA model is integral to health system reform, and must be included in any comprehensive health system reform proposal that hopes to be effective in containing costs, providing access to health care services and promoting the quality and safety of health care services; (2) opposes any proposal that would mandate or impose enterprise liability concepts. Federal funding to evaluate the comparative advantages and disadvantages of enterprise liability may be best spent studying the operation, effect on liability costs and patient safety/injury prevention results of liability channeling systems that already exist and function as close analogs to the enterprise liability model (BOT Rep. I-93-53); and (3) supports strong patient safety initiatives and the investigation of alternative dispute resolution models, appropriate uses of practice parameters in medical liability litigation and other reform ideas that have the potential to decrease defensive medicine costs and more fairly and cost-effectively compensate persons injured in the course of receiving health care services. (BOT Rep. III, A-93; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: BOT Rep. 28, A-03; Reaffirmation A-04)	Retain – this policy remains relevant.
H-435.991	Professional Liability Countersuits	Our AMA supports the principle that the "special injury" element required to win a malicious prosecution countersuit in some jurisdictions should be eliminated. (Res. 44, I-84; Reaffirmed: Sunset Report, I-98; Reaffirmed: Sub. Res. 914, I-04)	Retain – this policy remains relevant.
D-35.994	Scope of Practice Participants in	Our AMA Advocacy Resource Center will work at the invitation of AMA component societies to oppose legislative	Retain – this policy remains relevant.

	Health Plans	mandates on health care plans that may lead to inappropriate scope of practice expansion of non-physician providers. (Res. 923, I-04)	
D-110.994	Inappropriate Extension of Patent Life of Pharmaceuticals	Our AMA will continue to monitor the implementation of the newly-enacted reforms to the Hatch-Waxman law to see if further refinements are needed that would prevent inappropriate extension of patent life of pharmaceuticals, and work accordingly with Congress and the Administration to ensure that AMA policy concerns are addressed. (BOT Rep. 21, A-04)	Retain – this policy remains relevant.
D-120.980	Regulation of Media-Based Drug Sales Without Good Faith Medical Examination	Our AMA will develop and promote model federal legislation to eliminate the sale, without a legitimate prescription, of prescription drugs over the Internet, if such bills to establish national standards in this area are not forthcoming. (Sub. Res. 520, A-04)	Retain – this policy remains relevant.
D-125.996	Regulation of Pharmacy Benefit Manager Contracts	Our AMA, in conjunction with state medical associations, will develop legislation and/or regulatory language to: (1) increase the transparency of the business practices of pharmacy benefit managers (PBMs) with drug manufacturers, health plans, employers, and physicians to minimize conflicts of interest; and (2) to require pharmacy benefit managers to provide information to allow health plans, employers, and physicians to verify if they have met their contractual obligations. (Res. 533, A-03; Reaffirmation A-04)	Rescind – the intent of this directive has been accomplished by Board adoption of state model legislation, titled “Appropriate Use of Prior Authorization Act.”
D-435.985	Use of Countersuits to Discourage Frivolous Lawsuits	Our AMA will advise members of the option for countersuits against plaintiffs and attorneys who have filed frivolous lawsuits against physicians. (Sub. Res. 914, I-04)	Retain – this policy remains relevant.
D-510.997	Job Requirements for the Under Secretary for Health, Department of Veterans Affairs	Our AMA will strongly advocate, directly and in conjunction with Association of American Medical Colleges and other appropriate interested organizations, that Section 8 language in H.R. 4231 maintain the required search committee, the current four-year term of appointment, and the requirement that the Under Secretary of Health of the Department of Veterans Affairs be a medical doctor. (Res. 233, A-04)	Rescind – this bill is no longer relevant and has not been introduced in subsequent sessions of Congress.

## 20. UTILIZATION OF EHR AND THE PRACTICE OF “CUTTING AND PASTING” OR CLONING

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

### HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

See Policies [D-175.985](#) and [D-478.995](#).

### INTRODUCTION

At the 2013 Annual Meeting, the AMA House of Delegates amended Policy D-175.985 to call for our AMA to study the impact of EHR clinical documentation tools and shortcuts on patient safety, quality of care and safe harbor laws.

This report provides an overview of the use of “cutting and pasting” (more appropriately and hereafter referred to as “Copy and Paste”) templates or other techniques for documenting information in the electronic health record (EHR) and their impact on patient safety and quality of care. Safe harbors from the federal physician self-referral law (Stark) allow for donations of EHR products to physicians and were recently extended to 2021 in response to significant AMA advocacy. However, these safe harbor laws have no bearing on EHR clinical documentation methods and are not addressed further in this report.



## BACKGROUND

Copy and Paste, sometimes referred to as cloning, is a feature of the EHR that enables users to select information from one source and replicate it in another location.<sup>1</sup> It is intended to reduce the time required for clinical documentation.

Templates facilitate rapid capture of structured data in the EHR often through a single click of a checkbox. This can result in similar or identical documentation from one patient visit to another and has raised concerns about over documentation.

Scrutiny of Copy and Paste has arisen from physician complaints that it degrades the quality of clinical notes in the EHR, often generating overlong notes that are difficult to navigate and may adversely affect quality of care. Evidence indicates that a majority of physicians use the Copy and Paste function in the EHR. According to a September 2013 American Health Informatics Association (AHIMA) report,<sup>2</sup> three studies found that from 74 to 90 percent of physicians use this feature.

A 2006 study of 167,076 VA records found that copying of the clinical examination occurred frequently, in about 3% of all exams, or in 25% of patient charts<sup>3</sup>. The study distinguished between select text copied and pasted from other records and clinical exam copying. It suggested that clinical exam copying degrades the quality of the medical record but did not discover it caused harm to patients.

The study also found that there were, “few widely accepted standards or rules established about copying and pasting in medical records and suggested,... as this behavior becomes better understood, health care systems will need to address its relevance, and develop standards, procedures, and surveillance.” The author added that it would be an extreme response to remove the copy and paste feature and that less severe measures might include showing copied and non-copied text in different colors. The author also recommended additional clinician education related to this capability.

The use of both Copy and Paste and templates has also raised concerns about over-documentation to support higher-level E/M codes. A May 2012 OIG report<sup>4</sup> focusing on higher level E/M codes from 2001-2010 determined that higher-level E/M codes were billed over this period; it did not find that physicians billed inappropriately. Since that report, no quantitative studies have linked Copy and Paste to fraudulent billings. While intentional fraud may account for some use of inaccurate billing codes, other unintentional factors, including lack of time for accurate clinical documentation, poorly designed systems and inadequate user education are just as likely to produce errors in E/M coding.

As observed by one industry analyst, Dr. Donald Simborg, “Although it was widely acknowledged that, indeed, billings, particularly E&M code levels, had increased after hospitals and practices had switched to EHRs, there were mixed opinions as to how much of this increase represented legitimate improvements in documentation and even legitimate improvements in overall care, and how much was fraudulent. Opinions are mixed primarily because all we have are opinions, not facts, as this issue has not been studied.”<sup>5</sup>

Despite this lack of proof, in August 2012, National Government Services (a Medicare contractor) announced that, “Cloned documentation will be considered misrepresentation of the medical necessity requirement for coverage of services due to the lack of specific individual information for each unique patient. Identification of this type of documentation will lead to denial of services for lack of medical necessity and the recoupment of all overpayments made.”<sup>6</sup>

## DISCUSSION

A search of the literature does not reveal any studies specifically linking the use of templates or Copy and Paste and adverse events or poor quality care.

The literature does support that, by addressing overall EHR usability, patient safety and quality of care can improve. Zhang and Walji define usability as “how useful, usable, and satisfying a system is for the intended users to accomplish goals by performing certain sequences of tasks.”<sup>7</sup>

AMIA Board of Directors convened a task force to formulate recommendations for enhancing patient safety and quality of care by improving the usability of EHRs. After over a year of focused research by subcommittees, the task force produced 10 recommendations in four areas: (1) human factors health information technology (IT) research; (2) health IT policy; (3) industry recommendations; and (4) recommendations for the clinician end-user of EHR software. The AMIA task force concluded “some health IT may facilitate certain types of adverse events and medical errors, and that these problems may be related to usability issues.” While AMIA notes that their recommendations are not meant to address all aspects of the safe and effective use of EHRs, “they help focus attention on critical usability issues that adversely affect patient safety and the quality of care.”<sup>8</sup>

An article by Ancker, et al examines, “the safe and effective use of EHR as a property resulting from the careful integration of multiple factors in a broad sociotechnical framework.”<sup>9</sup> Rather than narrowly focusing on specific EHR functions like templates, copying, cutting and pasting, this article suggests that EHR effectiveness be examined in the context of a broader sociotechnical framework—The Triangle Evaluation Model adapted from Donabedian—with subsequent validation through additional study. The authors note that “research on the effects of health IT may oversimplify complex issues if health IT is treated as a simple categorical variable (present or absent, or before or after). Capturing more detailed predictor variables about the technology, users, and the surrounding context increases the ability to interpret findings and compare studies...”

The authors have used the Triangle Evaluation Model in the evaluation of electronic prescribing and were one of the first to demonstrate that electronic prescribing was effective at reducing prescribing error rates in community-based office practices.<sup>10</sup> Of interest in another, unpublished study examining pre-post introduction of a new EHR system, introduction of the new system resulted in an increased rate of eprescribing errors that returned to baseline at one-year. A survey of physicians suggested that they perceived the original, locally developed system to be faster and easier to use, that the clinical decision support alerts in the new system led to alert fatigue and that few users knew how to use system shortcuts.

The federal government has mandated that physicians adopt EHRs through a schedule of penalties, fee cuts and barriers to participation in certain accountable care organization. Physicians, however, spend extra time entering data into the EHR, which cuts into time with patients and can extend the length of the workday. There is little guidance available to physicians on how best to structure work after adopting an EHR to address concerns about productivity losses.<sup>11</sup> In addition, EHR use requires clinicians to adopt new workflows and new communication patterns to avoid errors that may result from overdependence on technology.

Productivity enhancing tools such as templates and the appropriate use of Copy and Paste in the EHR are important to cultivate continued physician use of electronic health records. Penalizing physicians for appropriate use of these features could be a further detriment to continued adoption of EHR technology and to participation in Medicare and Medicaid programs. Physicians should rather be educated about the appropriate use of these tools and, the approving physician must always validate the accuracy of the clinical record regardless of whether presented in paper or electronic form.

The nation faces an access to care issue because of the aging population and the increasing eligibility for Medicaid and commercial coverage under the Affordable Care Act. Opportunities exist to improve EHR usability and enable physicians to better serve patients. AMA recently commissioned RAND to study factors affecting physician satisfaction. Although the original focus of the study did not include the EHR, it quickly became clear that EHRs had a significant impact on physician satisfaction. The study authors reported that, “Electronic health records (EHRs) had important effects on physician professional satisfaction, both positive and negative. Physicians, practice leaders, and other staff noted the potential of EHRs to further improve both patient care and professional satisfaction in the future, as EHR technology—especially user interfaces and health information exchange—improves. However, for many physicians, the current state of EHR technology significantly worsened professional satisfaction in multiple ways. Poor EHR usability, time-consuming data entry, interference with face-to-face patient care, inefficient and less fulfilling work content, inability to exchange health information between EHR products, and degradation of clinical documentation were prominent sources of professional dissatisfaction.”<sup>12</sup>

As a result of the RAND report, one of the AMA’s strategic focus areas—Professional Satisfaction and Practice Sustainability—has made EHR usability a priority, has begun to engage directly with the EHR vendor community to effect change and has formed a panel of expert advisers to develop standards for EHR usability.

## CONCLUSION

“Uncertainty creeps into medical practice through every pore. Whether a physician is defining a disease, making a diagnosis, selecting a procedure, observing outcomes, assessing probabilities, assigning preferences, or putting it all together, he is walking on very slippery terrain. It is difficult for non-physicians, and for many physicians, to appreciate how complex these tasks are, how poorly we understand them, and how easy it is for honest people to come to different conclusions.”<sup>13</sup>

Our AMA must continue to take a leadership role, in collaboration with other physician associations and industry leaders, to examine physician use and experience with EHRs. AMA should support efforts that will lead to the refinement of EHRs and promote more transparency in the vendor marketplace. AMA should also continue to focus on its current advocacy around usability, workflow and patient safety through advocacy with the ONC and other avenues as appropriate.

Currently, there is no evidence that features such as Copy and Paste or the use of templates adversely affect quality of care or patient safety but there is evidence that EHR usability can affect both. In addition, EHR usability is an important factor affecting physician satisfaction. Federal incentive programs and the uptake of new care delivery and payment models, have led to a majority of physicians already using EHRs. It is important to continue educating the physician community about best practices in technology use and workflow, but also to directly engage with the EHR vendor community to promote improved usability so that cost savings and improvements in the quality of care can be achieved while promoting patient safety and physician satisfaction.

## RECOMMENDATIONS

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

1. That American Medical Association Policy D-175.985, “The CMS Electronic Medical Records Initiative Should Not Be Used to Detect Alleged Fraud by Physicians” be reaffirmed.
2. That our AMA directly engage the EHR vendor community to promote improvements in EHR usability.

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- <sup>12</sup> Friedberg, et al. (2013). Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy. Santa Monica, CA: RAND Corporation.
- <sup>13</sup> Eddy DM. Variations in physician practice: the role of uncertainty. Health Aff 1984;3:74–89.

#### APPENDIX – Current AMA Policy

##### D-175.985 The CMS Electronic Medical Records Initiative Should Not Be Used To Detect Alleged Fraud by Physicians

1. Our AMA will (A) communicate its concerns about the plan recently announced by the Centers for Medicare and Medicaid Services (CMS), in which CMS is to use data from the electronic medical record incentive program in the pursuit of fraud, waste and abuse; and (B) seek active involvement in the drafting of all program directives for CMS's electronic medical record initiative, including all directives about potential data capture and subsequent audit processes.
2. Our AMA will lead an effort in concert with the Centers for Medicare and Medicaid Services to establish specific guidance to be utilized by entities that audit documentation generated by an electronic health record.
3. Such guidance will provide specific protocols used by Medicare and Medicaid auditors to allege a service is not reasonable and necessary based on the generation of an electronic health record.
4. Our AMA will inform state and specialty societies about available AMA resources to assist physicians with audits of electronic health records and prominently feature on their website information about methods, resources, and technologies related to appeals of electronic health record audits and Medicare and Medicaid overpayment recoveries as a members-only benefit.
5. Our AMA believes that the use of timesaving features, such as cloning, templates, macros, "pull forward technology", auto-population and identical language in EMRs, by itself is not an indication of inaccurate documentation or incorrect coding.
6. Our AMA believes that audit results that imply incorrect coding must specifically indicate which portion of the chart language either does not accurately reflect the office visit or reflects unnecessary care.
7. Our AMA will: (1) develop guidelines in conjunction with the Centers for Medicare & Medicaid Services to provide clear and direct guidance to physicians concerning the permissible use for coding and billing of electronic health record (EHR) clinical documentation tools, such as templates, macros, cutting and pasting, and cloning, and (2) study the impact of EHR clinical documentation tools and shortcuts on patient safety, quality of care and safe harbor laws. (Res. 212, A-10; Appended: Res. 206, I-11; Appended: Res. 715, A-13)

## 21. UPDATE ON CORPORATE RELATIONSHIPS

*Informational report; no reference committee hearing.*

### HOUSE ACTION: FILED

#### PURPOSE

The purpose of this informational report is to update the House of Delegates (HOD) on the results of the Corporate Review process from January 1 through December 31, 2013. Corporate activities that associate the American Medical Association (AMA) name or logo with a company, non-Federation association or foundation, or include commercial support, must undergo review and recommendations by the Corporate Review Team (CRT) Policy G-630.040 (Appendix A).

#### BACKGROUND

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

#### YEAR 2013 RESULTS

In 2013, 25 new activities were considered and approved through the Corporate Review Process. Of the 25 projects recommended for approval, five were conferences or events, four were education or grant programs, eight were collaborations, one was a business arrangement, three were member service provider programs, and four were AMA Foundation programs (Appendix B).

## CONCLUSION

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

### APPENDIX A - Corporate Review Process Overview

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

The CRT evaluates each project with the following criteria:

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

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

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

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

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

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

### APPENDIX B - Summary of Corporate Review Recommendations for 2013

<b>Project No.</b>	<b>Project Description</b>	<b>Corporations</b>	<b>Approval Date</b>
CONFERENCES/EVENTS			
2201-0044	National Journal Countdown to Transformation - AMA as a "Presenting Level Underwriter" at the National Journal symposium on ACA implementation.	National Journal National Journal Daily Blue Cross Blue Shield Association	05/15/2013
2203-0409	National Health Care Innovation Summit - AMA to co-sponsor the First National Healthcare Innovation Summit.	University of California, Los Angeles New England Healthcare Institute	05/15/2013

<b>Project No.</b>	<b>Project Description</b>	<b>Corporations</b>	<b>Approval Date</b>
4401-0138	IMG Desserts from Around the World Reception - Funding for the International Medical Graduate's dessert reception.	American Association of Physicians of Indian Origin Association of Pakistani Physicians of North America Association of Philippine Physicians in America Association of Haitian Physicians Abroad Association of Kerala Medical Graduates Korean-American Medical Association of the US Indian Physicians of Illinois National Arab American Medical Association National Hispanic Medical Association Islamic Medical Association Missouri State Medical Society Michigan State Medical Society American Academy of Family Physicians American Academy of Pediatrics Illinois State Medical Society	01/07/2013
4401-0373	Medical Student Section Vendor Fair -A vendor fair featuring AMA approved business partners targeted to medical students.	Epocrates, Inc. Lippincott Williams & Wilkins McGraw-Hill Education The Merck Publishing Group PACE MD/PACE MedSpanish Lexi-Comp, Inc. Medscape Rosetta Stone 3M™ Littman® Stethoscopes Skyscape, Inc. Thieme Medical Publishers, Inc. Doximity, Inc.	12/11/2013
6602-0409	Accelerating Change in Medical Education Conference - A conference to engage medical schools and the health sector regarding reforms to the undergraduate medical education curriculum.	Purdue Pharma L.P. Lilly USA, LLC Pfizer, Inc. Genentech, Inc.	03/20/2013
<b>EDUCATION/GRANT ACTIVITIES</b>			
1101-0094	Closing the Referral Loop - The first improvement initiative of the PCPI Quality Improvement Program.	The Wright Center for Graduate Medical Education Pennsylvania Department of Health	10/18/2013
1101-0230	Rand/AMA Physician Satisfaction Research - Co-branded physician satisfaction research report with Rand Corporation.	RAND Corporation	08/12/2013
2201-0340	RX/WTTW Film Sponsorship - AMA sponsorship of a film regarding physicians creating higher-value health care solutions.	David Grubin Productions, Inc. WTTW Chicago North Shore - LIJ Health System	06/27/2013
6602-0408	Physicians of Tomorrow - Chicago-Area scholarships - Arthur Foundation funding to support scholarships for Chicago-area medical students.	The Arthur Foundation	01/09/2013
<b>COLLABORATIONS/ AFFILIATIONS</b>			
1104-0487	AMA participation in Y-USA/CMS Diabetes Prevention Program - AMA participation in a pilot test for the Y diabetes prevention program for Medicare eligible patients.	American Hospital Association YMCA Centers for Medicare & Medicaid Services American Academy of Family Physicians American Diabetes Association National Council of La Raza National Council on Aging American Heart Association The National Association of City and County Health Officers	04/19/2013

<b>Project No.</b>	<b>Project Description</b>	<b>Corporations</b>	<b>Approval Date</b>
1104-0488	Diabetes Prevention and Control Alliance (DPCA) - AMA affiliation for patient education and enrollment in Y-USA diabetes prevention sites.	Diabetes Prevention and Control Alliance YMCA	06/14/2013
2201-0043	Healthway Relationship - AMA participation and name and logo association in a policy group on health information exchanges.	Healthway, Inc.	02/07/2013
2202-0100	Diabetes Advocacy Alliance - AMA participation in the Diabetes Advocacy Alliance.	Novo Nordisk, Inc. Diabetes Advocacy Alliance	11/19/2013
2203-0049	CAQH EFT Enrollment Tool - AMA support and association of CAQH regarding their enrollment tool.	CAQH	06/14/2013
2204-0048	AMA-HIMSS Podcasts - AMA collaboration with HIMSS on health information exchange-related topics.	Health Information and Management Systems Society (HIMSS)	03/11/2013
2207-0323	Alliance for the Proper Use of Medicines - AMA participation in and logo association with an alliance of organizations to explore solutions for inappropriate use of medications.	Teva Pharmaceutical Industries Ltd. CVS Pharmacy Cardinal Health	07/16/2013
3301-0415	AMA/MGMA Clinical Practice Improvements - A co-branded relationship with MGMA for clinical operations practice improvement models.	Medical Group Management Association	12/11/2013
<b>MEMBER SERVICE PROVIDER PROGRAMS</b>			
5505-0037	UPS AMA Member Value Program - New preferred providers for the AMA Member Value Program.	United Parcel Service (UPS) Meridian One Corporation	08/12/2013
5505-0038	Volvo AMA Member Value Program - A new preferred provider for the AMA member Value Program.	Volvo	08/12/2013
5505-0092	AMAIA Personal Umbrella Insurance Policy - New personal umbrella policy (PUP) with United States Liability Insurance Group.	United States Liability Insurance Group.	08/26/2013
<b>BUSINESS ARRANGEMENTS</b>			
5504-0448	New Doctor Finder - An improved Doctor Finder web site helps patients find physicians.	IMS Health Incorporated	08/15/2013
<b>AMA FOUNDATION PROGRAMS</b>			
6602-0036	AMAF Excellence in Medicine Awards – Continuation of Pfizer funding to support the AMA Foundation Excellence in Medicine Awards.	Pfizer, Inc.	01/07/2013
6602-0037	AMAF Minority Scholars Fund – Continuation of Pfizer funding to support the Foundation Minority Scholars Fund.	Pfizer, Inc.	01/07/2013
6602-0401	AMAF Healthy Communities/Healthy America – Continuation of funding for grants to free clinics implementing diabetes management and education projects.	Lilly USA, LLC	01/07/2013
6602-0404	AMAF Foundation Healthy Living Grant Program - Funding for the Healthy Living grant program for community non-profits.	Purdue Pharma L.P. Teva Pharmaceutical Industries Ltd.	05/14/2013

## 22. RESTRICTING PRESCRIPTIONS TO MEDICARE BENEFICIARIES (RESOLUTIONS 212-A-13 AND 230-A-13)

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

### HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTIONS 212-A-13 AND 230-A-13 AND REMAINDER OF REPORT FILED

*See Policy [H-95.941](#).*

#### INTRODUCTION

At the American Medical Association (AMA) 2013 Annual Meeting, two resolutions were introduced regarding Medicare and Medicaid enrollment requirements for ordering and referring providers. Resolution 212-A-13, “Restricting Prescriptions to Medicare Beneficiaries”, introduced by the New York Delegation, called for the following:

That our AMA support federal legislation to repeal provisions in Patient Protection and Affordable Care Act that require physicians to enroll in Medicare, Medicaid and other governmentally sponsored health insurance programs as a condition of referring, ordering or prescribing for patients enrolled in these programs.

In addition, Resolution 230-A-13, “Rights of Medicare Beneficiaries to Receive Covered Services”, introduced by the Louisiana Delegation, called for the following:

That our AMA recognize the legitimacy of a contractual right of a Medicare Part B beneficiary to receive the benefits of coverage for any item or service that is covered by Medicare Part B and provided by an enrolled provider or supplier, regardless of whether the ordering or certifying physician or eligible professional is enrolled in the Medicare program; and be it further

That our AMA challenge by appropriate legal means the Affordable Care Act, Section 6405, requirement that physicians and eligible professionals must enroll in Medicare to order and certify certain Medicare covered items and services including home health, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), imaging, and clinical laboratory, and will also seek repeal of these provisions.

Testimony on these resolutions highlighted confusion regarding the complexity of the Medicare and Medicaid enrollment requirements for ordering and referring physicians. To better educate physicians on this issue, the House of Delegates referred Resolutions 212 and 230.

#### BACKGROUND

##### *Medicare Enrollment of Ordering and Referring Physicians*

In 2009, Medicare began sending informational messages to laboratories, imaging centers, DMEPOS suppliers and home health agencies when they submitted claims that listed ordering or referring physicians who did not have a Medicare enrollment record in the Medicare Internet-based Provider Enrollment, Chain, and Ownership System (PECOS). The Centers for Medicare & Medicaid Services (CMS) based the policy on a statutory requirement that claims include National Provider Identifier (NPI) information.<sup>1</sup> CMS’ rationale was that the agency needed information regarding the ordering or referring provider to ensure that payments for such orders and referrals were not fraudulent or abusive. The informational messages caused concern in the medical community about nonpayment, fueled in part by significant operational problems in the Internet-based PECOS system. At the time, our AMA strongly objected to this policy and was effective in getting CMS to pull the policy back and not to condition payment on the PECOS enrollment of the ordering or referring provider.<sup>2</sup>

In 2010, Congress enacted section 6405 of the Affordable Care Act (ACA), which requires that providers who order or refer for durable medical equipment (DME) and home health care services enroll in Medicare and also permits the Secretary of the Department of Health and Human Services (HHS) to extend this requirement to other services.



Like CMS in 2009, Congress viewed this statute as necessary to protect the Medicare trust funds from fraudulent or abusive activities and enacted section 6405 under its program integrity provisions.

Soon thereafter, CMS promulgated an interim final rule to implement section 6405 which required physicians who order or certify certain clinical laboratory, imaging, durable medical equipment, prosthetics and orthotics, or home health services to enroll in Medicare via PECOS.<sup>3</sup> The final rule had many problems that our AMA strongly opposed through numerous communications with CMS and a formal letter signed by our AMA and forty national medical specialty societies.<sup>4</sup>

Following this advocacy, CMS published a subsequent final rule on April 27, 2012, that adopted many AMA suggestions and improved the original regulation by: (1) allowing physicians with legacy enrollment records, in addition to PECOS records, to satisfy the requirement; (2) excluding physician referrals from the final rule; (3) allowing medical residents who have provisional licenses, or are otherwise permitted by state law, to enroll; and (4) committing to notice prior to the initiation of claims edits to effectuate the rule.<sup>5</sup> Importantly, following AMA concerns about mandatory participation in Medicare, CMS also clarified that physicians who have a valid opt-out affidavit on file are not required to enroll.

Our AMA worked very closely with CMS and the Medical Group Management Association (MGMA) after the publication of the final rule to identify operational issues and concerns in regard to the requirement, leading the agency to a judicious approach and a delay on full implementation of the requirement until January 6, 2014.<sup>6</sup> A positive result of this advocacy has been the establishment of a streamlined enrollment process for physicians who order or refer. Soon thereafter, CMS proposed that the enrollment requirements be extended to prescribers of Part D drugs, a proposal which our AMA strongly opposes and is continuing to vigorously push back against. For example, on March 7, 2014, the AMA submitted formal comments to CMS outlining serious concerns about patient access to prescription drugs under the proposed policy.<sup>7</sup> Therein the AMA stressed that operational problems concerning prescriber enrollment are likely to result in denied patient access to care.

#### *Medicaid Enrollment of Ordering and Referring Physicians*

The ACA also included Medicaid enrollment requirements for ordering and referring physicians.<sup>8</sup> CMS promulgated these requirements in February 2011, applying the Medicaid enrollment requirements to prescribing of Medicaid-covered drugs or other items, referrals to laboratories, and referrals to other providers or facilities.<sup>9</sup> CMS clarified that the enrollment requirement does not apply to referrals for patients in a risk-based managed care plan. CMS also subsequently released guidance to states which allowed states to establish streamlined enrollment processes for ordering and referring providers, similar to the aforementioned Medicare process.<sup>10</sup>

Since the enactment of the Medicaid ordering and referring enrollment requirement, our AMA has engaged heavily with state medical societies to ensure that they have robust resources to shape the enrollment requirement implementation in their state. Our AMA has prepared a model bill for state medical societies to ensure that physicians are not unduly burdened by the requirement, and has conducted extensive outreach to offer AMA support in those states implementing the requirement.<sup>11</sup>

## DISCUSSION

Program integrity oversight of the Medicare and Medicaid programs continues to be a hot topic on Capitol Hill, and there is ongoing bipartisan agreement that Congress needs to do more to protect the Medicare and Medicaid trust funds from fraudulent or abusive practices.

In general, there is little appetite in Congress for repealing or eliminating existing fraud and abuse laws and regulations, particularly those recently enacted in the ACA. In fact, many congressional members have publicly questioned and requested information from CMS officials regarding the status of not-yet-implemented fraud and abuse provisions of the ACA for the specific purpose of ensuring that the provisions be fully implemented in short order.<sup>12</sup> Another disincentive for repeal of fraud and abuse provisions is that they may require legislative offsets. There is also concern that if a legislative repeal of the Medicare and Medicaid ordering and referring requirements is pursued in Congress and is not well received, there may be increased pressure on the Administration to implement the requirements more aggressively.

Engagement with the Administration on these matters has therefore been viewed as the more fruitful course, and has been strongly pursued by our AMA. In response to robust AMA advocacy, the Administration has implemented many fraud and abuse programs, particularly those enacted as part of the ACA, with an eye toward decreased regulatory burden on physicians, and has targeted enforcement toward higher-risk providers instead of physicians. With this in mind, as described throughout this report, our AMA has worked closely with CMS to ensure that the Medicare and Medicaid enrollment requirements for ordering and referring physicians are implemented judiciously and are not unduly burdensome and has been successful in this regard.

Because our AMA has observed a keen interest in strict program integrity measures on Capitol Hill, and has been alternatively successful with the Administration in tailoring these programs so as to minimize physician burden, continued engagement with the Administration and state medical societies is the best avenue for success in reducing the impact of the ordering and referring enrollment requirements on physicians. This strategy will remain vitally important as our AMA continues its strong advocacy with the Administration to oppose Medicare enrollment for prescribers of Part D drugs, a matter which has already been decided by Congress per section 6405, but which is still pending at CMS.

## RECOMMENDATION

The Board of Trustees recommends that the following recommendation be adopted in lieu of Resolutions 212-A-13 and 230-A-13 and the remainder of the report filed:

1. That our American Medical Association work with the Centers for Medicare & Medicaid Services and state medical societies as needed to preserve access to care and eliminate the burden of provisions in the Patient Protection and Affordable Care Act that require physicians to enroll in Medicare, Medicaid and other governmentally sponsored health insurance programs as a condition of referring, ordering or prescribing for patients enrolled in these programs.
2. That our AMA support federal legislation to eliminate the burden of provisions in the Patient Protection and Affordable Care Act that require physicians to enroll in Medicare, Medicaid and other governmentally sponsored health insurance programs as a condition of referring, ordering or prescribing for patients enrolled in these programs.

## REFERENCES

- <sup>1</sup> CMS initially based this policy on Section 1833(q) of the Social Security Act. The AMA objected at the time, stating that the ordering and referring enrollment proposal was outside the bounds of authority granted to CMS in Section 1833(q).
- <sup>2</sup> Letter to Charlene Frizzera, Acting Administrator, CMS, from the AMA, the American Optometric Association, and fifty four other organizations. November 16, 2009. Available at: <http://www.ama-assn.org/resources/doc/washington/administration-pecos-sign-on-letter.pdf>
- <sup>3</sup> 75 FR 24437.
- <sup>4</sup> Letter to Marilyn Tavenner, Acting Administrator, CMS, from the AMA and forty medical specialty societies. May 28, 2010. Available at: <http://www.ama-assn.org/resources/doc/washington/medicare-ifr-sign-on-28may2010.pdf>
- <sup>5</sup> 77 FR 25283.
- <sup>6</sup> AMA, MGMA, and CMS worked together to develop a fact sheet for physicians in regard to the ordering and referring enrollment requirements. Through the court of this work, numerous operational issues and concerns were identified and resolved. The fact sheet is available at: <http://www.ama-assn.org/resources/doc/washington/medicare-enrollment-important-dates.pdf>
- <sup>7</sup> Letter to Marilyn Tavenner, Administrator, CMS, from James L. Madara. March 7, 2014. Available at: <http://www.ama-assn.org/resources/doc/washington/medicare-part-d-letter-07march2014.pdf>
- <sup>8</sup> Section 6401 of the Affordable Care Act.
- <sup>9</sup> 76 FR 5862.
- <sup>10</sup> Center for Medicaid and CHIP Services. *Informational Bulletin on Medicaid / CHIP Provider Screening and Enrollment*. December 23, 2011. Available at: <http://www.medicare.gov/Federal-Policy-Guidance/downloads/CIB-12-23-11.pdf>
- <sup>11</sup> AMA. *An Act to streamline the Medicaid enrollment process for ordering and referring physicians or other professionals*. Available at: <http://www.ama-assn.org/resources/doc/arc/medicaid-streamlined-enrollment-model-bill.pdf>
- <sup>12</sup> For example, on March 28, 2013, members of the U.S. Senate Finance Committee sent a letter to HHS Secretary Kathleen Sebelius urging the implementation of Section 6401(a)(6) of the ACA regarding the imposition of a temporary moratorium on the enrollment of new providers and suppliers. Available at: <http://www.finance.senate.gov/newsroom/ranking/release/?id=bff00d29-2753-458b-bae5-41ab581bb786>.

**23. NON-PHYSICIAN PRACTITIONERS CERTIFYING MEDICARE PATIENTS' NEED  
FOR THERAPEUTIC SHOES AND INSERTS  
(RESOLUTION 213-I-12)**

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED  
IN LIEU OF RESOLUTION 213-I-12 AND  
REMAINDER OF REPORT FILED**  
*See Policy [H-160.905](#).*

#### INTRODUCTION

At the 2013 Interim Meeting, the House of Delegates referred Board of Trustees Report 2-I-12. This report responded to Resolution 213-I-12, sponsored by the Idaho Delegation which asked:

That our American Medical Association (AMA) support authorization of physician assistants and nurse practitioners under the supervision of an MD or DO to certify Medicare beneficiaries' need for therapeutic shoes and/or inserts;

That our AMA advocate for the authorization of physician assistants and nurse practitioners under the supervision of an MD or DO to certify Medicare beneficiaries' need for therapeutic shoes and/or inserts to the Centers for Medicare and Medicaid Services and, if federal law must be amended, advocate to Congress.

In response to reference committee testimony at the 2012 Interim Meeting, Board of Trustees Report 2 proposed definitions of such terms as "physician-led" in the context of team-based health care; however this report was referred for further refinement. As Council on Medical Service Report 6-A-14 addresses the definition of "physician-led," this report will address only the issues presented in Resolution 213-I-12.

#### THERAPEUTIC SHOES AND INSERTS

Recognizing the importance of foot care in the treatment of diabetes, the Centers for Medicare and Medicaid Services (CMS) has authorized coverage of therapeutic shoes and inserts for individuals with diabetes since 1993. Medicare Part B covers therapeutic shoes and inserts and a fitting each calendar year<sup>1</sup> for individuals with diabetes or diabetic foot disease.<sup>2</sup> Claims for therapeutic shoes for diabetics are processed by the Durable Medical Equipment Regional (DME) Carriers (DMERCs), though CMS does not consider therapeutic shoes for diabetics DME or orthotics, but a separate category of coverage under Medicare Part B.<sup>3</sup>

Pursuant to the Medicare Benefit Policy Manual, the need for diabetic shoes must be certified by a physician who is a doctor of medicine or a doctor of osteopathy and who is responsible for diagnosing and treating the patient's diabetic systemic condition through a comprehensive plan of care.<sup>4</sup> Annually, this managing physician must:

- Document in the patient's medical record that the patient has diabetes;
- Certify that the patient is being treated under a comprehensive plan of care for diabetes, and that the patient needs diabetic shoes; and
- Document in the patient's record that the patient has one or more of the following conditions:
  - Peripheral neuropathy with evidence of callus formation;
  - History of pre-ulcerative calluses;
  - History of previous ulceration;
  - Foot deformity;
  - Previous amputation of the foot or part of the foot; or
  - Poor circulation.<sup>5</sup>

Therapeutic shoes or inserts cannot be certified by a podiatrist, physician assistant (PA), nurse practitioner (NP) or clinical nurse specialist. However, once the physician has certified the need for the shoes and inserts, these professionals are permitted to sign the order for the shoes and inserts.

Following physician certification, a podiatrist or other qualified physician must prescribe the shoes.<sup>6</sup> The footwear must then be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, an orthotist or a prosthetist.<sup>7</sup> The certifying physician may not furnish the diabetic shoes unless the certifying physician is the only qualified individual in the area.<sup>8</sup>

Therapeutic shoes and inserts can help to prevent complications related to diabetic peripheral neuropathy and vascular disease. The restriction on non-physician certification of therapeutic shoes and inserts places an unnecessary burden on physicians and may cause a delay in care for treatment or require extra foot care visits for the patient.

## DISCUSSION

The issue presented—whether it is appropriate for NPs and PAs to certify Medicare beneficiaries' need for therapeutic shoes and/or inserts under certain practice settings—allows for consideration of such terms as “physician-led,” “supervision” and “collaboration.”

As has been mentioned, Council on Medical Service Report 6-A-14 addresses the definition of “physician-led.” Federal law<sup>9</sup> uses three levels of “supervision” to designate professional services provided by non-physician personnel:

1. General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
2. Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.
3. Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

The word “collaboration” is considerably more difficult to define, being largely dependent on context. While Merriam-Webster defines collaborate as “work[ing] jointly with others or together especially in an intellectual endeavor,” in the context of state scope of practice laws the word “collaborative” often denotes a physician-led model of care. Yet some argue that collaborative practice is a step down the path to independent practice—particularly in the state legislative and regulatory arenas.

With the above context in mind, your Board of Trustees believes that a physician-led model of care is the most appropriate framework through which to consider the issue of whether a NP or PA should be allowed to certify Medicare patients' need for therapeutic shoes and inserts.

Allowing NPs and PAs who practice in physician-led health care teams to certify Medicare patients' need for therapeutic shoes and inserts is consistent with AMA policy on physician-led, interprofessional health care teams<sup>10</sup> and provides physicians with an option to potentially ease patient access and decrease administrative burden. Therefore, your Board of Trustees recommends that our AMA support authorization of PAs and NPs who practice in physician-led teams to certify Medicare beneficiaries' need for therapeutic shoes and/or inserts.

## RECOMMENDATIONS

The Board of Trustees recommends that the following recommendation be adopted in lieu of Resolution 213-I-12 and that the remainder of the report be filed.

Our American Medical Association supports authorization of physician assistants, and nurse practitioners who practice in physician-led teams to certify Medicare beneficiaries' need for therapeutic shoes and/or inserts.

## REFERENCES

<sup>1</sup> For each individual, coverage of the footwear and inserts is limited to one of the following within one calendar year: No more than one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts;

or No more than one pair of depth shoes and three pairs of inserts (not including the non-customized removable inserts provided with such shoes). Medicare Covered Benefit Policy Manual. Chapter 15.Revised 01-14-14.  
 2 Centers for Medicare and Medicaid Services (CMS). Medicare Covered Benefit Policy Manual, Section 15, Chapter 40. Revised 01-14-14.  
 3 See Social Security Act (SSA) §1861(s)(12) and §1833(o).  
 4 Centers for Medicare and Medicaid Services (CMS). Medicare Covered Benefit Policy Manual, Section 15, Chapter 40. Revised 01-14-14. See also SSA §1861(s)(12) and §1833(o).  
 5 *Id.*  
 6 *Id.*  
 7 *Id.*  
 8 It is left to the discretion of each carrier to determine the meaning of “in the area.”  
 9 42 CFR 410.32(b)(3). CMS uses these three levels of “supervision” to designate professional services provided by non-physician or “auxiliary” personnel under physician supervision. The Code of Federal Regulations similarly uses these three levels of “supervision” for inpatient and outpatient diagnostic services.  
 10 AMA Policy H-160.912, The Structure and Function of Interprofessional Health Care Teams.

## 24. 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 goes on to call for our AMA to “immediately direct sufficient funds toward a multi-pronged campaign to accomplish these goals” and 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.

### PAY-FOR-PERFORMANCE

Work has continued with congressional committees of jurisdiction to address the shortcomings of the pay-for-performance policies contained in proposed legislation, the “SGR Repeal and Medicare Provider Payment Modernization Act of 2014” (H.R. 4015 and S. 2000). In December, both the Senate Committee on Finance and the House Committee on Ways and Means reported legislation to repeal the Sustainable Growth Rate (SGR) and replace it with payment policies that are designed to encourage higher value care. The House Committee on Energy and Commerce had previously reported similar legislation. Following the adoption of legislation by each committee, our AMA and many other state and national specialty medical societies continued our strong advocacy as the committees worked to meld their three visions into one coherent policy. At each stage of this process, improvements were made in the legislation that brought it more in line with AMA policies on pay-for-performance (H-450.947 and H-450-944). Specifically:

- Under current law, the Physician Quality Reporting System (PQRS) will provide only penalties and no bonuses beginning in 2017. Early versions of the current legislation retained this structure. As introduced, H.R. 4015 and S. 2000 would have sunset PQRS penalties in 2018.
- Under current law, EHR Meaningful Use penalties are scheduled to be 3 percent in 2017, 4 percent in 2018, and 5 percent in 2019 and subsequent years. Under the proposed legislation, these penalties would have sunset in 2018.
- Under current law, Value Based Modifier (VBM) penalties/bonuses begin for all physicians in 2017 with the potential for cuts of at least 2 percent. The proposed legislation would have sunset the penalties in 2018 and allowed the Secretary to apply VBM to physicians “as appropriate.”
- These current penalty programs would have been replaced by the Merit-based Incentive Payment System (MIPS) beginning in 2018. At no point would potential penalties under MIPS have been greater than under current law and in the earlier years, they would have been less. Unlike current law, bonus payments would have been available for high performing physicians, beginning with potential bonuses of 4 percent in 2018 and phasing up to 9 percent in 2021 and beyond.

- The final bill also eliminated the proposed “tournament model” where only physicians in the top tiers relative to their peers would have received bonus payments. Physicians would have known in advance what targets must be met in order to earn bonus payments.
- Physicians who chose to participate in alternative payment models would have received bonus payments of 5 percent for successful participation in models which include two-sided risk or medical homes.
- \$40 million would have been available annually from 2015-2019 for technical assistance to small practices.
- Measure development included a significant role for physician organizations and \$75 million would have been available for these activities.
- Additionally, the Secretary was granted significant flexibility to address the needs of individual practices or specialties where appropriate measures may not be available.

Each of these developments moved the proposed legislation in the direction of AMA policy. AMA will continue to work with legislators and regulators to further improve upon these policies as the opportunities arise.

#### REPEAL AND APPROPRIATE REPLACEMENT OF THE SGR

As discussed above, the “SGR Repeal and Medicare Provider Payment Modernization Act of 2014” (H.R. 4015/S. 2000) was introduced in both the House and the Senate with bipartisan and bicameral support of the leadership of the three committees of jurisdiction and the GOP Doctors Caucus. Following the coordinated activities of our AMA and state and national medical specialty associations during the National Advocacy Conference, H.R. 4015 secured 118 cosponsors. In addition to the opportunities for significant bonus payments, the legislation provided for 5 years of 0.5 percent payment updates with additional updates available in the years outside of the budget window. The estimated cost of this legislation was in excess of \$130 billion.

House action on the legislation took place on March 14, 2014. In a disappointing development, the House Leadership chose to offset the cost of the bill by delaying the individual mandate portion of the Affordable Care Act, contrary to AMA policy. The Congressional Budget Office estimated that this action would result in 13 million fewer people having health insurance and produce premium increases of 10 percent to 20 percent for those that do obtain coverage. Our AMA had coordinated a letter of support for H.R. 4015 that garnered the signatures of more than 600 state medical associations and national medical specialty societies and their state affiliates. However, given the budget offset included by the House Rules Committee, our AMA sent a strongly worded letter to the House calling for all parties to return to the bargaining table to identify solutions to the pay-for issue that would pass both the House and the Senate. Ultimately, the House passed the bill by a vote of 238-181. The Senate declined to take up the measure.

On March 11, 2014, Sen. Ron Wyden (D-OR) the new chairman of the Senate Finance Committee introduced the “Medicare SGR Repeal and Beneficiary Access Improvement Act” (S. 2110). The bill text consisted of the bipartisan and bicameral policies included in H.R. 4015/S. 2000 plus the language of the so-called extender provisions and other matters that had previously been reported by the Senate Finance Committee. This proposal did not include an offset for the \$180 billion cost. The next day, Sen. Orrin Hatch (R-UT), the ranking member of the committee, introduced the “Responsible Medicare SGR Repeal and Beneficiary Access Improvement Act” (S. 2122), consisting of the text of S. 2110 and including repeal of the ACA individual mandate as a budget offset. Senator Wyden spent the next two weeks working to build support for his bill.

Sensing that no agreement was at hand, Senate Majority Leader Harry Reid (D-NV) and House Speaker John Boehner (R-OH) quietly negotiated a temporary SGR patch bill that also included numerous extenders and other policies. Their agreement included a one year extension of Medicare physician payments at current rates. The bill, the “Protecting Access to Medicare Act” (H.R. 4302) was introduced on March 26. It was brought to the floor on March 27 under suspension of the rules. This procedure is intended to limit debate on noncontroversial measures and requires a two-thirds majority to pass. During the course of floor action on the 27th, it became clear that the House lacked the votes to pass the bill due to the vocal opposition of organized medicine. Following a recess however, with only a few members on the floor, the House was quickly brought into session and the bill brought up and passed by voice vote. Most members were unaware that the bill had even been passed. The controversial decision to “quick vote” this bill reportedly had the approval of the respective leaders of both parties. Furthermore, members of the House were able to avoid going on the record as standing for or against organized medicine.

On Monday, March 31, H.R. 4302 was brought to the Senate floor under an agreement between the leaders that would require 60 votes for both waiving budget points of order against the bill and for passage. During the debate, Senator Ron Wyden twice asked for unanimous consent to instead take up a new SGR repeal bill, S. 2157, the “Commonsense Medicare SGR Repeal and Beneficiary Access Improvement Act” (S. 2157) which he had introduced the previous week. That motion was twice objected to, first by Senator Jeff Sessions (R-AL) and then by Senator Orrin Hatch (R-UT). Both Senators in turn asked consent to bring up the Hatch bill (S. 2122) with Senator Wyden raising objections to both requests. At the end of the day, the Senate waived the budget act and adopted H.R. 4302 by a vote of 64-35, clearing it for the White House.

Our AMA is disappointed that Congress turned its back on a SGR repeal policy that enjoys bipartisan and bicameral support. On a positive note, the patch legislation does provide for an additional year delay in the implementation of ICD-10, consistent with AMA policy. However the impact of the instability sowed by the SGR outweighs any positive provision of the bill. We will continue to pursue options for moving this policy forward over the coming months consistent with AMA policies H-390.855, H-390.844, H-390.852 and D-390.953 in the hope that the lame duck session of Congress will provide an opportunity to adopt good policy outside of the bright lights of electoral politics.

#### REPEAL AND REPLACE THE INDEPENDENT PAYMENT ADVISORY BOARD (IPAB)

At this time, no individuals have been nominated to serve on the IPAB, and Congress has continued to deny funding necessary for the Board’s operation. Due to continued slow growth in Medicare spending, conditions that would require recommendations from the IPAB have not been met.

Our AMA continues to support adoption of legislation introduced by Senator John Cornyn (R-TX) and Representative Phil Roe, MD (R-TN), the “Protecting Seniors Access to Medicare Act” (H.R. 351 and S. 351). This legislation is consistent with AMA policy H-165.833. The House version of the bill currently has 221 cosponsors, more than enough for passage. The Senate version currently has 36 cosponsors, short of the necessary 60 to ensure passage. Our AMA continues to advocate for support and adoption of these bills and remains hopeful that action will be taken by the end of the current Congress. While opposition in the Senate remains strong, the author of the IPAB provisions has announced that he will not be seeking reelection, possibly improving the outlook for repeal for the 114<sup>th</sup> Congress.

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

These items have strong support in AMA policy and lie at the heart of consumer-directed care.

##### *Medical Savings Accounts*

Most Medical Savings Accounts (MSAs) and Health Savings Accounts (HSAs), when paired with High Deductible Health Plans (HDHPs), qualify as creditable coverage under the ACA (Policy H-165.852). Additionally, as outlined below, the AMA is working to repeal restrictions on the use of MSA distributions for over the counter medications.

##### *Flexible Spending Accounts*

Our AMA continues to work with the Health Choices Coalition in support of legislation to repeal ACA provisions that bar the use of Flexible Spending Account (FSA) funds and MSA funds for over-the-counter medications without a prescription. Several bills, including the “Restoring Access to Medication Act” (H.R. 2835 and S. 1647), by Representative Lynn Jenkins (R-KS) and Senator Pat Roberts (R-KS), have been introduced to provide relief from these provisions. Though the bill was reported from the Committee on Ways and Means in the 112<sup>th</sup> Congress, there has been no action in the current Congress. Reluctance to move legislation that would produce meaningful improvements in the ACA continues to be a challenge. Our AMA continues to advocate on this issue.

##### *Medicare Patient Empowerment Act*

The “Medicare Patient Empowerment Act” (H.R. 1310 and S. 236), by Representative Tom Price, MD (R-GA) and Senator Lisa Murkowski (R-AK) has been reintroduced in the 113<sup>th</sup> Congress, consistent with Policy D-390.960,

though no action has been taken. During the development of the “SGR Repeal and Medicare Provider Payment Modernization Act,” the issue was discussed at some length. Though not ultimately included, some form of private contracting might be possible as an Alternative Payment Model under the bill if approved by a future Secretary of the Department of Health and Human Services. Additionally, the bipartisan SGR bill (H.R. 4015/S. 2000) would have repealed the current requirement that physicians who have opted out of Medicare reaffirm their decision every two years.

## STEPS TO LOWER HEALTH CARE COSTS

This item relates to several objectives discussed below.

### *Steps That Will Likely Produce Reduced Health Care Costs*

One of the primary focuses of our AMA’s Improving Health Outcomes strategic issue area is increasing the number of sites offering the Diabetes Prevention Program. This program, piloted by the Centers for Disease Control and Prevention, focuses on behavior modification for those diagnosed with pre-diabetes (Policy H-440.844). Our AMA, working in coordination with the American Diabetes Association and the YMCA of the USA, has worked to build support for the Medicare Diabetes Prevention Act (S. 452 and H.R. 962), introduced by Senator Al Franken (D-MN) and Representative Susan Davis (D-CA). These bills would provide for Medicare coverage for the Diabetes Prevention Program. In a study by the firm Avalere, ten-year savings to the Medicare program were calculated at a very conservative \$1.3 billion. It is hoped that this legislation will be similarly scored by the Congressional Budget Office and can be advanced to enactment this year.

### *Lower Health Insurance Premiums*

Our AMA continues to seek opportunities in both the legislative and regulatory arenas to promote policies, such as the medical loss ratio, that will result in lower health insurance premiums.

### *Provide for the Sustainable Expansion of Health Care Coverage*

As discussed in the previous report, our AMA was successful in including five of seven essential elements of health care reform outlined in Policy H-165.838 in the ACA. These were: 1) Health insurance coverage for all Americans; 2) Insurance market reforms that expand choice of affordable coverage and eliminate denials for pre-existing conditions or due to arbitrary caps; 3) Assurance that health care decisions will remain in the hands of patients and their physicians, not insurance companies or government officials; 4) Investments and incentives for quality improvement and prevention and wellness initiatives; and 5) Streamline and standardize insurance claims processing requirements to eliminate unnecessary costs and administrative burdens. Not included in the final agreement were: 1) Repeal of the Medicare physician payment formula that triggers steep cuts and threaten seniors’ access to care; and 2) implementation of medical liability reforms to reduce the cost of defensive medicine. Our AMA continues to oppose Congressional efforts that would undermine the sustainability of the ACA.

### *Protect Medicare for Future Generations*

Our AMA continues to work to identify opportunities to implement numerous policies to strengthen Medicare, including Policies D-330.924, H-330.896 and H-330.889. Our AMA remains engaged with the committees of jurisdiction as they explore potential efforts to tackle entitlement reform in the 114<sup>th</sup> Congress.

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

Our AMA remains opposed to Section 2706(a) and continues to seek opportunities for its repeal. The “Protect Patient Access to Quality Health Professionals Act” (H.R. 2817) has been introduced by Representative Andy Harris, MD (R-MD) with the support of our AMA and several other medical societies (Policies H-35.968 and H-165.833). To date, the bill does not have any cosponsors.

On April 29, 2013, the Departments of HHS, Labor and Treasury released a Frequently Asked Questions (FAQ) document regarding Section 2706(a) that emphasized that the provision “does not require plans or issuers to accept all types of providers into a network” nor does it “govern provider reimbursement rates, which may be subject to



quality, performance, or market standards and considerations.” This interpretation did not sit well with the provision’s author who included instructions in the Labor-HHS-Education Appropriations Subcommittee report for Fiscal Year 2014 that the FAQ be rewritten so that it complies with congressional intent. While the Departments did not issue changes in the timeframe instructed by the Subcommittee, the Departments did release on March 7, 2014, a Request for Information (RFI) that signals their intent to reconsider their interpretation of this section of law. Our AMA will be reviewing the RFI and pressing the Administration to continue their conservative views on the construction of this provision. AMA will also look to reenergize efforts to build support for H.R. 2817 in the coming months.

#### MULTI-PRONGED CAMPAIGN TO ACCOMPLISH THESE GOALS

Each of the items raised in Policy D-165.938 remains central to ongoing efforts to improve the health care system for patients and physicians. Efforts to address these issues are currently underway as discussed above and in ongoing work through our AMA core areas of strategic focus and are covered by existing funding.

#### ADDITIONAL AMA EFFORTS

As an additional point of information, our AMA is working with the Centers for Medicare and Medicaid Services (CMS) to address problems that may arise with plans offered on the health care exchanges. The AMA has established an email address, [ExchangePlans@AMA-ASSN.ORG](mailto:ExchangePlans@AMA-ASSN.ORG), to receive reports from state and national medical societies about systemic problems that arise as physicians begin to provide care to those covered by exchange plans. As issues are identified, AMA will advocate with CMS to resolve the problems as quickly as possible. Though reports of problems have been limited, our AMA stands ready to assist.

#### CONCLUSION

The issues reviewed in this report are central to our AMA’s ongoing mission. This report will be updated for future AMA HOD meetings as directed by Policy D-165.938.

#### APPENDIX

##### D-165.938 Redefining AMA’s Position on ACA and Healthcare Reform

1. Our AMA will develop a policy statement clearly stating this organization’s policies on the following aspects of the Affordable Care Act (ACA) and healthcare reform: A. Opposition to all P4P or VBP that fail to comply with the AMA’s Principles and Guidelines; B. Repeal and appropriate replacement of the SGR; C. Repeal and replace the Independent Payment Advisory Board (IPAB) with a payment mechanism that complies with AMA principles and guidelines; D. Support for Medical Savings Accounts, Flexible Spending Accounts, and the Medicare Patient Empowerment Act (“private contracting”); E. Support steps that will likely produce reduced health care costs, lower health insurance premiums, provide for a sustainable expansion of healthcare coverage, and protect Medicare for future generations; F. Repeal the non-physician provider non-discrimination provisions of the ACA. 2. Our AMA will immediately direct sufficient funds toward a multi-pronged campaign to accomplish these goals. 3. There will be a report back at each meeting of the AMA HOD. (Res. 231, A-13)

##### 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-450.944 Protecting Patients' Rights

Our AMA opposes Medicare pay-for-performance initiatives (such as value-based purchasing programs) that do not meet our AMA's "Principles and Guidelines for Pay-for-Performance," which include the following five Principles: (1) ensure quality of care; (2) foster the patient/physician relationship; (3) offer voluntary physician participation; (4) use accurate data and fair reporting; and (5) provide fair and equitable program incentives. (Sub. Res. 902, I-05; Reaffirmation A-06; Reaffirmation I-06; Reaffirmation A-07)

#### H-390.855 Replacement of Sustainable Growth Rate System

Our AMA continues to assign a top priority to the prevention of further Medicare payment cuts due to the Sustainable Growth Rate system and to seek replacement of the Sustainable Growth Rate system with payment updates that reflect increases in the cost of medical practice. (Res. 910, I-04; Reaffirmed: CMS Rep. 4, A-05; Reaffirmed: BOT Rep. 35, A-05; Reaffirmation A-06; Reaffirmation I-06; Reaffirmation I-08; Reaffirmed: Sub. Res. 222, I-10)

#### H-390.844 Recognizing the Diversity of Practice Models in the Transition from the SGR to a Higher Performing Medicare Program

1. Our AMA continues to advocate for a transition from the sustainable growth rate payment formula to new payment models that:

A. Emphasize the importance of physician leadership and accountability to deliver high quality and value to our patients; B. Reflect and preserve the diversity of physician-led practice models (including, for example, integrated systems of care, patient-centered medical homes, regional health collaboratives, and other practice models, including private practice); and C. Provide opportunities for physicians to determine payment models that work best for their patients, their practices, their specialties, and their regions.

2. Our AMA, while working to help implement new payment models, continues to advocate that:

A. fee-for-service, as well as private practice medicine, be included as continued options that can provide efficient, ethical, high quality, high value, patient-centered care; B. the viability of a private practice option be preserved for the benefit of patients and our members; and C. physicians should be free to determine the basic method of payment for their services, and have the right to establish their compensation arrangements including private contracting at a level which they believe fairly reflects the value of their professional judgment and services.

3. Our AMA continues to educate members on Medicare payment and delivery issues as they develop. (Sub. Res. 216, A-13; Reaffirmation I-13)

#### H-390.852 Legislative Action to End Medicare SGR Problems

1. Our AMA, working with our state and specialty society colleagues, will pursue enactment of legislation that provides for at least two years of positive updates that accurately reflect the increases in costs of caring for Medicare beneficiaries and lays the groundwork for complete repeal in the near future. 2. The AMA's ultimate goal continues to be complete repeal of the SGR and

its replacement with a fair and equitable payment system that adequately reflects increases in the cost of caring for Medicare beneficiaries. (BOT Rep. 31, A-07; Reaffirmation I-08)

#### D-390.953 Sustainable Growth Rate Repeal

1. Our AMA supports SGR repeal and continues to strongly advocate for the AMA's Pay-for-Performance Principles and Guidelines (AMA Policy H-450.947). 2. Our AMA will advocate with CMS and Congress for alternative payment models, developed in concert with specialty and state medical organizations, including private contracting as an option. 3. Our AMA will continue to advocate for future positive updates in the Medicare physician fee schedule. (Sub. Res. 226, I-13)

#### H-165.833 Amend the Patient Protection and Affordable Care Act (PPACA)

1. Our AMA continues to advocate to achieve needed reforms of the many defects of the federal Patient Protection and Affordable Care Act (PPACA) law so as to protect the primacy of the physician-patient relationship. These needed changes include but are not limited to:

- repeal of the Independent Payment Advisory Board (IPAB); - study of the Medicare Cost/Quality Index; - repeal of the non-physician provider non-discrimination provision; - enactment of comprehensive medical liability reform; - enactment of long term Medicare physician payment reform including permitting patients to privately contract with physicians not participating in the Medicare program; - enactment of antitrust reform to permit independently practicing physicians to collectively negotiate with health insurance companies; and - expanding the use of health savings accounts as a means to provide health insurance coverage.

2. Our AMA will vigorously work to change the PPACA to accurately represent our AMA Policy. (Res. 217, A-11; Reaffirmation A-12; Reaffirmed: Res. 239, A-12; Reaffirmed: CMS Rep. 5, I-12)

#### H-165.852 Health Savings Accounts

It is the policy of the AMA that:

(1) high-deductible health insurance plans issued to families in conjunction with Health Savings Accounts (HSAs) be allowed to apply lower, per-person deductibles to individual family members with the permitted levels for per-person deductibles being the same as permitted levels for individual deductibles, and with the annual HSA account contribution limit being determined by the full family deductible or the dollar-limit for family policies; (2) contributions to HSAs should be allowed to continue to be tax deductible until legislation is enacted to replace the present exclusion from employees' taxable income of employer-provided health expense coverage with tax credits for individuals and families; (3) advocacy of HSAs continues to be incorporated prominently in its campaign for health insurance market reform; (4) activities to educate patients about the advantages and opportunities of HSAs be enhanced; (5) efforts by companies to develop, package, and market innovative products built around HSAs continue to be monitored and encouraged; (6) HSAs continue to be promoted and offered to AMA physicians through its own medical insurance programs; and (7) legislation promoting the establishment and use of HSAs and allowing the tax-free use of such accounts for health care expenses, including health and long-term care insurance premiums and other costs of long-term care, be strongly supported as an integral component of AMA efforts to achieve universal access and coverage and freedom of choice in health insurance. (CMS Rep. 11 - I-94; Reaffirmed by Sub. Res. 125 and Sub. Res. 109, A-95; Reaffirmed by CMS Rep. 7, A-97; Reaffirmation A-97; Reaffirmed: CMS Rep. 5, I-97; Reaffirmation I-98; Reaffirmed: CMS Rep. 5 and 7, I-99; CMS Rep. 10, I-99; Appended by Res. 220, A-00; Reaffirmation I-00; Reaffirmed Res. 109 & Reaffirmation A-01; Reaffirmed: CMS Rep. 2, I-01; Reaffirmation A-02; CMS Rep. 3, I-02; Reaffirmed: CMS Rep. 3, A-03; Reaffirmation I-03; CMS Rep. 6, A-04; Reaffirmation A-04; Consolidated: CMS Rep. 7, I-05; Reaffirmation A-07; Reaffirmation A-10; Reaffirmed: CMS Rep. 2, A-11; Reaffirmed: CMS Rep. 9, A-11; Reaffirmed: Res. 239, A-12; Reaffirmed: CMS Rep. 5, I-12)

#### D-390.960 Assuring Patients' Continued Access to Physician Services

1. Our AMA will immediately formulate legislation for an additional payment option in Medicare fee for service that allows patients and physicians to freely contract, without penalty to either party, for a fee that differs from the Medicare payment schedule and in a manner that does not forfeit benefits otherwise available to the patient. This legislative language shall be available to our AMA members no later than September 30, 2010. 2. Our AMA is committed to a well funded and priority legislative and grassroots campaign to ensure passage of legislation in the US Congress that will ensure Medicare patients can keep their benefits when they privately contract with any physician of their choice with the AMA's "Medicare Patient Empowerment Act" as the centerpiece legislation the AMA supports. 3. Our AMA will report back to the AMA House of Delegates on its progress in ensuring passage of the Medicare Patient Empowerment Act or similar legislation. (Sub. Res. 204, A-10; Appended: Res. 202, I-10)

#### H-440.844 Expansion of National Diabetes Prevention Program

Our AMA: (1) supports evidence-based, physician-prescribed diabetes prevention programs, (2) supports the expansion of the NDPP to more CDC-certified sites across the country; and (3) will support coverage of the NDPP by Medicare and all private insurers. (Sub. Res. 911, I-12)

#### H-165.838 Health System Reform Legislation

1. Our American Medical Association is committed to working with Congress, the Administration, and other stakeholders to achieve enactment of health system reforms that include the following seven critical components of AMA policy: a. Health insurance coverage for all Americans b. Insurance market reforms that expand choice of affordable coverage and eliminate denials for pre-existing conditions or due to arbitrary caps c. Assurance that health care decisions will remain in the hands of

patients and their physicians, not insurance companies or government officials d. Investments and incentives for quality improvement and prevention and wellness initiatives e. Repeal of the Medicare physician payment formula that triggers steep cuts and threaten seniors' access to care f. Implementation of medical liability reforms to reduce the cost of defensive medicine g. Streamline and standardize insurance claims processing requirements to eliminate unnecessary costs and administrative burdens.

2. Our American Medical Association advocates that elimination of denials due to pre-existing conditions is understood to include rescission of insurance coverage for reasons not related to fraudulent representation.

3. Our American Medical Association House of Delegates supports AMA leadership in their unwavering and bold efforts to promote AMA policies for health system reform in the United States.

4. Our American Medical Association supports health system reform alternatives that are consistent with AMA policies concerning pluralism, freedom of choice, freedom of practice, and universal access for patients.

5. AMA policy is that insurance coverage options offered in a health insurance exchange be self-supporting, have uniform solvency requirements; not receive special advantages from government subsidies; include payment rates established through meaningful negotiations and contracts; not require provider participation; and not restrict enrollees' access to out-of-network physicians.

6. Our AMA will actively and publicly support the inclusion in health system reform legislation the right of patients and physicians to privately contract, without penalty to patient or physician.

7. Our AMA will actively and publicly oppose the Independent Medicare Commission (or other similar construct), which would take Medicare payment policy out of the hands of Congress and place it under the control of a group of unelected individuals.

8. Our AMA will actively and publicly oppose, in accordance with AMA policy, inclusion of the following provisions in health system reform legislation:

a. Reduced payments to physicians for failing to report quality data when there is evidence that widespread operational problems still have not been corrected by the Centers for Medicare and Medicaid Services

b. Medicare payment rate cuts mandated by a commission that would create a double-jeopardy situation for physicians who are already subject to an expenditure target and potential payment reductions under the Medicare physician payment system

c. Medicare payments cuts for higher utilization with no operational mechanism to assure that the Centers for Medicare and Medicaid Services can report accurate information that is properly attributed and risk-adjusted

d. Redistributed Medicare payments among providers based on outcomes, quality, and risk-adjustment measurements that are not scientifically valid, verifiable and accurate

e. Medicare payment cuts for all physician services to partially offset bonuses from one specialty to another

f. Arbitrary restrictions on physicians who refer Medicare patients to high quality facilities in which they have an ownership interest.

9. Our AMA will continue to actively engage grassroots physicians and physicians in training in collaboration with the state medical and national specialty societies to contact their Members of Congress, and that the grassroots message communicate our AMA's position based on AMA policy.

10. Our AMA will use the most effective media event or campaign to outline what physicians and patients need from health system reform.

11. AMA policy is that national health system reform must include replacing the sustainable growth rate (SGR) with a Medicare physician payment system that automatically keeps pace with the cost of running a practice and is backed by a fair, stable funding formula, and that the AMA initiate a "call to action" with the Federation to advance this goal.

12. AMA policy is that creation of a new single payer, government-run health care system is not in the best interest of the country and must not be part of national health system reform.

13. AMA policy is that effective medical liability reform that will significantly lower health care costs by reducing defensive medicine and eliminating unnecessary litigation from the system should be part of any national health system reform. (Sub. Res. 203, I-09; Reaffirmation A-10; Reaffirmed in lieu of Res. 102, A-10; Reaffirmed in lieu of Res. 228, A-10; Reaffirmed: CMS Rep. 2, I-10; Reaffirmed: Sub. Res. 222, I-10; Reaffirmed: CMS Rep. 9, A-11; Reaffirmation A-11; Reaffirmed: CMS Rep. 6, I-11; Reaffirmed in lieu of Res. 817, I-11; Reaffirmation I-11; Reaffirmation A-12; Reaffirmed in lieu of Res. 108, A-12; Reaffirmed: Res. 239, A-12; Reaffirmed: Sub. Res. 813, I-13)

#### D-330.924 Reform the Medicare System

Our AMA will renew its commitment for total reform of the current Medicare system by making it a high priority on the AMA legislative agenda beginning in 2009 and the AMA's reform efforts will be centered on our long-standing policy of pluralism (AMA Policy H-165.844), freedom of choice (H-165.920, H-373.998, H-390.854), defined contribution (D-330.937), and balance billing (D-380.996, H-385.991, D-390.969). (Res. 834, I-08; Reaffirmed: CMS Rep. 6, A-09)

#### H-330.896 Strategies to Strengthen the Medicare Program

Our AMA supports the following reforms to strengthen the Medicare program, to be implemented together or separately, and phased-in as appropriate:

1. Restructuring beneficiary cost-sharing so that patients have a single premium and deductible for all Medicare services, with means-tested subsidies and out-of-pocket spending limits that protect against catastrophic expenses. The cost-sharing structure should be developed to provide incentives for appropriate utilization while discouraging unnecessary or inappropriate patterns of care. The use of preventive services such as those recommended by the US Preventive Health Task Force should also be encouraged. Simultaneously, policymakers will need to consider modifications to Medicare supplemental insurance (i.e., Medigap) benefit design standards to ensure that policies complement, rather than duplicate or undermine, Medicare's new cost-sharing structure.

2. Offering beneficiaries a choice of plans for which the federal government would contribute a standard amount toward the purchase of traditional fee-for-service Medicare or another health insurance plan approved by Medicare. All plans would be subject to the same fixed contribution amounts and regulatory requirements. Policies would need to be developed, and sufficient resources allocated, to ensure appropriate government standard-setting and regulatory oversight of plans.

3. Restructuring age-eligibility requirements and incentives to match the Social Security schedule of benefits. (CMS Rep. 10, A-07; Reaffirmed: CMS Rep. 5, I-12)

#### H-330.889 Strengthening Medicare for Current and Future Generations

1. It is the policy of our AMA that a Medicare defined contribution program should include the following:

a. Enable beneficiaries to purchase coverage of their choice from among competing health insurance plans, which would be subject to appropriate

regulation and oversight to ensure strong patient and physician protections. b. Preserve traditional Medicare as an option. c. Offer a wide range of plans (e.g., HMOs, PPOs, high-deductible plans paired with health savings accounts), as well as traditional Medicare. d. Require that competing private health insurance plans meet guaranteed issue and guaranteed renewability requirements, be prohibited from rescinding coverage except in cases of intentional fraud, follow uniform marketing standards, meet plan solvency requirements, and cover at least the actuarial equivalent of the benefit package provided by traditional Medicare. e. Apply risk-adjustment methodologies to ensure that affordable private health insurance coverage options are available for sicker beneficiaries and those with higher projected health care costs. f. Set the amount of the baseline defined contribution at the value of the government's contribution under traditional Medicare. g. Ensure that health insurance coverage is affordable for all beneficiaries by allowing for adjustments to the baseline defined contribution amount. In particular, individual defined contribution amounts should vary based on beneficiary age, income and health status. Lower income and sicker beneficiaries would receive larger defined contributions. h. Adjust baseline defined contribution amounts annually to ensure that health insurance coverage remains affordable for all beneficiaries. Annual adjustments should reflect changes in health care costs and the cost of obtaining health insurance. i. Include implementation time frames that ensure a phased-in approach. 2. Our AMA will advocate that any efforts to strengthen the Medicare program ensure that mechanisms are in place for financing graduate medical education at a level that will provide workforce stability and an adequate supply of physicians to care for all Americans. 3. Our AMA will continue to explore the effects of transitioning Medicare to a defined contribution program on cost and access to care. (CMS Rep. 5, I-12)

#### H-35.968 Averting a Collision Course Between New Federal Law and Existing State Scope of Practice Laws

1. Our AMA will: (A) work to repeal new Public Health Service Act Section 2706, so-called provider "Non-Discrimination in Health Care," as enacted in PPACA, through active direct and grassroots lobbying of and formal AMA written communications and/or comment letters to the Secretary of Health and Human Services and Congressional leaders and the chairs and ranking members of the House Ways and Means and Energy and Commerce and Senate Finance Committees; and (B) promptly initiate a specific lobbying effort and grassroots campaign to repeal the provider portion of the Patient Protection and Affordable Care Act's "Non-Discrimination in Health Care" language, including direct collaboration with other interested components of organized medicine. 2. Our AMA will: (A) create and actively pursue legislative and regulatory opportunities to repeal the so called "Non-discrimination in Health Care" clause in Public Health Service Act Section 2706, as enacted in the Patient Protection and Affordable Care Act; (B) lead a specific lobbying effort and grassroots campaign in cooperation with members of the federation of medicine and other interested components of organized medicine to repeal the provider portion of PPACA's "Non-Discrimination in Health Care" language; and (C) report back at the 2013 Annual Meeting. (Res. 220, A-10; Appended: Res. 241, A-12; Appended: BOT Rep. 8, I-12)

#### H-165.833 Amend the Patient Protection and Affordable Care Act (PPACA)

1. Our AMA continues to advocate to achieve needed reforms of the many defects of the federal Patient Protection and Affordable Care Act (PPACA) law so as to protect the primacy of the physician-patient relationship. These needed changes include but are not limited to:  
 - repeal of the Independent Payment Advisory Board (IPAB); - study of the Medicare Cost/Quality Index; - repeal of the non-physician provider non-discrimination provision; - enactment of comprehensive medical liability reform; - enactment of long term Medicare physician payment reform including permitting patients to privately contract with physicians not participating in the Medicare program; - enactment of antitrust reform to permit independently practicing physicians to collectively negotiate with health insurance companies; and - expanding the use of health savings accounts as a means to provide health insurance coverage. 2. Our AMA will vigorously work to change the PPACA to accurately represent our AMA Policy. (Res. 217, A-11; Reaffirmation A-12; Reaffirmed: Res. 239, A-12; Reaffirmed: CMS Rep. 5, I-12)

### **25. CMS DEFINITION OF "RESIDENT PHYSICIAN" (RESOLUTION 923-I-13)**

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

#### **HOUSE ACTION: RECOMMENDATIONS ADOPTED (RESOLUTION 923-I-13 NOT ADOPTED) AND REMAINDER OF REPORT FILED**

Resolution 923-I-13, "CMS Definition of 'Resident Physician'", introduced by the Resident and Fellow Section and referred by the House of Delegates, asked that our American Medical Association (AMA) "advocate, in conjunction with appropriate stakeholders, that the Centers for Medicare & Medicaid Services (CMS) use our AMA definition of resident when formulating rules and regulations."

Testimony heard during Reference Committee K urged referral of this item as it was noted that this resolution is more complex than it appears and could have unforeseen consequences.

## BACKGROUND

In the final regulation that implements the Physician Payment Sunshine Act (Sunshine Act) or Open Payments, CMS exempts medical residents from its definition of “covered recipients,” for whom industry must track and report any transfers of value or payments of \$10 or more. The impetus for Resolution 923-I-13 is to secure a similar exemption for medical fellows based on the rationale that fellows, like residents, are continuing their medical training.

The AMA Bylaws, Glossary of Terms (B-14.01) states: “Resident - The term ‘resident’ as applied to qualifications for membership in the Resident and Fellow Section, and eligibility for our AMA Resident dues rate, shall include only: (1) members serving in residencies approved by the ACGME or AOA; (2) members serving in fellowships approved by the ACGME or AOA; (3) members serving fellowships in subspecialty training when such program is affiliated with and under the supervision of an approved residency training program; (4) members serving fellowships in structured clinical training programs for periods of at least one year, to broaden competency in a specialized field; (5) members serving, as their primary occupation, in a structured educational program to broaden competency in a specialized field, provided it is begun upon completion of medical school, residency, or fellowship training; and (6) members serving as active military and public health service residents who are required to provide service after their internship as general medical officers, including dive medical officers, or flight surgeons before their return to complete a residency program and are within the first five years of service after internship.” The Bylaws also state that “The terms in this Glossary were chosen after consideration and consultation by the Council on Constitution and Bylaws, members of the House of Delegates, and AMA staff. The terms herein represent those terms that convey meanings or contain definitions for which further explanation will help readers’ understanding of the Constitution and Bylaws. Some terms are meant to convey a specific definition while others are meant to provide a more rich understanding of a particular group. All effort has been made to follow AMA Policy, although it should be noted that this Glossary is not AMA policy.”

The definition of a resident in the AMA Bylaws glossary specifically applies to qualifications for membership and is not AMA policy. There is no evidence that the AMA intended this definition to serve other purposes, and there are no other AMA policies that define either a resident or a fellow.

## DISCUSSION

As early as 2001, states had begun to pass laws, resolutions and regulations concerning pharmaceutical marketing and interactions with physicians, other prescribers and consumers. Eight states had passed legislation that required industry reporting on interactions with physicians and other prescribers, and a growing number of state legislatures were considering similar bills. At the federal level, congressional interest and investigations into physician and industry interactions also grew, and, by 2006, members of Congress began to call for sweeping federal legislation that would require public reporting of both direct and indirect transfers of funding from industry resources to physicians and teaching hospitals. At the same time, national and regional media outlets highlighted physician-industry interactions that raised concerns about prescriber independence from industry influence. Coinciding with the foregoing, prominent medical publications and others in the medical profession, including deans of medical schools and medical students, were calling for the termination of interactions altogether, which would place significant limits on the dissemination of medical knowledge and stymie innovation. In this context, bipartisan legislation, the Sunshine Act, was included in the Affordable Care Act (ACA). The Sunshine Act was touted as interjecting greater transparency into the interactions between physicians and teaching hospitals on the one hand and industry on the other.

The Sunshine Act mandates that manufacturers of drugs, medical devices, and biologicals that participate in US federal health care programs must begin tracking any transfers of value or payments of \$10 or more (as indexed by Consumer Price Index) to physicians and teaching hospitals. Manufacturers will submit the reports to the Secretary of the Department of Health and Human Services (HHS) on an annual basis. In addition, the Sunshine Act mandates that manufacturers and group purchasing organizations (GPOs) must report ownership interests held by physicians and their close family members. The majority of the information contained in the transparency reports will be available on a public, searchable website later this year, according to CMS.

Industry must report payments or “transfers of value” to physicians and teaching hospitals. Manufacturers are required to describe how the recipient received the payment (such as cash or cash equivalent, in-kind items or



services, or stock, stock option[s], or any other ownership interest, dividend, profit, or other return on investment). In addition, manufacturers must provide a reason for the payment. The statute identifies categories of transfers and payments that must be reported, including consulting fees, grant, research, honoraria, and charitable contributions, and specifies transfers of value that are not subject to reporting, including product samples intended for patient use, educational materials that directly benefit patients or are intended for patient use, the loan of a covered device to permit evaluation, items or services provided under a contractual warranty, a transfer of anything of value to a physician when the physician is a patient, discounts (including rebates), and in-kind items used for the provision of charity care. Though the statute and final regulation exclude transfers of value of less than \$10, unless the aggregate amount transferred to a physician by a manufacturer exceeds \$100, manufacturers must track all transfers in order to report transfers of value that are less than \$10, but cumulatively exceed \$100.

The Sunshine Act also provides that manufacturers, as well as GPOs, are required to report on interests held by physicians and their immediate family members. The transparency report must include the dollar amount invested, the value and terms of ownership or investment interest, and any payment provided to a physician owner or investor. However, ownership or investment interests in publicly traded security and mutual funds are excluded from reporting.

Manufacturers and GPOs that fail to submit timely and accurate transparency reports are subject to penalties. Since physicians are not required to submit reports, they are not subject to any Sunshine Act penalties. However, the statute provides that CMS must provide physicians at least 45 days to challenge false or misleading reports prior to publication because inaccurate reports may damage a physician's reputation, professional standing, employment, grantee status and participation in organizations.

The AMA successfully advocated for the inclusion of statutory language to ensure: (1) the scope of the reporting was reduced to primarily direct transfers; (2) certain transfers would be excluded, such as samples intended for patient use; and (3) physicians would have an absolute right to review and dispute reports before such reports were made public.

#### *Sunshine Act Regulation and AMA Advocacy*

After passage of the Sunshine Act, the HHS Secretary delegated responsibility for transparency report oversight to CMS. The agency was required to issue final regulations by October 2011, but instead issued a proposed regulation in December 2011 and accepted comments on the proposed rule until February 17, 2012. The AMA prepared and submitted a sign-on comment letter to the proposed rule covering a broad number of issues along with 49 medical specialty societies and 43 state medical associations. In addition, the AMA joined a sign-on letter submitted by national organizations involved in continuing medical education (CME) in the United States. CMS did not issue final regulations until early last year. The AMA has continued to advocate for changes to comply with the statute and congressional intent in the following five broad areas:

- CMS is required to publish accurate transparency reports. CMS has established a process that is unlikely to ensure accurate reporting or a reasonable opportunity to correct false, misleading, or inaccurate reports by arbitrarily limiting the ability of physicians to receive ongoing updates of transfers, payments, and ownership interests that manufacturers and GPOs intend to report and further limiting physicians' ability to review and challenge incorrect reports.
- Congress did not authorize CMS to expand reporting to indirect transfers (not otherwise specified in the statute). Although Congress limited reporting to direct payments/transfers of value to physicians, CMS initially expanded the category of transfers subject to reporting to a broad category of in-direct transfers in the proposed rule, but in the final rule has taken steps to align the regulation with the statute.
- Congress excluded certified CME. CMS proposed reporting standards that would have included indirect transfers that occur through certified or accredited CME even though Congress specifically excluded certified CME. Through AMA advocacy along with Federation members, the final regulation excludes from reporting certified or accredited CME from a number of organizations that have requirements prohibiting industry influence.

- CMS is required to ensure accurate attribution and not allowed to use estimates. CMS initially proposed attributing a transfer of value/payment to a physician even when a physician did not receive value directly (and even in some instances indirectly) based on employment, affiliation, or association with an entity or person that did receive a direct transfer. The AMA successfully advocated that all reporting must be based on actual transfers—not estimates. However, manufacturer implementation of these requirements continues to raise concerns since physicians may not have adequate time or information to challenge incorrect or misleading reports.
- The proposed rule imposes a significant paperwork burden on physicians. CMS has underestimated the paperwork requirements of ensuring that manufacturers/GPOs are accurately reporting, and the process as outlined in the proposed and final regulations imposes ongoing and time-intensive paperwork obligations on physicians.

AMA advocacy remains ongoing to address the concerns outlined above as well as other related to the AMA's challenge to the legal sufficiency of the CMS decision to require manufacturers to include textbooks and reprints of peer reviewed articles in the reporting requirement.

#### *The Sunshine Act: Residents and Fellows*

The Sunshine Act provides that physicians are subject to the reporting requirement. The statutory definition of “a covered recipient” includes “doctors of medicine, osteopathy, dentists, podiatrists, optometrists, and chiropractors.” (The statute excludes physician employees of manufacturers.) CMS issued regulations further clarifying who constituted a covered recipient. CMS determined that only those physicians who are currently licensed would be subject to the reporting requirement. The agency excluded residents from the reporting requirement because “some States require or allow residents to obtain licenses to practice, whereas other States do not require or allow residents to obtain them.” CMS noted that residents are excluded from the reporting requirement for two reasons. First, the agency concluded that residents should not be treated differently based on the state where they reside and the resultant differences in state licensure requirements. Thus, CMS rejected defining covered recipients to include only those residents who are licensed. Second, CMS concluded that including all residents would be administratively burdensome since some do not have a state license or a National Provider Identifier (NPI) that would facilitate tracking and aggregation. After evaluating the inclusion of only those residents who are licensed or, alternatively, including all residents in the reporting requirement, CMS determined that all residents should be excluded from the reporting requirement. CMS received inquiries concerning the status of fellows and issued guidance providing:

The final rule exempted payments to medical residents from the reporting requirements solely due to operational and data accuracy concerns regarding aggregation of payments or other transfers of value to residents, many of whom have neither a National Provider Identifier (NPI) nor a State professional license. Because these same concerns do not generally apply to physicians in Fellowship training, payments to Fellows are not exempt from the reporting requirements.

The congressional intent in passing the Sunshine Act was to promote transparency in the interactions between physicians, teaching hospitals and industry in an accurate, fair and efficient manner. The AMA continues to advocate for significant modifications to the Sunshine Act implementing regulations and agency guidance consistent with the statute and congressional intent. There remain serious challenges with implementation of the Sunshine Act tracking, registration, and reporting requirements as well as the agency's interpretation of central provisions—particularly those related to physician due process and accurate reporting. In contrast, the agency's decision to exclude residents from the reporting requirement was grounded in the agency's obligation to ensure accurate and fair reporting without imposing cost-prohibitive tracking obligations on manufacturers and GPOs.

Efforts to seek reconsideration of whether fellows and residents should be treated similarly for purposes of the Sunshine Act and other CMS-administered programs may not necessarily result in the agency concluding the fellows should also be excluded from reporting. While this would be a reasonable decision, the agency could potentially reverse course and require reporting for residents and fellows, even though this would lead to inaccurate reporting and a substantial increase in the reporting burden to all involved, from manufacturers to residents and fellows. Furthermore, developing a broad application of advocating to treat residents and fellows interchangeably for all CMS purposes could have unanticipated negative consequences and would limit the AMA's ability to advocate based on relevant circumstances and factors relevant to any given program or policy.

## RELEVANT AMA POLICY

H-140.848, “Physician Payments Sunshine Act,” states that “Our AMA will continue its efforts to minimize the burden and unauthorized expansion of the Sunshine Act by the Centers for Medicare & Medicaid Services (CMS) and will recommend to the CMS that a physician comment section be included on the ‘Physician Payments Sunshine Act’ public database.”

## CONCLUSION

The AMA definition of a resident is derived from the Glossary of the AMA Bylaws but is not AMA policy. Applying the AMA definition to advocate that fellows should be excluded from the reporting requirements of the Sunshine Act, or for other regulatory purposes, could have unintended negative consequences, such as reversing CMS’ reporting exemption for residents, and may impede the AMA’s work to address other challenges with implementation of the Sunshine Act.

## RECOMMENDATION

The Board of Trustees recommends that Resolution 923-I-13 not be adopted and the remainder of this report be filed.

### **26. CONFORMING BIRTH CERTIFICATE POLICIES TO CURRENT MEDICAL STANDARDS FOR TRANSGENDER PATIENTS (RESOLUTION 5-A-13)**

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

#### **HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 5-A-13 AND REMAINDER OF REPORT FILED**

*See Policy [H-65.967](#).*

## BACKGROUND

The Resident and Fellow Section introduced Resolution 5-A-13, “Conforming Birth Certificate Policies to Current Medical Standards for Transgender Patients,” which was referred to the American Medical Association (AMA) Board of Trustees (BOT) for a report back to the House of Delegates (HOD) at the 2014 Annual Meeting. Resolution 5-A-13 asked:

That our AMA support policies that allow for a change of sex designation on birth certificates for transgender individuals based upon verification by a physician that the individual has undergone gender transition according to applicable medical standards of care;

That our AMA support eliminating any government requirement that an individual have undergone surgery in order to change the sex designation on birth certificates; and

That our AMA support that any change of sex designation on an individual’s birth certificate not hinder access to medically appropriate preventive care.

Resolution 5 asks for support of identical policies as Resolution 4-A-13, which was adopted by the HOD Policy H-65.967. The Reference Committee was concerned about disagreement in the medical community over what constitutes a medical change in sex, and the possible long-term and unintended consequences of changing the sex on one’s birth certificate prior to surgery, including the ramifications for insurance coverage of reproductive care. This report will discuss the concerns raised by Resolution 5 and propose adopting recommendations in lieu of Resolution 5. Input for this report was provided by the LGBT Advisory Committee.

## DISCUSSION

### *Current Medical Understandings of Gender Transition*

A person's gender identity refers to one's self-identification as a man or a woman, as distinct from one's anatomical sex at birth. Usually, people born with the physical characteristics of males identify and live their lives as men, and those with physical characteristics of females identify and live their lives as women. However, one's gender identity does not always align with one's anatomical birth sex. This discordance can sometimes lead to gender dysphoria, i.e., a feeling of stress and discomfort with one's anatomical sex. Gender dysphoria, if clinically significant and persistent, is diagnosed as gender dysphoria (GD).

GD is recognized as a serious medical condition in both the International Classification of Diseases-10 (ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), published by the American Psychiatric Association.<sup>1</sup> It is characterized by a persistent and often intense discomfort with one's anatomical sex and with one's primary and secondary sex characteristics. This conflict can create intense emotional pain and suffering that is intractable, severe and often incapacitating.<sup>2</sup> If left medically untreated, this condition predictably results in dysfunction, debilitating depression and, for some people, suicidality and death.

The World Professional Association For Transgender Health, Inc. (WPATH) (formerly known as "The Harry Benjamin International Gender Dysphoria Association, Inc."),<sup>3</sup> has established internationally accepted standards of care (SOC) for the treatment of people with GD.<sup>4</sup> For people with severe GD, the course of care includes gender transition, a medical protocol for enabling the individual to live as the sex that is consistent with the person's gender identity, often referred to as a person's affirmed gender or sex. The current SOC recommend a medically appropriate combination of mental health care, social transition (sometimes referred to as the "real life experience"), hormone therapy and/or sex reassignment surgery. The determination of the proper level and combination of treatments necessary for gender transition rests with the individual treating physician in consultation with the patient and other treating mental health professionals.

For many persons, social transition and hormone therapy may be sufficient to treat GD. Others will require a different therapeutic regime, including gender affirmation surgery. As set forth in the SOC, "while many individuals need both hormone therapy and surgery to alleviate their gender dysphoria, others need only one of these treatment options and some need neither. Some patients may need hormones, a possible change in gender role, but not surgery; others may need a change in gender role along with surgery, but not hormones."<sup>5</sup>

As with most serious medical conditions, the correct course of treatment for any given individual is a decision made by the treating physician and the patient, with the goal of enabling the patient to achieve genuine and lasting comfort with his or her gender. As explained in the SOC, "Treatment is individualized: What helps one person alleviate gender dysphoria might be very different from what helps another person. This process may or may not involve a change in gender expression or body modifications."<sup>6</sup>

The only effective treatment of GD is medical care to support the person's ability to live fully consistent with one's gender identity. Efforts to change a person's gender identity are futile and, like sexual orientation change efforts, can have a disastrously negative impact on the patient. An established body of medical research studies demonstrates the effectiveness and medical necessity of mental health care, social transition, hormone therapy and sex reassignment surgery as forms of therapeutic treatment for people diagnosed with GD.<sup>7</sup>

### *Eliminating the Requirement that Individuals Undergo Surgery in Order to Change Their Sex Designation on Birth Certificates*

While originally intended as a record of the existence and circumstances of birth, the birth certificate now is used widely in determining eligibility for employment, obtaining other documents (e.g., driver's licenses, social security cards, passports, and other state identification documents), establishing school records, proving age, and enrolling in government programs. Birth certificates are also used extensively to assist in determining eligibility for public assistance and other benefits, to enroll children in school, and as proof of age eligibility for sports and other age restricted activities.

Across the country, laws governing corrections to gender markers on birth certificates are relatively uniform in large part because many states adopted the relevant provisions of the 1977 revision of the Model State Vital Statistics Act (MSVSA), which recommended that corrections to gender markers on birth certificates be granted after applicants change their sex by “surgical procedure” and provide a court order to that effect.<sup>8</sup> The only states which allow corrections to gender markers on birth certificates on the basis of “clinically appropriate treatment,” as opposed to surgery, are California, Vermont and Washington.<sup>9</sup>

In 2008 the American Psychological Association (APA) released the following statement: “Be it resolved that the APA encourages legal and social recognition of transgender individuals consistent with their gender identity and expression, including access to identity documents consistent with their gender identity and expression...” The basis for changing gender markers on identity documents according to the APA is a person’s “social transition,” not a specific medical event, such as hormone therapy or surgery.<sup>10</sup>

Health experts in GD, including WPATH, in the interest of the health and well-being of transgender people, reject that a person should have to undergo surgery or accept sterilization as a condition of obtaining an accurate birth certificate.<sup>11</sup> For many individuals, surgery may even be counter-indicated. WPATH has urged governments to eliminate surgical requirements as part of the process for changing identity documents because such requirements serve as a barrier to effective treatment.<sup>12</sup> In addition, WPATH issued a statement condemning surgical requirements in 2010, stating “no person should have to undergo surgery or accept sterilization as a condition of gender recognition.” The WPATH Board of Directors urged governments and other authoritative bodies to move to eliminate requirements for identity recognition that require surgical procedures.<sup>13</sup>

Also in 2010, the US Department of State abandoned its surgery-based policy in favor of a new policy requiring a letter from a physician (without reference to the patient’s surgical status) to update the birth certificates of US citizens born in other countries.

Accordingly, it is timely for the AMA to support eliminating any government requirement that an individual must have undergone surgery in order to change the sex designation on a birth certificate. Further, given that state vital statistics statutes specify when gender markers on birth certificates can be changed, the AMA should support modernizing state vital statistics statutes to ensure accurate gender markers on birth certificates.

*Any Change in an Individual’s Sex Designation on a Birth Certificate Should not Hinder Access to Medically Necessary or Appropriate Care*

Possessing accurate identification documents that are consistent with a person’s gender identity is essential to basic social and economic functioning in our country. Access to employment, housing, health care and travel all hinge on having appropriate documentation. In addition, having identity documents with incorrect sex designation can expose transgender individuals to bias, discrimination, harassment, and even violence, particularly when transgender individuals must disclose those inaccurate identity documents for inspection.<sup>14</sup> These outcomes, according to WPATH, “may have a deleterious impact on a person’s social integration and personal safety.”<sup>15</sup> Disproportionate discrimination, harassment and violence against transgender individuals have been shown to contribute to health disparities within the transgender community.<sup>16</sup> Unfortunately, there are unintended consequences to changing an individual’s sex designation on a birth certificate, such as creating an inconsistency between the gender noted on the birth certificate and the individual’s anatomical sex.

Government records that reflect the sex indicated on a person’s birth certificate can affect what gender people are considered to be by their health insurance providers, their health systems, their state’s medical assistance program or Medicare. Depending on what gender is recorded in these records, certain treatments, screenings and procedures may be disallowed, despite the fact that the best practice is to screen and treat all of a person’s bodily organs, regardless of a person’s gender identity and regardless of whether or not the treatment relates to gender transition. For example a transgender woman may be denied gynecological services because they are only covered for females.<sup>17</sup> The literature is replete with anecdotal evidence of transgender individuals being denied medically necessary treatment both related to gender transition and ordinary preventive medical care. Insurance companies have denied reimbursement for treatment related to transgender individual’s anatomy because such does not match up with the sex recorded on their insurance records. Common health problems that receive routine treatment in other contexts may not receive adequate attention when the patient is transgender.<sup>18</sup>

Several state insurance commissions have enacted policies that now require an insurer to cover any sex-specific mandated coverage, if medically necessary, regardless of whether a person has transitioned to live as the sex that is different from the sex identified in the statute. In other words, a Pap smear mandate would be applicable to a biological female who self-identifies as male, and a prostate screening mandate would be applicable to a biological male who self-identifies as female.<sup>19</sup> Another state has prohibited the denial, cancellation, limitation or refusal to issue or renew health coverage because of a person's sexual orientation, which has been defined to include transgender status.<sup>20</sup>

Physicians with experience in health care needs of transgender patients can be difficult to locate, and transgender patients often encounter discrimination from physicians rather than understanding. Testimony from transgender individuals indicates that many health care professionals routinely refuse to treat even non-transition related health issues.<sup>21</sup> Some transgender patients do not want transition-related services at all, but prefer to receive medical care from physicians who have worked with other gender-variant individuals and understand how to approach non-normative gender expression or behavior.<sup>22</sup>

Best medical practices reflect that individuals should receive the care that is appropriate regardless of whether or not it matches with the gender on the birth certificate. The American Congress of Obstetricians and Gynecologists recognizes that transgender individuals who were anatomically female at birth but are now living as a male will continue needing breast and reproductive organ screening, unless they have had a mastectomy or had their ovaries, uterus and/or cervix removed. Services that ob-gyns should be able to offer transgender patients include preventive care, Pap tests, sexually transmitted infection screenings, etc.<sup>23</sup>

The sex indicated on a birth certificate or insurance card or other identity document should have no bearing on the health care services made available to transgender individuals. The American Medical Association should adopt the position that a person's sex designation on a birth certificate should not hinder access to medically appropriate preventive care.

## RECOMMENDATIONS

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 5-A-13 and the remainder of this report be filed:

1. That our AMA Policy H-65.967 be reaffirmed.
2. That our AMA support elimination of any requirement that individuals undergo gender affirmation surgery in order to change their sex designation on birth certificates and support modernizing state vital statistics statutes to ensure accurate gender markers on birth certificates.
3. That our AMA support that any change of sex designation on an individual's birth certificate not hinder access to medically appropriate preventive care.

## REFERENCES

- <sup>1</sup> *Diagnostic and Statistical Manual of Mental Disorders*, America Psychiatric Association, (4<sup>th</sup> ed. 2000).
- <sup>2</sup> *Principles of Transgender Medicine and Surgery*, Ettner, Monstrey, & Eyler, Eds (2007).
- <sup>3</sup> WPATH ("World Professional Association for Transgender Health, Inc.") is the leading, international, professional organization devoted to the understanding and treatment of gender identity disorders and is actively involved in supporting, educating, and advocating on behalf of individuals diagnosed with gender identity disorder. The organization's membership includes licensed professionals in the disciplines of medicine, internal medicine, endocrinology, plastic and reconstructive surgery, urology, gynecology, psychiatry, nursing, psychology, neuropsychology, and other disciplines.  
<http://www.wpath.org/About.htm>.
- <sup>4</sup> <http://www.wpath.org/soc.htm>.
- <sup>5</sup> *Id.*, 2.
- <sup>6</sup> *Id.*, 5.
- <sup>7</sup> Brown G R: A review of clinical approaches to gender dysphoria. *J Clin Psychiatry*. 51(2):57-64, 1990. Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. *Qual Life Res*. 15(9):1447-57, 2006. Best L, and Stein K. (1998) "Surgical gender reassignment for male to female transsexual people." Wessex Institute DEC report 88; Blanchard R, et al. "Gender dysphoria, gender reorientation, and the clinical management of transsexualism." *J Consulting and Clinical Psychology*. 53(3):295-304. 1985; Cole C, et al. "Treatment of gender dysphoria (transsexualism)." *Texas Medicine*.

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- 8 Model State Vital Statistics Act and Regulations § 21(e) (Ctr. For Disease Control & Prevention 1992), *available at* <http://www.cdc.gov/nchs/data/misc/mv-sact92b.pdf>.
- 9 Wash. Rev. Code Ann. § 43.70.150 (West 2009); 18 V.S.A. § 5112(b) (West 2011); CA HL & S § 1004430 (West 2012).
- 10 APA Policy Statement: Transgender, Gender Identity & Gender Expression Non-Discrimination, *available at* <http://www.apa.org/about/policy/transgender.aspx>.
- 11 The WPATH Identity Recognition Statement, June 16, 2010 (*available at* <http://www.wpath.org/documents/Identity%20Recognition%20Statement%206-6-10%20on%20letterhead.pdf>) states: "No person should have to undergo surgery or accept sterilization as a condition of identity recognition. If a sex marker is required on an identity document, that marker could recognize the person's lived gender, regardless of reproductive capacity. The WPATH Board of Directors urges governments and other authoritative bodies to move to eliminate requirements for identity recognition that require surgical procedures."
- 12 Press Release, World Prof. Ass'n for Transgender Health (June 16, 2010), *available at* [www.wpath.org](http://www.wpath.org).
- 13 Press Release, World Prof. Assn for Transgender Health (June 16, 2010), *available at* <http://www.wpath.org/documents/Identity%20Recognition%20Statement%206-6-10%20on%20letterhead.pdf>.
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- 19 Oregon Insurance Division Bulletin INS 2012-01; State of California Department of Insurance Bulletin 2007-2 (Implementation of AB 1586: Insurance Gender Non-discrimination); Vermont Department of Financial Regulation, Division of Insurance Bulletin No. 174. (Guidance Regarding Prohibited Discrimination on the Basis of Gender Dysphoria Surgery and Related Health Care)
- 20 State of Colorado, Department of Regulatory Agencies, Division of Insurance, Bulletin No. B-4.49.
- 21 Jaime M. Grant et al., *Injustice at Every Turn: A Report of the National Transgender Discrimination Survey* 73-74 (2011) *available at* [http://transequality.org/PDFs/NTDS\\_Report.pdf](http://transequality.org/PDFs/NTDS_Report.pdf) (reporting that 19% of a national sample of transgender individuals had been refused care by a medical provider due to their transgender or gender non-conforming status)
- 22 Evan Eyler, Primary Medical Care of the Gender Variant Patient, in *Principles of Transgender Medicine and Surgery* 15, 19-21 (Randi Ettner et al. eds., 2007)
- 23 The American College of Obstetrics and Gynecologists, *Ob-Gyns: Prepare to Treat Transgender Patients* (November 21, 2011)

## **27. HOSPITAL POLICIES ON INTERACTION WITH INDUSTRY (RESOLUTION 6-I-13)**

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED  
IN LIEU OF RESOLUTION 6-I-13  
REMAINDER OF REPORT FILED AND  
See Policy [H-225.948](#).**

At its 2013 Interim Meeting, the House of Delegates referred Resolution 6-I-13, “Restrictions on Marketing in Hospitals and Medical Centers,” to the Board of Trustees for report. Resolution 6, which was introduced by the California delegation, asked the AMA to:

1. Support policies, duly adopted by a medical staff or facility governing body within its scope of authority, that (a) govern the level and content of contact between physicians and pharmaceutical, device and other medical product representatives in hospital and medical center settings in order to minimize undue external influence over medical judgment and patient care as necessary and appropriate for the particular medical staff or facility; and (b) promote education, training, operative orientation and coaching as the focus of such contact; and
2. Urge the American Hospital Association to support such policies.

Testimony on Resolution 6 noted that the AMA has already established extensive policy on physician interaction with industry, including comprehensive policy on industry representatives in clinical settings, gifts to physicians from industry, and financial relationships with industry in continuing medical education, among other issues. Many of those testifying expressed concern that the resolution, which in some respects paraphrases existing AMA policy, would reopen debate on the AMA’s well-balanced and importantly nuanced ethical guidance on industry interaction. Testimony also questioned whether Resolution 6 describes an appropriate role for the organized medical staff in the development of hospital policies on industry interaction.

### BACKGROUND

Physicians have an ethical obligation to “continue to study, apply, and advance scientific knowledge” and to “maintain a commitment to medical education” throughout their careers.<sup>1,2</sup> This dedication to lifelong learning is particularly important “in an environment of rapidly changing information and emerging technology.”<sup>3</sup>

Education and training provided or facilitated by pharmaceutical, device, and other industry representatives can play an important role in physicians’ attainment of knowledge and their mastery of skills, especially to the extent that such activities focus on novel treatments and technologies. Education and training from industry representatives can also ultimately play an important role in enhancing patient safety and quality of care.<sup>4</sup>

However, because the “interests and obligations of medicine and industry diverge in important ways,”<sup>5</sup> interaction between physicians and industry representatives, even if for the express purpose of education and training, holds the potential to create real and perceived financial and other conflicts of interest. While these conflicts can take many forms, a primary and ever-present concern is the potential of physician-industry interactions to influence physician practice and prescribing decisions, regardless of whether this influence is apparent to the physician or whether it negatively affects patient outcomes.

### DISCUSSION

#### *Hospital Policies on Industry Interaction*

In a 2011 report on financial relationships with industry in continuing medical education, the AMA Council on Ethical and Judicial Affairs (CEJA) observed that medicine and industry are faced with an “increasingly urgent challenge ... to devise ways to preserve strong, productive collaborations for the benefit of patients and the public at the same time they take clear effective action to avoid relationships that could undermine public trust.”<sup>5</sup> It is in this spirit that many hospitals, notably including all Veterans Health Administration (VHA) hospitals, have already established policies governing interaction between hospital personnel and industry representatives.<sup>6-13</sup>



Existing hospital policies on interaction with industry seek to minimize inappropriate influence of industry representatives on medical judgment and patient care. Additionally, these policies address a variety of concerns stemming from the very presence of industry representatives in the hospital setting, such as patient and visitor safety, patient privacy and confidentiality, and disruption of patient care. A cursory review of such policies reveals a number of common themes, including access by industry representatives to sites and patients, acceptance by hospital personnel of gifts and compensation, industry support for educational activities, and industry support for and collaboration in research. Not surprisingly, policies vary considerably in both content and comprehensiveness according to the type of facility in question; for instance, academic medical center policies generally address matters of industry-sponsored research in much greater detail than do the policies of community hospitals.

#### *AMA Guidance on Interaction with Industry*

Real and perceived conflicts of interest arising from physician-industry interaction in the hospital setting are not entirely avoidable. For example, within the context of continuing medical education provided in the hospital, individuals who have financial or other interests in the subject matter, such as industry representatives, may be best suited—or even the only ones appropriately suited—to deliver the education and training physicians need. Recognizing this reality, the AMA has developed comprehensive policy explicating how medicine may collaborate with industry without compromising the “independence and commitment to fidelity and service that define the medical profession.”<sup>3</sup>

This substantial body of AMA policy offers ethical guidance on each of the common themes, noted above, that run throughout hospital policies on industry interaction (see appendix for full text of cited policies):

- Site and patient access by industry representatives:
  - E-5.0591 Patient Privacy and Outside Observers to the Clinical Encounter
  - E-8.047 Industry Representatives in Clinical Settings
- Acceptance of gifts and compensation:
  - E-8.06 Prescribing and Dispensing Drugs and Devices
  - E-8.061 Gifts to Physicians from Industry
- Industry support for educational activities:
  - E-9.0115 Financial Relationships with Industry in Continuing Medical Education
- Industry support for and collaboration on research:
  - E-8.031 Conflicts of Interest: Biomedical Research
  - E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials
  - H-460.981 University-Industry Cooperative Research Ventures

It is no mere coincidence that AMA guidance on industry interaction is similar to the guidance offered by hospital policies. Rather, it appears that in some cases AMA policy has driven the development of hospital policies, as evidenced by reference to AMA ethical opinions throughout some hospitals’ policies. All hospitals would be well served to take this approach and implement policies on industry interaction consistent with AMA policy.

#### *Role of the Medical Staff in Developing Hospital Policies on Industry Interaction*

Regardless of the particulars of a hospital’s policy on industry interaction, it is essential that the hospital’s organized medical staff play a role in its development and ultimately approve its content. Medical staff engagement in this regard is important for at least two reasons. First, some of the concerns stemming from industry interaction are matters of quality and patient safety, areas for which primary responsibility has been vested in the medical staff.<sup>14,15</sup> Second, policies on industry interaction can affect multiple aspects of physician practice and professionalism—for example, whether and how physicians distribute sample medications, the availability of continuing medical education opportunities in the hospital setting, the prospect that a physician will be publically named in a manufacturer’s reporting of payments to physicians as required by the Physician Payments Sunshine Act, or the availability of funding for research. Given their profound influence on quality, patient safety, and physician practice and professionalism, hospital policies on industry interaction should be developed with appropriate input from, and should ultimately be approved by, the organized medical staff.

## CONCLUSION

Collaboration between medicine and industry has “driven innovation in patient care, contributed to the economic well-being of the community, and provided significant resources (financial and otherwise) for professional education, to the ultimate benefit of patients and the public.”<sup>5</sup> However, because the interests and obligations of medicine and industry differ, this collaboration holds the potential to create real and perceived conflicts of interest, and ultimately threats to quality and patient safety, which medicine and industry must strive to address. The AMA has developed comprehensive policy to help physicians ensure that their collaboration with industry does not compromise their professionalism or the quality and safety of the care they deliver. Hospitals, many of them taking a cue from AMA policy, have sought to address these conflicts and their attendant threats by developing policies governing the interaction of hospital personnel with pharmaceutical, medical device, and other industry representatives within the hospital setting. The AMA should encourage all hospitals to develop such policies, consistent with AMA policy and with appropriate involvement of and approval by the organized medical staff.

## RECOMMENDATION

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 6-I-13 and that the remainder of this report be filed:

1. That our American Medical Association (AMA) encourage all hospitals to adopt policies governing the interaction of hospital personnel—including both employed physicians and independent members of the medical staff, as well as other hospital staff—with pharmaceutical, medical device, and other industry representatives within the hospital setting. Such policies should: (a) be developed through a collaborative effort of the hospital’s organized medical staff, administration, and governing body, and approved by the organized medical staff; and (b) be consistent with applicable AMA policy and ethical opinions on the subject of medicine-industry interaction, including but not limited to:
  - E-1.001 Principles of Medical Ethics
  - E-5.0591 Patient Privacy and Outside Observers to the Clinical Encounter
  - E-8.03 Conflicts of Interest: Guidelines
  - E-8.031 Conflicts of Interest: Biomedical Research
  - E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials
  - E-8.047 Industry Representatives in Clinical Settings
  - E-8.06 Prescribing and Dispensing Drugs and Devices
  - E-8.061 Gifts to Physicians from Industry
  - E-9.0115 Financial Relationships with Industry in Continuing Medical Education
  - H-460.981 University-Industry Cooperative Research Ventures.
2. That our AMA inform the American Hospital Association of the AMA’s position on hospital policies governing the interaction of hospital personnel with pharmaceutical, medical device, and other industry representatives within the hospital setting.

## REFERENCES

1. AMA Policy E-1.001. Principles of Medical Ethics: Principle V.
2. AMA Policy E-9.011. Continuing Medical Education.
3. AMA Policy E-9.0115. Financial Relationships with Industry in Continuing Medical Education.
4. AMA Policy E-8.047. Industry Representatives in Clinical Settings.
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14. AMA Policy H-225.957. Principles for Strengthening the Physician-Hospital Relationship.
15. AMA Policy E-4.05. Organized Medical Staff.

#### APPENDIX - Relevant AMA Policy

##### E-1.001 Principles of Medical Ethics

###### PREAMBLE:

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
- II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
- V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
- IX. A physician shall support access to medical care for all people.

Adopted June 1957; revised June 1980; revised June 2001

##### E-4.05 Organized Medical Staff

The organized medical staff performs essential hospital functions even though it may often consist primarily of independent practicing physicians who are not hospital employees. The core responsibilities of the organized medical staff are the promotion of patient safety and the quality of care. Members of the organized medical staff may choose to act as a group for the purpose of communicating and dealing with the governing board and others with respect to matters that concern the interest of the organized medical staff and its members. This is ethical so long as there is no adverse effect on patient safety and the quality of care. (IV, VI) Issued July 1983; Updated June 1994 and June 2004.

##### E-5.0591 Patient Privacy and Outside Observers to the Clinical Encounter

Outside observers are individuals who are present during patient-physician encounters and are neither members of a health care team nor enrolled in an educational program for health professionals such as medical students. Physicians are ethically and legally responsible for safeguarding patient privacy and, therefore, must inform outside observers about medical standards of confidentiality and require them to agree to these standards. Outside observers may be present during the medical encounter only with the patient's explicit agreement. Physicians should avoid situations in which an outside observer's presence may negatively influence the medical interaction and compromise care. The presence of outside observers during encounters between physicians and patients who lack decision-making capacity should not be permitted, except under rare circumstances and with consent of the parent or legal guardian. Physicians should not accept payment from outside observers because accepting such payment may undermine the patient-physician relationship. (I, IV, VIII) Issued November 2005 based on the report "Patient Privacy and Outside Observers to the Clinical Encounter," adopted June 2005.

##### E-8.03 Conflicts of Interest: Guidelines

Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician to unnecessarily hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit

is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit. (II) Issued July 1986; Updated June 1994.

#### E-8.031 Conflicts of Interest: Biomedical Research

Avoidance of real or perceived conflicts of interest in clinical research is imperative if the medical community is to ensure objectivity and maintain individual and institutional integrity. All medical centers should develop specific guidelines for their clinical staff on conflicts of interest. These guidelines should include the following rules: (1) once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, she or he, as an individual, cannot ethically buy or sell the company's stock until the involvement ends and the results of the research are published or otherwise disseminated to the public; (2) any remuneration received by the researcher from the company whose product is being studied must be commensurate with the efforts of the researcher on behalf of the company; and (3) clinical investigators should disclose any material ties to companies whose products they are investigating, including financial ties, participation in educational activities supported by the companies, participation in other research projects funded by the companies, consulting arrangements, and any other ties. The disclosures should be made in writing to the medical center where the research is conducted, organizations that are funding the research, and journals that publish the results of the research. An explanatory statement that discloses conflicts of interest should accompany all published research. Other types of publications, such as a letters to the editor, should also include an explanatory statement that discloses any potential conflict of interest. In addition, medical centers should form review committees to examine disclosures by clinical staff about financial associations with commercial corporations. (II, IV) Issued March 1992 based on the report "Conflicts of Interest in Biomedical Research," adopted December 1989 (JAMA. 1990; 263: 2790-2793); Updated June 1999 based on the report "Conflicts of Interest: Biomedical Research," adopted December 1998.

#### E-8.0315 Managing Conflicts of Interest in the Conduct of Clinical Trials

As the biotechnology and pharmaceutical industries continue to expand research activities and funding of clinical trials, and as increasing numbers of physicians both within and outside academic health centers become involved in partnerships with industry to perform these activities, greater safeguards against conflicts of interest are needed to ensure the integrity of the research and to protect the welfare of human subjects. Physicians should be mindful of the conflicting roles of investigator and clinician and of the financial conflicts of interest that arise from incentives to conduct trials and to recruit subjects. In particular, physicians involved in clinical research should heed the following guidelines: (1) Physicians should agree to participate as investigators in clinical trials only when it relates to their scope of practice and area of medical expertise. They should have adequate training in the conduct of research and should participate only in protocols which they are satisfied are scientifically sound. (2) Physicians should be familiar with the ethics of research and should agree to participate in trials only if they are satisfied that an Institutional Review Board has reviewed the protocol, that the research does not impose undue risks upon research subjects, and that the research conforms to government regulations. (3) When a physician has treated or continues to treat a patient who is eligible to enroll as a subject in a clinical trial that the physician is conducting, the informed consent process must differentiate between the physician's roles as clinician and investigator. This is best achieved when someone other than the treating physician obtains the participant's informed consent to participate in the trial. This individual should be protected from the pressures of financial incentives, as described in the following section. (4) Any financial compensation received from trial sponsors must be commensurate with the efforts of the physician performing the research. Financial compensation should be at fair market value and the rate of compensation per patient should not vary according to the volume of subjects enrolled by the physician, and should meet other existing legal requirements. Furthermore, according to Opinion 6.03, "Fee Splitting: Referral to Health Care Facilities," it is unethical for physicians to accept payment solely for referring patients to research studies. (5) Physicians should ensure that protocols include provisions for the funding of subjects' medical care in the event of complications associated with the research. Also, a physician should not bill a third party payer when he or she has received funds from a sponsor to cover the additional expenses related to conducting the trial. (6) The nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process. Disclosure to participants also should include information on uncertainties that may exist regarding funding of treatment for possible complications that may arise during the course of the trial. Physicians should ensure that such disclosure is included in any written informed consent. (7) When entering into a contract to perform research, physicians should ensure themselves that the presentation or publication of results will not be unduly delayed or otherwise obstructed by the sponsoring company. (II, V) Issued June 2001 based on the report "Managing Conflicts of Interest in the Conduct of Clinical Trials," adopted December 2000 (JAMA. 2002; 287: 78-84).

#### E-8.047 Industry Representatives in Clinical Settings

Manufacturers of medical devices may facilitate their use through industry representatives who can play an important role in patient safety and quality of care by providing information about the proper use of the device or equipment as well as technical assistance to physicians. Because of their obligation to protect their patients, physicians must strive to prevent industry representatives from breaching patient privacy and confidentiality, and seek to verify that they are properly credentialed and do not exceed the bounds of their training. Physicians may fulfill these obligations by satisfying themselves that the facility has suitable mechanisms in place to accomplish these functions. Physicians or their designees must disclose to patients the anticipated presence and roles of industry representatives during clinical encounters, and obtain patients' approval. This requires neither disclosure of the representative's specific identity nor a formal informed consent process. (I, IV, V) Issued November 2007 based on the report "Industry Representatives in Clinical Settings," adopted June 2007.

## E-8.06 Prescribing and Dispensing Drugs and Devices

- (1) Physicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient.
- (2) Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved.
- (3) Physicians may own or operate a pharmacy, but generally may not refer their patients to the pharmacy. Exceptionally, a physician may refer patients to his or her pharmacy in accord with guidelines established in Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician." Physicians may dispense drugs within their office practices provided such dispensing primarily benefits the patient.
- (4) In all instances, physicians should respect the patient's freedom of choice in selecting who will fill their prescriptions as they are in the choice of a physician and, therefore, have the right to have a prescription filled wherever they wish. (See Opinions 9.06, "Free Choice," and 8.03, "Conflicts of Interest: Guidelines.") Physicians should not urge patients to fill prescriptions from an establishment which has entered into a business or other preferential arrangement with the physician with respect to the filling of the physician's prescriptions.
- (5) A third party's offer to indemnify a physician for lawsuits arising from the physician's prescription or use of the third party's drug, device, or other product, introduces inappropriate incentives into medical decision making. Such offers, regardless of their limitations, therefore constitute unacceptable gifts. This does not address contractual assignments of liability between employers or in research arrangements, nor does it address government indemnification plans.
- (6) Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. Since a prescription is part of the patient's medical record, the patient is entitled to a copy of the physician's prescription for drugs or devices, including eyeglasses and contact lenses. Therefore, physicians should not discourage patients from requesting a written copy of a prescription. (II, III, IV, V) Issued June 2002. This opinion is a consolidation of previous Opinions 6.04, "Fee Splitting: Drug or Device Prescription Rebates;" 8.06, "Drugs and Devices: Prescribing;" and 8.07, "Gifts to Physicians: Offers of Indemnity."

## E-8.061 Gifts to Physicians from Industry

Many gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries serve an important and socially beneficial function. For example, companies have long provided funds for educational seminars and conferences. However, there has been growing concern about certain gifts from industry to physicians. Some gifts that reflect customary practices of industry may not be consistent with the Principles of Medical Ethics. To avoid the acceptance of inappropriate gifts, physicians should observe the following guidelines:

- (1) Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. The use of drug samples for personal or family use is permissible as long as these practices do not interfere with patient access to drug samples. It would not be acceptable for non-retired physicians to request free pharmaceuticals for personal use or use by family members.
- (2) Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (eg, pens and notepads).
- (3) The Council on Ethical and Judicial Affairs defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where
  - (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and
  - (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or conflict of interest should be made.
- (4) Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference.
- (5) Subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted outside of modest meals or social events held as a part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses.
- (6) Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations.

- (7) No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures. (II)

Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990 (JAMA. 1991; 265: 501); Updated June 1996 and June 1998.

#### E-9.011 Continuing Medical Education

Physicians should strive to further their medical education throughout their careers, to ensure that they serve patients to the best of their abilities and live up to professional standards of excellence. Participating in certified continuing medical education (CME) activities is critical to fulfilling this professional commitment to lifelong learning. As attendees of CME activities, physicians should:

- (a) Select activities that are of high quality and are appropriate for the physician's educational needs.
- (b) Choose activities that are carried out in keeping with ethical guidelines and applicable professional standards.
- (c) Claim only the credit commensurate with the extent of participation in the CME activity.
- (d) Decline any subsidy offered by a commercial entity other than the physician's employer to compensate the physician for time spent or expenses of participating in a CME activity. (I, V) Issued December 1993; Updated June 1996; Updated November 2012; Amended June 2013.

#### E-9.0115 Financial Relationships with Industry in Continuing Medical Education

In an environment of rapidly changing information and emerging technology, physicians must maintain the knowledge, skills, and values central to a healing profession. They must protect the independence and commitment to fidelity and service that define the medical profession.

Financial or in-kind support from pharmaceutical, biotechnology or medical device companies that have a direct interest in physicians' recommendations creates conditions in which external interests could influence the availability and/or content of continuing medical education (CME). Financial relationships between such sources and individual physicians who organize CME, teach in CME, or have other roles in continuing professional education can carry similar potential to influence CME in undesired ways.

CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations promotes confidence in the independence and integrity of professional education, as does CME in which organizers, teachers, and others involved in educating physicians do not have financial relationships with industry that could influence their participation. When possible, CME should be provided without such support or the participation of individuals who have financial interests in the educational subject matter.

In some circumstances, support from industry or participation by individuals who have financial interests in the subject matter may be needed to enable access to appropriate, high-quality CME. In these circumstances, physician-learners should be confident that vigorous efforts will be made to maintain the independence and integrity of educational activities.

Individually and collectively physicians must ensure that the profession independently defines the goals of physician education, determines educational needs, and sets its own priorities for CME. Physicians who attend CME activities should expect that, in addition to complying with all applicable professional standards for accreditation and certification, their colleagues who organize, teach, or have other roles in CME will:

- (a) be transparent about financial relationships that could potentially influence educational activities.
- (b) provide the information physician-learners need to make critical judgments about an educational activity, including:
  - (i) the source(s) and nature of commercial support for the activity; and/or
  - (ii) the source(s) and nature of any individual financial relationships with industry related to the subject matter of the activity; and
  - (iii) what steps have been taken to mitigate the potential influence of financial relationships.
- (c) protect the independence of educational activities by:
  - (i) ensuring independent, prospective assessment of educational needs and priorities;
  - (ii) adhering to a transparent process for prospectively determining when industry support is needed;
  - (iii) giving preference in selecting faculty or content developers to similarly qualified experts who do not have financial interests in the educational subject matter;
  - (iv) ensuring a transparent process for making decisions about participation by physicians who may have a financial interest in the educational subject matter;
  - (v) permitting individuals who have a substantial financial interest in the educational subject matter to participate in CME only when their participation is central to the success of the educational activity; the activity meets a demonstrated need in the professional community; and the source, nature, and magnitude of the individual's specific financial interest is disclosed; and
  - (vi) taking steps to mitigate potential influence commensurate with the nature of the financial interest(s) at issue, such as prospective peer review. (I, V) Issued November 2011 based on the report "Financial Relationships with Industry in Continuing Medical Education," adopted June 2011.

## H-225.957 Principles for Strengthening the Physician-Hospital Relationship

....

- (1) The organized medical staff and the hospital governing body are responsible for the provision of quality care, providing a safe environment for patients, staff and visitors, and working continuously to improve patient care and outcomes, with the primary responsibility for the quality of care rendered and for patient safety vested with the organized medical staff. These activities depend on mutual accountability, interdependence, and responsibility of the organized medical staff and the hospital governing body for the proper performance of their respective obligations.
- (2) The organized medical staff, a self-governing organization of professionals, possessing special expertise, knowledge and training, discharges certain inherent professional responsibilities by virtue of its authority to regulate the professional practice and standards of its members, and assumes primary responsibility for many functions, including but not limited to: the determination of organized medical staff membership; performance of credentialing, privileging and other peer review; and timely oversight of clinical quality and patient safety....

(Res. 828, I-07; Reaffirmed in lieu of Res. 730, A-09; Modified: Res. 820, I-09; Reaffirmed: Res. 725, A-10; Reaffirmation A-12)

## H-225.971 Credentialing and the Quality of Care

It is the policy of the AMA:

- (1) that the hospital medical staff be recognized within the hospital as the entity with the overall responsibility for the quality of medical care;
- (2) that hospital medical staff bylaws reaffirm The Joint Commission standard that medical staffs have "overall responsibility for the quality of the professional services provided by individuals with clinical privileges";
- (3) that each hospital's quality assurance, quality improvement, and other quality-related activities be coordinated with the hospital medical staff's overall responsibility for quality of medical care;
- (4) that the hospital governing body, management, and medical staff should jointly establish the purpose, duties, and responsibilities of the hospital administrative personnel involved in quality assurance and other quality-related activities; establish the qualifications for these positions; and provide a mechanism for medical staff participation in the selection, evaluation, and credentialing of these individuals;
- (5) that the hospital administrative personnel performing quality assurance and other quality activities related to patient care report to and be accountable to the medical staff committee responsible for quality improvement activities;
- (6) that the purpose, duties, responsibilities, and reporting relationships of the hospital administrative personnel performing quality assurance and other quality-related activities be included in the medical staff and hospital corporate bylaws;
- (7) that the general processes and policies related to patient care and used in a hospital quality assurance system and other quality-related activities should be developed, approved, and controlled by the hospital medical staff; and
- (8) that any physician hired or retained by a hospital to be involved solely in medical staff quality of care issues be credentialed by the medical staff prior to employment in the hospital. (BOT Rep. T, I-92; Reaffirmed: CMS Rep. 10, A-03; Modified: CMS Rep. 4, A-13)

## H-460.981 University-Industry Cooperative Research Ventures

- (1) Academic institutions and industrial firms should establish explicit guidelines, policies and goals for cooperative research ventures that will best accommodate the interests and integrity of both organizations. The mission of academic institutions should not be compromised in any manner through participation in cooperative ventures.
- (2) Faculty members should disclose the nature of and time spent in university-industry research ventures. When their major orientation becomes commercial development rather than teaching and research, faculty members should take a leave of absence or leave the university to pursue their dominant interest.
- (3) Regardless of the nature of the partnership arrangement, patent and licensing rights emanating from university-industry cooperative ventures should accrue to university, investigator and industry by a mechanism agreed upon in advance. The degree to which a research project depends on proprietary information should be a prime consideration during the planning stages of a university-industry cooperative venture. Proprietary information can rightfully be viewed as being excluded from full disclosure of research results and, thus, its confidentiality should be maintained by both parties.
- (4) Universities should not engage in research at the expense of the educational mission of the institutions. Monetary profits emanating from cooperative ventures should accrue to the university, investigators and industry by an agreeable mechanism.
- (5) The free and expeditious communication of research findings to the scientific community should be a major objective of academia and industry. Reasonable delays for review of patentable subject matter and for filing of a patent application should be permitted.
- (6) The federal government should encourage the participation of small businesses in cooperative research ventures, and should continue to support starter programs for such projects. The federal government should be charged with conducting an ongoing analysis of the productivity and capacity of the nation's biomedical research enterprise, with the university-industry partnership as the focal point of the analyses.
- (7) State and local governments should be encouraged to provide a legislative, economic and research environment conducive to the establishment of university and industry cooperatives ventures.
- (8) Private industry should increase its financial support of university-industry cooperative ventures in biomedical research. (BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CSAPH Rep. 3, A-07)

## D-140.981 Ethical Guidelines on Gifts to Physicians from Industry

Our AMA shall:

- (1) communicate to all medical school deans and residency program directors the importance of including education on ethical guidelines regarding gifts to physicians from industry within the ethics curriculum of their medical student and housestaff education programs;
- (2) communicate to all medical school deans and residency program directors the content of CEJA Opinion E-8.061 and shall recommend that it or another nationally-recognized ethical guideline be used as the basis for educational content on this issue;
- (3) recommend to all medical school deans and residency program directors that appropriate policies be developed for medical students, housestaff and faculty in their respective institutions regarding the issue of gifts to physicians from industry;
- (4) work with the Association of American Medical Colleges (AAMC) and the American Association of Colleges of Osteopathic Medicine (AACOM) to encourage the Liaison Committee on Medical Education and the American Osteopathic Association Commission on Osteopathic College Accreditation to require all medical schools to make known to students the existence of the physician-industry financial disclosure databases that exist or will be created by 2013 as required by the Patient Protection and Affordable Care Act; and
- (5) work with AAMC and AACOM to encourage all medical school faculty to model professional behavior to students by disclosing the existence of financial ties with industry, in accordance with existing disclosure policies at each respective medical school. (Res. 13, A-02; Reaffirmed: Res. 303, A-05; Appended: Res. 308, A-11)

**28. QUALIFICATIONS, SELECTION, AND ROLE OF HOSPITAL MEDICAL DIRECTORS  
AND OTHERS PROVIDING MEDICAL MANAGEMENT SERVICES  
(RESOLUTION 821-I-13)**

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

**HOUSE ACTION: RECOMMENDATIONS ADOPTED  
IN LIEU OF RESOLUTION 821-I-13 AND  
REMAINDER OF REPORT FILED**

*See Policy [H-235.981](#).*

At its 2013 Interim Meeting, the House of Delegates (HOD) referred Resolution 821-I-13, "Qualifications, Selection, and Role of Hospital Medical Directors and others Providing Medical Management Services," to the Board of Trustees for report. Resolution 821, which was introduced by the Organized Medical Staff Section, asked the AMA to amend policy H-235.981 to reflect the following principles not addressed by the current policy:

1. Individuals employed by or under contract with hospitals or health systems to provide medical management services should in all cases be licensed physicians;
2. An individual providing medical management services in a single hospital should be a member of the organized medical staff of that hospital;
3. An individual providing medical management services at the system level need be a member in good standing of only one medical staff within the system, provided that he or she works in collaboration with the elected leaders of the medical staffs throughout the system and with any hospital-level medical managers; and
4. The organized medical staff should maintain overall responsibility for the quality of care provided to patients by the hospital.

Although testimony supported the spirit of Resolution 821, the HOD was reticent to adopt such broad changes to policy before its members had had ample opportunity to review the details of the proposed amendments. Members also expressed concern regarding the proposed policy's treatment of licensure and medical staff membership requirements for individuals retained by multi-hospital health systems to provide medical management services at the system level.

**BACKGROUND**

In 2012, Chicago media reported that a physician who had allowed his medical licensure to lapse more than a decade earlier had been serving as chief medical officer (CMO) at a Chicago-area hospital for eight years. Administrators at the hospital in question acknowledged that they knew at the time they hired him that the physician was not licensed to practice medicine. Despite public criticism of this decision, administrators insisted that because



the CMO did not directly treat patients, there was no need for him to maintain his medical license; administrators even suggested that their next CMO would not necessarily be a licensed physician, either.<sup>1,2</sup>

The story was soon picked up by a national healthcare media outlet, which contacted the AMA for comment. A review of relevant AMA policy revealed that while current AMA policy asserts that hospital medical directors should be physicians, it does not explicitly state that they should be licensed to practice medicine. The policy review identified three additional limitations of the existing policy, including:

- The policy is specific to “hospital medical directors” and so could be viewed as excluding others in positions with similar duties, such as CMOs, vice presidents for medical affairs (VPMAs), etc.
- The policy contains no requirement that hospital medical directors or individuals in similar positions be members of the hospital’s organized medical staff.
- While the policy recognizes the medical staff’s specific responsibility for overseeing the quality of the professional services provided by individuals with clinical privileges, it does not acknowledge the medical staff’s broader responsibility for the overall quality of care provided to patients by the hospital.

## DISCUSSION

### *Applicability of AMA Policy to All Individuals Providing Medical Management Services*

Policy H-235.981 addresses the qualifications, selection, and role of “hospital medical directors.” While that may have been an appropriate term when the policy was adopted in 1989, hospital management has evolved significantly in the last two and a half decades, accompanied by a “proliferation of C-Suite titles.”<sup>3</sup> Today, individuals with a range of titles perform the duties or a portion thereof of a traditional hospital medical director—for example, CMOs and VPMAs. Rather than insert a constantly shifting laundry list of such titles into AMA policy, Policy H-235.981 should be amended such that it broadly addresses individuals employed by or under contract with hospitals/health systems to provide medical management services.

### *Licensure of Individuals Providing Medical Management Services*

Individuals employed by or under contract with hospitals/health systems to provide medical management services typically do not, at least in their roles as medical managers, provide care to individual patients. Nevertheless, medical managers consistently rely on their medical training, experience, and perspective to make decisions and take actions that influence the individual patient care decisions of physicians and other clinicians providing care throughout the hospital. CMOs, VPMAs, and others in similar positions arguably are thus engaged in the practice of medicine and, as such, should be licensed to practice medicine and required to maintain that licensure as a means of ensuring that their requisite knowledge and skills remain intact.<sup>4,5</sup>

This seemingly simple tenet is complicated by situations in which a physician is hired to provide medical management services at the system level—and not directly at any individual hospital—by a health system that spans multiple states. Ideally, this physician would be licensed to practice medicine in each of the states in which the health system has a hospital that would be influenced by the physician’s provision of system-level medical management services. Unfortunately, given the time, energy, and other resources required of a physician to obtain and maintain licensure in multiple states (five or more states in some instances), this expectation could be burdensome, and therefore may be unworkable in practice.

It would be more practical to expect a physician providing system-level medical management services to be licensed in at least one state in which the health system has a hospital over which the physician will exert influence. This one-state requirement would be broadened to include licensure in other states if so required by state law—for example, if a state deemed a physician providing medical management services, even if at the system level, to be engaged in the practice of medicine in that state. Notwithstanding differences in state licensure requirements, this balanced solution ensures at a minimum that physicians serving as system-level CMOs, VPMAs, etc. have and maintain the medical knowledge and skills essential to providing effective medical management services.

### *Medical Staff Membership of Individuals Providing Medical Management Services*

AMA policy, as well as federal regulation, vest in the organized medical staff primary responsibility for the overall quality of care provided to patients by the hospital.<sup>6-8</sup> Moreover, AMA policy maintains that hospital administrative personnel performing quality assurance and other quality activities related to patient care should report to and be accountable to the medical staff.<sup>8</sup> In some sense, then, CMOs, VPMAAs, and other medical managers tasked with improving quality of care may be viewed as extensions of the medical staff who assist the staff in fulfilling its statutory responsibilities. In order to effectively perform their own duties, medical managers must therefore develop strong working relationships with and seek to truly understand the perspective of medical staffs and their members. It is only through the development of such relationships, which are best facilitated by membership and active participation in the medical staff, that medical managers can create hospital policies, procedures, and initiatives that are in touch with the clinical and professional needs of the medical staff, and that ultimately are in the best interest of the patients served by the hospital. For this reason, CMOs, VPMAAs, and others providing medical management services should be members of the medical staffs of the hospitals for which they provide such services.

As with licensure requirements, this principle is complicated by situations in which a system-level medical manager exerts influence over multiple hospitals. Consider for example a physician who is employed by a large multi-hospital system to provide medical management services at the system level, and who therefore has the potential to influence the care provided at tens or even hundreds of hospitals spanning multiple states. While it is appealing to suggest that this physician should be a member of each of the medical staffs of the hospitals over which he or she may exert influence, this requirement may be infeasible in practice for a variety of reasons—for example:

- A system-level medical manager, especially one whose care for individual patients is limited by his or her medical management duties, would be hard-pressed to meet the admissions or inpatient care volume requirements established by each medical staff within the system.
- A system-level medical manager likely would not be able to fulfill the membership obligations of multiple medical staffs, such as meeting attendance, call coverage, etc.
- A system-level medical manager for a multi-state health system would have to be licensed in multiple states in order to serve on medical staffs across the system, an expectation which may be unworkable in practice as noted above.

Medical staffs conceivably could create new staff categories for system-level medical managers that would exempt them from these and other potentially burdensome requirements. However, creating categories of this nature defeats the purpose of requiring medical staff membership in the first place, as appointment to ex-officio categories would stimulate little more than token involvement of the medical manager in the activities of the medical staff.

Fortunately, the management structure of most health systems prevents this complication from usurping the medical staff's ultimate responsibility for the quality of care provided in the hospital. After all, system-level medical managers *should* be working in collaboration not only with the medical staffs of the hospitals they oversee, but also with any hospital-level medical managers (who should themselves be members of the medical staff, as discussed above). Consequently, it may not be imperative for an individual providing medical management services at the system level to maintain medical staff membership at each and every hospital within the system. Nevertheless, system-level medical managers should maintain medical staff membership in at least one hospital within the system to ensure that they do not become too far removed from the clinical settings in which the policies and initiatives they help to shape will ultimately be implemented.

### *Medical Staff Responsibility for Quality and Safety*

As currently written, Policy H-235.981 asserts that “the organized medical staff should maintain overall responsibility for the quality of the professional services provided by individuals with clinical privileges....” While this is not an inaccurate statement, it is an incomplete description of the role of the medical staff in quality and safety. As noted above, the medical staff is responsible for the *overall* quality of medical care provided to patients by the hospital.<sup>6-8</sup> In addition to ensuring the quality of care provided by clinicians granted privileges, the medical staff's broad responsibility in this regard includes duties such as providing leadership in the development of and participating in performance improvement activities, for example.<sup>9,10</sup> This distinction is particularly important in the delineation of the role of a CMO, VPMA, or other medical manager; regardless of that individual's role, the medical staff, not a CMO or VPMA, must retain primary responsibility for quality and safety.

## CONCLUSION

Medical directors, CMOs, VPMA, CQOs, and others who provide medical management services should be licensed physicians and members of the organized medical staff. Furthermore, even when a hospital or health system retains an individual to provide such services, the organized medical staff should remain responsible for the overall quality of care provided to patients by the hospital. Existing AMA policy does not adequately address these principles and should therefore be amended accordingly.

## RECOMMENDATION

The Board of Trustees recommends that the following be adopted in lieu of Resolution 821-I-13 and that the remainder of the report be filed:

1. That our American Medical Association (AMA) amend Policy H-235.981 to read as follows:

H-235.981 ~~The Qualifications, Selection, and Role of the Hospital~~ Medical Directors, Chief Medical Officers, Vice Presidents for Medical Affairs, and Others Employed by or Under Contract with Hospitals/Health Systems to Provide Medical Management Services

- (1) Our AMA supports the following guidelines regarding the ~~qualifications and selection role of the hospital medical director~~ individuals employed by or under contract with a hospital/health system to provide medical management services, such as medical directors, chief medical officers, and vice presidents for medical affairs:
  - (a) The hospital governing body, management, and medical staff should jointly (i) determine if there is a need to employ or contract with one or more ~~a medical director~~ individuals to provide medical management services; (ii) establish the purpose, duties, and responsibilities of ~~this~~ these positions; (iii) establish the qualifications for ~~this~~ these positions; and (iv) ~~provide~~ establish and sustain a mechanism for input from and participation by elected leaders of the medical staff ~~input into~~ the selection, evaluation, and termination of ~~the hospital medical director~~ individuals holding these positions.
  - (b) An individual employed by or under contract with a hospital/health system to provide medical management services should be a physician (MD/DO).
  - (c) A physician providing medical management services at a single hospital should be licensed to practice medicine in the same state as the hospital for which he or she provides such services. Additionally, he or she should be a member in good standing of the organized medical staff of the hospital for which he or she provides medical management services.
  - (d) Where feasible, a physician providing medical management services at the system level for a multi-hospital health system should be licensed to practice medicine in each of the states in which the health system has a hospital that will be influenced by the physician's work. At a minimum, the physician should be licensed in at least one state in which the health system has a hospital over which the physician will exert influence, and in as many other states as may be required by state licensing law.
  - (e) Where feasible, a physician providing medical management services at the system level for a multi-hospital health system should be a member in good standing of the medical staff of each of the hospitals that will be influenced by the physician's work. At a minimum, the physician should: (i) be a member in good standing of at least one of the medical staffs of the hospitals that will be influenced by the physician's work; and (ii) work in collaboration with elected medical staff leaders throughout the system and with any individuals who provide medical management services at the hospital level.
- (2) Our AMA supports the following guidelines regarding the role of the organized medical staff vis-à-vis individuals employed by or under contract with hospitals/health systems to provide medical management services:

- (a) The purpose, duties, and responsibilities of ~~the medical director~~ individuals employed by or under contract with the hospital/health system to provide medical management services should be included in the medical staff bylaws and in the hospital/health system corporate bylaws.
- (b) ~~(3)~~ The organized medical staff should maintain overall responsibility for the quality of care provided to patients by the hospital, including the quality of the professional services provided by individuals with clinical privileges, and should have the responsibility of reporting to the governing body.
- (c) ~~(4)~~ The chief elected officer of the medical staff should represent the medical staff to the administration, governing body, and external agencies.
- (d) ~~(5)~~ Government regulations ~~which~~ that would mandate that a hospital medical director who any individual not elected or appointed by the medical staff would have authority over the medical staff should be opposed.

~~The hospital medical director shall be a physician.~~

## REFERENCES

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## APPENDIX 1 - Clean Version of Policy H-235.981 Showing Proposed Amendments

H-235.981 – Qualifications, Selection, and Role of Medical Directors, Chief Medical Officers, Vice Presidents for Medical Affairs, and Others Employed by or Under Contract with Hospitals/Health Systems to Provide Medical Management Services

1. Our AMA supports the following guidelines regarding the qualifications and selection of individuals employed by or under contract with a hospital/health system to provide medical management services, such as medical directors, chief medical officers, and vice presidents for medical affairs:
  - a. The hospital governing body, management, and medical staff should jointly: (i) determine if there is a need to employ or contract with one or more individuals to provide medical management services; (ii) establish the purpose, duties, and responsibilities of these positions; (iii) establish the qualifications for these positions; and (iv) establish and sustain a mechanism for input from and participation by elected leaders of the medical staff in the selection, evaluation, and termination of individuals holding these positions.
  - b. An individual employed by or under contract with a hospital or health system to provide medical management services should be a physician (MD/DO).
  - c. A physician providing medical management services at a single hospital should be licensed to practice medicine in the same state as the hospital for which he or she provides such services. Additionally, he or she should be a member in good standing of the organized medical staff of the hospital for which he or she provides medical management services.
  - d. Where feasible, a physician providing medical management services at the system level for a multi-hospital health system should be licensed to practice medicine in each of the states in which the health system has a hospital that will be influenced by the physician's work. At a minimum, the physician should be licensed in at least one state in which the health system has a hospital over which the physician will exert influence, and in as many other states as may be required by state licensing law.

- e. Where feasible, a physician providing medical management services at the system level for a multi-hospital health system should be a member in good standing of the medical staff of each of the hospitals that will be influenced by the physician's work. At a minimum, the physician should: (i) be a member in good standing of at least one of the medical staffs of the hospitals that will be influenced by the physician's work; and (ii) work in collaboration with elected medical staff leaders throughout the system and with any individuals who provide medical management services at the hospital level.
2. Our AMA supports the following guidelines regarding the role of the organized medical staff vis-à-vis individuals employed by or under contract with hospitals/health systems to provide medical management services:
    - a. The purpose, duties, and responsibilities of individuals employed by or under contract with the hospital/health system to provide medical management services should be included in the medical staff bylaws and in the hospital/health system corporate bylaws.
    - b. The organized medical staff should maintain overall responsibility for the quality of care provided to patients by the hospital, including the quality of the professional services provided by individuals with clinical privileges, and should have the responsibility of reporting to the governing body.
    - c. The chief elected officer of the medical staff should represent the medical staff to the administration, governing body, and external agencies.
    - d. Government regulations that would mandate that any individual not elected or appointed by the medical staff would have authority over the medical staff should be opposed.

#### APPENDIX 2 - Relevant AMA Policy

##### H-225.950 AMA Principles for Physician Employment

(1) (e) Assuming a title or position that may remove a physician from direct patient-physician relationships – such as medical director, vice president for medical affairs, etc. – does not override professional ethical obligations. Physicians whose actions serve to override the individual patient care decisions of other physicians are themselves engaged in the practice of medicine and are subject to professional ethical obligations and may be legally responsible for such decisions....  
(BOT Rep. 6, I-12)

##### H-225.957 Principles for Strengthening the Physician-Hospital Relationship

....

(1) The organized medical staff and the hospital governing body are responsible for the provision of quality care, providing a safe environment for patients, staff and visitors, and working continuously to improve patient care and outcomes, with the primary responsibility for the quality of care rendered and for patient safety vested with the organized medical staff. These activities depend on mutual accountability, interdependence, and responsibility of the organized medical staff and the hospital governing body for the proper performance of their respective obligations.

(2) The organized medical staff, a self-governing organization of professionals, possessing special expertise, knowledge and training, discharges certain inherent professional responsibilities by virtue of its authority to regulate the professional practice and standards of its members, and assumes primary responsibility for many functions, including but not limited to: the determination of organized medical staff membership; performance of credentialing, privileging and other peer review; and timely oversight of clinical quality and patient safety....

(Res. 828, I-07; Reaffirmed in lieu of Res. 730, A-09; Modified: Res. 820, I-09; Reaffirmed: Res. 725, A-10; Reaffirmation A-12)

##### H-225.971 Credentialing and the Quality of Care

It is the policy of the AMA: (1) that the hospital medical staff be recognized within the hospital as the entity with the overall responsibility for the quality of medical care; (2) that hospital medical staff bylaws reaffirm The Joint Commission standard that medical staffs have "overall responsibility for the quality of the professional services provided by individuals with clinical privileges"; (3) that each hospital's quality assurance, quality improvement, and other quality-related activities be coordinated with the hospital medical staff's overall responsibility for quality of medical care; (4) that the hospital governing body, management, and medical staff should jointly establish the purpose, duties, and responsibilities of the hospital administrative personnel involved in quality assurance and other quality-related activities; establish the qualifications for these positions; and provide a mechanism for medical staff participation in the selection, evaluation, and credentialing of these individuals; (5) that the hospital administrative personnel performing quality assurance and other quality activities related to patient care report to and be accountable to the medical staff committee responsible for quality improvement activities; (6) that the purpose, duties, responsibilities, and reporting relationships of the hospital administrative personnel performing quality assurance and other quality-related activities be included in the medical staff and hospital corporate bylaws; (7) that the general processes and policies related to patient care and used in a hospital quality assurance system and other quality-related activities should be developed, approved, and controlled by the hospital medical staff; and (8) that any physician hired or retained by a hospital to be involved

solely in medical staff quality of care issues be credentialed by the medical staff prior to employment in the hospital. (BOT Rep. T, I-92; Reaffirmed: CMS Rep. 10, A-03; Modified: CMS Rep. 4, A-13)

#### E-8.02 Ethical Guidelines for Physicians in Administrative or Other Non-clinical Roles

The practice of medicine focuses primarily on diagnosis and treatment of disease and injury, but its concerns extend broadly to include human experiences related to health and illness. Throughout their formal education and their practice of medicine, physicians profess and are therefore held to standards of medical ethics and professionalism, such as those expressed in the AMA Code of Medical Ethics. Complying with these standards enables physicians to earn the trust of their patients and the general public. Trust is essential to successful healing relationships and, therefore, to the practice of medicine. The ethical obligations of physicians are not suspended when a physician assumes a position that does not directly involve patient care. Rather, these obligations are binding on physicians in non-clinical roles to the extent that they rely on their medical training, experience, or perspective. When physicians make decisions in non-clinical roles, they should strive to protect the health of individuals and communities. (I, V, VII) Issued June 1994 based on the report "Ethical Guidelines for Medical Consultants," adopted December 1992; Updated June 1998; Revised November 2007.

### **29. FAIR ACCESS TO SCIENCE AND TECHNOLOGY RESEARCH ACT OF 2013 FOR IMPROVED ACCESS TO MEDICAL RESEARCH (RESOLUTION 610-A-13)**

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

#### **HOUSE ACTION: RECOMMENDATION ADOPTED (RESOLUTION 610-A-13 NOT ADOPTED) AND REMAINDER OF REPORT FILED**

At the 2013 Annual Meeting, the House of Delegates referred Resolution 610 to the Board of Trustees. Resolution 610, introduced by the Texas delegation, calls upon our AMA to urge its members and physicians across the country to support initiatives about open access to research literature, including two bills in Congress described in this report.

#### **BACKGROUND**

Many commercial publishers of medical journals [e.g., Elsevier, Wiley, and Wolters Kluwer] keep their research articles behind a pay wall indefinitely, available only to paid subscribers. Because these publishers bundle unrelated products together, libraries may feel pressured to buy journals they do not want within expensive packages that contain the limited number of medical journals faculty and students prefer and need.

Unlike the commercial publishers, our AMA permits access to peer-reviewed medical research articles, including those supported by government research grants. All research articles published in *JAMA* are available to the public for free after six months on The JAMA Network website. Research articles in our nine specialty journals are free to the public 12 months after publication; those journals publish print editions between 6 and 12 times a year, and not weekly as *JAMA* does. Making all research content in JAMA Network titles freely available within 12 months complies with the NIH Public Access mandate released in January 2008, and also protects the newsworthiness, value, and business model.

This is also in compliance with AMA Policy D-460.977, which directs that our AMA will: (1) continue to work with publishing and professional organizations, and continue to work with Congress to prevent any changes to the current policy that requires public release of NIH research articles within 12 months of publication; and (2) continue to advocate that free content be accessed at the AMA's online journal web sites, rather than at a government site, to preserve our brand and to promote use of other AMA resources. (BOT Rep. 36, A-06)

Site license revenue is a primary source of revenue for our AMA Publishing division, especially as revenue from display advertising within our journals continues to decline. If all research articles were immediately free upon publication, there would be no incentive for industry or institutional customers to buy site license subscriptions to The JAMA Network. The NIH Public Access mandate, that became federal law in 2009, provides for a delay of up to 12 months for biomedical journals as reasonable, and yet some commercial publishers have flouted even that. A Harvard Library memorandum cited in testimony on Resolution 610-A-13 plainly directed its criticism at two commercial publishers, not scholarly journal and association publishers such as our AMA.

The Fair Access to Science and Technology Research Act (FASTR) was introduced in the 113<sup>th</sup> Congress as S. 350 and H. 708, on February 14, 2013. These bills require that: 1) federal departments and agencies with an annual extramural research budget of \$100 million to develop a policy to ensure researchers submit an electronic copy of the final manuscript accepted for publication in a peer-reviewed journal; 2) the manuscript is preserved in a stable digital repository maintained by that agency or in another suitable repository that permits free public access, interoperability, and long-term preservation; and 3) each taxpayer-funded manuscript be made available to the public online and without cost, no later than six months after the article has been published in a peer-reviewed journal. Both bills were immediately referred to a committee, where they remain. Neither committee has conducted a hearing, and no votes have been scheduled. The Senate bill has one sponsor and three cosponsors; the House bill is cosponsored by 14 members.

In harmony with D-460.977, our AMA is an active member of the Association of American Publishers (AAP) and its journal division known as Professional Scholarly Publishers (PSP). Both oppose FASTR, as an unfunded mandate that puts the government in competition with the private sector and imposes regulatory burdens on agencies in which AMA has no clear strategic or advocacy interest, including the Departments of Agriculture, Commerce, Defense, Energy, Homeland Security and Transportation, as well as the EPA and NASA.

FASTR threatens traditional notions of copyright law, and respect for copyright law is vital to AMA's interests in much more than the journals it publishes. As AAP has stated, there are better models for providing for access to taxpayer-funded research without infringing upon copyright concerns.

Subsequent to FASTR being introduced, on February 22, 2013, the federal Office of Science and Technology Policy (OSTP) issued a memorandum on public access to peer-reviewed scientific publications reporting on federally funded research. To support compliance among funding agencies with the OSTP memo, AAP has taken a leadership role in an initiative, called [CHORUS](#), an acronym for the Clearing House for the Open Research of the United States. AMA is among more than 100 scholarly publishers that support this project, and CHORUS is now established as a not-for-profit organization. CHORUS is a full solution that provides the public access to publicly funded scientific findings via embargoed access to publishers' final approved, edited, and formatted papers. Ultimately, citizens, patients and researchers will be able to discover and access content from among these publishers without site licenses, or fees on a single pathway that interacts with publishers' journal platforms, allowing publishers to retain the web site traffic and customer relationships they depend upon in this competitive, digital environment. CHORUS is a sensible response to the demand for access to published papers after a reasonable embargo period, as it negates the need for government funding, construction, operation and oversight of new databases that would duplicate and compete with publishing platforms like our own [www.jamanetwork.com](http://www.jamanetwork.com).

#### DISCUSSION AND RECOMMENDATION

Resolution 610-A-13 is not consistent with AMA policy, the objectives of AMA Publishing, and the business model of The JAMA Network. For the reasons above, the Board believes our AMA should continue to oppose FASTR and similar legislation in cooperation with AAP/PSP and other scholarly journal publishers. In addition, the Board notes that our AMA will remain active in CHORUS, an initiative that balances the fair access to biomedical research with a private sector solution that supports a sustainable business and educational service model for society scholarly journals, like *JAMA* and The JAMA Network.

Therefore, the Board of Trustees recommends that Resolution 610-A-13 not be adopted, and the remainder of this report be filed.

### 30. AMA PERFORMANCE, ACTIVITIES AND STATUS IN 2013

*Informational report; no reference committee hearing.*

#### **HOUSE ACTION: FILED**

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

#### INTRODUCTION

The AMA's mission is to promote the art and science of medicine and the betterment of public health. The AMA is committed to improving the health of the nation through leadership, advocacy, outreach and innovation. Our broad reach and deep relationships allow us to advance results-focused initiatives that improve public health, medical education, practice sustainability and professional satisfaction. We are leading meaningful innovation to enable a better health care system for patients, physicians and the country.

#### STRATEGIC FOCUS AREAS

##### *Improving Health Outcomes*

The AMA has committed its talent, resources and reach to achieve measurable improvements in health outcomes, starting with a focus on risk factors for diabetes and cardiovascular disease: high blood glucose and high blood pressure. We are helping physicians and care teams address prediabetes and control high blood pressure by screening patients using accurate measurements, taking evidence-based action to address these conditions, and engaging with patients to encourage self-management.

##### Diabetes Prevention

We have partnered with the YMCA of the USA to help prevent the onset of diabetes among Medicare participants who have prediabetes. The AMA is beginning its work by increasing physician referrals of those patients to the YMCA's evidence-based Diabetes Prevention Program (DPP), with the longer-term goal of increasing referral of people of all ages who have prediabetes.

The AMA has begun our community-level work in three pilot locations: the state of Delaware, and the cities of Indianapolis, IN and Minneapolis/St. Paul, MN, where we have engaged physician practices to test our DPP referral models and feedback loop.

We created a new tool for our pilot practices to test and use, called "Preventing Type 2 Diabetes: A Guide to Refer Patients to the YMCA's Diabetes Prevention Program." This tool includes a step-by-step process from screening for prediabetes to referral that practices can adapt to fit into their workflows. Once the pilot phase is complete in mid-2014, we will refine our tools and expand to more cities and physician practices, creating more clinical-community linkages.

We are also collaborating with state and local medical societies to help us with promotion and spread, and we are engaging insurers to collaborate on strategies for expanded coverage of evidence-based community offerings, such as the DPP at the YMCA.

##### Cardiovascular Disease Prevention

To prevent heart disease, we are collaborating with two research centers within Johns Hopkins University: the Armstrong Institute for Patient Safety and Quality and the Johns Hopkins Center to Eliminate Cardiovascular Health Disparities. Our initial efforts are aimed at improving hypertension control rates, working in support of the US Department of Health and Human Services' "Million Hearts®" initiative and its goal of bringing the high blood pressure of 10 million more American under control by 2017.



As the first phase of our work to engage practices, people and communities in addressing hypertension control, we have initiated prototyping work with 10 physician practices (of differing sizes and patient populations) in Illinois and Maryland. For one year ending in October 2014, these practices are working together, and with AMA and Johns Hopkins, to develop and test a set of evidence-based recommendations, which we call “the M.A.P. for achieving optimal hypertension control.”

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

Members of the care teams at the pilot practice sites are incorporating the M.A.P. into their workflow to determine its sustainability and impact on consistently controlling patients’ high blood pressure. The AMA will take what it learns from these pilot practice sites to improve workflows in clinical care environments, then add community partners, and spread hypertension improvement to more practices nationwide.

#### *Accelerating Change in Medical Education (ACE)*

A year after its launch, the ACE initiative has exceeded expectations in leading partnerships to transform medical education. In the four months since the grant awards began, the 11 partner schools, the ACE Consortium, are working together on evaluation and rapid dissemination of best practices to other medical and health professions schools.

The Consortium will continue to share information and disseminate successful innovations during meetings scheduled this year. The spring meeting was held April 6-7 at the University of Michigan and focused on competency-based assessment, milestones and entrustable professional activities. The fall meeting will be held September 21-22 at Vanderbilt University.

#### Learning Environment Study (LES)

Work is ongoing in the LES to identify factors in the learning environment that either inhibit or promote the acquisition of professional values and the demonstration of professional behaviors by medical students and resident physicians. The longitudinal and multi-institutional design of the LES will yield data on the student experience throughout the four years of medical school and allow for comparison across varying medical education learning environments with regard to educational outcomes. A spring meeting of the LES institutions was planned for April 17 for data sharing and workgroup updates.

#### Liaison Committee on Medical Education (LCME)

In December 2013, a Memorandum of Understanding was established between the AMA, the Canadian Medical Association, the Association of American Medical Colleges and the Association of Faculties of Medicine of Canada to support the longstanding partnership between the United States and Canada in medical school accreditation. The agreement, signed by the sponsoring organizations of the Liaison Committee on Medical Education (LCME) and the Committee on Accreditation of Canadian Medical Schools (CACMS), formalized their partnership and will ensure medical school graduates in both nations meet their respective countries’ standards and are prepared for the next phase of their medical training.

#### *Physician Satisfaction and Practice Sustainability*

As the nation’s health care system continues to evolve, the AMA is dedicated to helping physicians navigate the environment successfully by ensuring sustainable physician practices that result in good health outcomes for patients and greater professional satisfaction for physicians. To that end, in 2013 the AMA, in partnership with RAND Corporation, completed its study to look at models of care delivery, payment, and professional satisfaction among physicians. Many things affect physician professional satisfaction, but a common theme identified is that physicians describe feeling stressed and unhappy when they see barriers preventing them from providing high quality patient care. Electronic health records were highlighted by many physicians as one of these issues. If these perceptions are correct, then solving these problems will be good for both patients and physicians. This study was featured in hundreds of news stories, including *New York Times*, *USA Today*, and in numerous state association publications.

Under the continued guidance of the Advisory Committee for Physician Satisfaction: Care Delivery and Payment, a four-part strategy of activities was established for 2014. These activities include:

- Development of practice-level solutions that, when applied collectively, will enhance the practice of medicine for physicians and enable informed decision-making about their practice environments. The development of these clinical operation modules will allow physicians more time to spend on patient care and less time on administrative burdens.
- Building off the successful Joint Leadership Conference on New Models of Care held in October 2013 sponsored by the AMA and the American Hospital Association and Health Affairs, we are developing a leadership model to be used by physicians and hospitals to pursue a true partnership when working together in a more combined fashion. This model identifies key principles and elements needed that will drive the effectiveness and success of such a partnership. A plan for rolling out this model will also be developed.
- Creating an EHR advisory committee in partnership with Advocacy to help identify EHR usability principles and establish partnerships and connections with vendors, regulators and physicians to identify and promote solutions for increasing usability of electronic health records by physicians and other health care professionals for the improvement of patient health.
- Understanding the growth and impact of new value-based payment models, including global payments, shared savings (e.g., accountable care organizations), physician-hospital gain-sharing, bundled payments, pay-for-performance, medical homes, and subscription/retainer arrangements, on physicians and physician practices. The AMA is again partnering with RAND Corporation, assisted by researchers at Weill Cornell Medical College, to conduct a study to describe the effects on physician work experience and practice sustainability of each investigated health care payment model. Based on this research, a more formal strategy will be adopted to influence new payment models for the betterment of physicians and the patients they serve.
- In collaboration with the American Hospital Association, we hosted a joint leadership conference on new models of care to expand the conversation among health care provider organizations, clinicians, and policymakers on the need for greater alignment and how care might be organized in the future to meet the goals of a more effective system.

## ADVOCACY

### *SGR Repeal*

Congressional momentum to eliminate the SGR continues. Through our “Fix Medicare Now” campaign and strong advocacy, the AMA has built momentum to eliminate Medicare’s flawed sustainable growth rate (SGR) formula. Repealing the SGR is the fiscally responsible way toward establishing a higher performing Medicare program. As 2013 came to a close, Congress had made more progress than ever—three congressional committees had approved legislative proposals to repeal the SGR formula. To help maintain momentum for negotiating a final bill to repeal the SGR, a three-month payment patch with a 0.5 percent update was signed into law at the end of December.

### *Regulatory Relief*

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

- Alignment of quality measurement programs;
- Delay of meaningful use stage 3;
- Extension until 2021 of the EHR donation exemptions from Stark and anti-kickback rules (for hospitals);
- Lowered threshold for PQRS reporting from 80 percent of applicable patients to 50 percent; and
- Expansion of time for physicians to challenge Sunshine Act reports to two years.

*Practice Tools and Research*

The AMA developed practical resources to help physician practices navigate new Health Insurance Portability and Accountability Act (HIPAA) privacy rules, the Sunshine Act, and electronic funds transfer (EFT) and electronic remittance advice (ERA) operating rules, while providing key research on physician practices and the health insurance marketplace. A benchmark study on physician practice arrangements showed that despite the increase in hospital employment, more than half of physicians were self-employed in 2012. Additionally, a 2013 update to the AMA Competition in Health Insurance Study found that the majority of commercial health insurance markets across the country are “highly concentrated” based on the 2010 Department of Justice/Federal Trade Commission merger guidelines.

*Adoption of Complex Chronic Care Management Codes*

The Centers for Medicare & Medicaid Services (CMS) agreed to adopt new codes to cover complex chronic care management beginning in 2015. The codes were developed by workgroups of the Current Procedural Terminology (CPT®) editorial panel and the AMA/Specialty Society RVS Update Committee (RUC).

*Grassroots Activity*

The AMA empowered thousands of physicians to voice their opinions to lawmakers in successful grassroots campaigns. This is evidenced by more than 789,331 emails and 5,743 phone calls to Capitol Hill as part of the “Fix Medicare Now” campaign and the more than 25,000 grassroots emails and over 40 in-district legislative visits generated by the “Save GME” campaign.

*State Level Advocacy*

Working in collaboration with state and specialty medical societies across the nation, the AMA achieved more than 85 state legislative and regulatory victories:

- Led medicine’s efforts to advance physician interests during Affordable Care Act (ACA) implementation in states across the country.
- Preserved medical liability reforms by supporting legislation in a number of states, including Florida, Georgia, Oklahoma and Pennsylvania.
- Promoted physician-led, team-based care in Texas, Kentucky, California, and other states.
- Worked collaboratively with 14 state medical associations to secure victories that protect the sanctity of the physician-patient relationship.
- Supported several national organizations in their adoption of legislative and regulatory recommendations for combating prescription drug abuse, diversion, overdose and death.

*Litigation Center*

The Litigation Center of the AMA and the state medical societies continued its activities at a high level of intensity across a wide spectrum of legal issues of concern to physicians, most particularly in cases that defend hard won reforms of the tort system, the right of organized medical staff self-governance, and physician interests in prompt and fair payment for services provided. In 2013, the United States Supreme Court decided 7 cases in which the Litigation Center [or the AMA individually] had filed amicus briefs to further AMA policy. In a landmark decision in which the Litigation Center filings played a critical role, the Court held that human genes are unpatentable. In another case, the Court held that physicians could bring an arbitration proceeding on a class basis to fight unfair payment practices of a managed care organization.

As of early 2014, the Litigation Center had filed amicus briefs in two additional cases before the Supreme Court. One of these urged the Court to review *North Carolina State Board of Dental Examiners v. Federal Trade Commission*, in which the United States Court of Appeals had held that a state professional licensure board could be subject to the federal antitrust laws for taking actions that restrained trade. In the other case, *McCullen v. Coakley*, the Litigation Center, along with the American Congress of Obstetricians and Gynecologists and the Massachusetts Medical Society, advised the Court of the medical complications which could ensue if pregnant women had to confront aggressive protestors in order to secure reproductive health services, including abortions.

## PRACTICE TOOLS

### *Business Products and Services*

Business Products and Services (BPS) continues to deliver high impact, profitable solutions/services that bring value to physicians and fund the AMA's mission-focused activities and operations.

BPS has focused on strengthening strategic relationships to create innovative new products and services that bring value to physicians and improve healthcare delivery. BPS continues to improve the usefulness and interoperability of CPT by creating value added coding solutions that will impact the next generation of CPT products and services reinforcing AMA's position as a leader in healthcare information management. We are also leveraging the AMA Masterfile to create new products and services that empower physicians to manage their online presence, enhance their ability to engage with patients and provide new advanced tools so that hospitals and insurers can cost effectively verify physician credentials.

### *Periodical Publishing*

2013 was a landmark year of innovation for AMA Publications, as we fully established *JAMA* and the JAMA Network as a family of journals, debuted new digital content and services, and redesigned and rebranded all of our titles.

January 2013 – all of the “Archives” specialty journals were formally renamed and rebranded as part of the JAMA Network (e.g., *JAMA Pediatrics*, *JAMA Surgery*, etc.). This further reinforced The JAMA Network as of a family or portfolio of journals.

March, 2013 – the JN Reader an HTML5 app debuted bringing content together across all 10 journals in an application that can be used on any digital device around the world.

July, 2013 – We debuted a full redesign of all 10 JAMA Network journals including *JAMA* itself. This was the first extensive redesign in over 20 years.

Landmark articles for the year included The State of US Health, 1990-2010 by US Burden of Disease Collaborators and the 2014 Evidence-based guidelines for the management of High Blood Pressure in Adults from the panel members appointed to the 8th Joint National Committee.

Theme issues included Critical Issues in US Health Care, Global Health, and Cardiovascular Disease.

## GOVERNANCE

We supported employed physicians and those considering employment through the “Resources for Employed Physicians” website. This year the AMA added a complementary section to the Physician-Hospital Employment Agreement to include the Physician-Group Practice Employment Agreement. We collaborated with the American Bar Association and the Chicago Medical Society to produce webinars, live education and materials on physician employment.

The Integrated Physician Practice Section exceeded participation goals, adopted policy supporting diversity in delivery systems and influenced AMA approaches for team-based care, reimbursement legislation, and practice regulation.

The AMA supported physicians practicing in hospitals by promoting through The Joint Commission (TJC), the strengthening of TJC's Primary Care Medical Home Standards to require physician participation, and separately retained gains achieved in the CMS Medicare Conditions of Participation strengthening hospital medical staff self-governance.

We advocated for the World Medical Association to adopt updates to the Declaration of Helsinki, which is a seminal global policy on clinical research involving humans. The revision was exclusively published in *JAMA*.

## AMA COUNCILS

### *Council on Constitution and Bylaws*

The Council on Constitution and Bylaws (CCB) updated the House of Delegates Reference Manual: Procedures, Policies and Practices and the AMA Constitution and Bylaws (with changes for A-13 and I-13). CCB amended the Bylaws to establish the Women Physician Section, and incorporated several bylaw amendments for the recently established Senior Physicians Section (SPS), including the virtual election of the SPS governing council by the entire SPS membership, and governing council election of the chair-elect.

CCB worked through the Board of Trustees to establish the inaugural Internal Operating Procedures (IOPs) of the two newly formed AMA sections: the Senior Physicians Section and the Women Physicians Section. The IOPs govern section membership, representation, elections, and meetings. The IOPs of the International Medical Graduates Section and the Young Physicians Section also were updated. The Board approved all IOPs. CCB's role in reviewing IOPs prior to Board approval is to ensure that there are no conflicts with AMA bylaws, ensure internal consistency and where appropriate ensure consistency with the IOPs of the other AMA sections.

Also, CCB, in collaboration with CLRPD, issued 4 reports related to the AMA policy project: (1) to sunset policy directives which were obsolete, duplicative or accomplished; (2) to consolidate relevant policies on lodging, meeting venues and social functions; (3) to review and sunset where appropriate those policies from 2003; and (4) to review and provide recommendations for sunset, retention and/or consolidation of AMA policies related to women physicians.

At the request of the Board of Trustees, CCB has been reviewing updated chapters from the *Code of Medical Ethics*, to see if CCB concurs with those changes CEJA believes are not substantial. CCB completed its review of the last 4 chapters of the *Code*.

### *Council on Ethical and Judicial Affairs*

Two reports by the Council on Ethical and Judicial Affairs (CEJA) updating existing ethics policy were adopted by the AMA House of Delegates in 2013, amending Opinions E-5.055, "Confidential Care for Minors," and E-8.061, "Gifts to Physicians from Industry." The House also adopted CEJA Report 5-I-13, which consolidated guidance from multiple opinions into overarching guidance addressing professionalism in health care systems. The recommendations of this report will be published as Opinion E-8.131 of the same title. In addition, under its ongoing project to review and modernize *the Code of Medical Ethics*, CEJA presented draft updated opinions of all remaining chapters to the Council on Constitution and Bylaws for review. Chapters previously reviewed by CCB were posted to CEJA's online forum for review and comment by delegates and alternate delegates to the House of Delegates.

### *Council on Science and Public Health*

The Council on Science and Public Health developed 11 reports for the House of Delegates in 2013. Two reports received significant national media attention "A Contemporary View of National Drug Control Policy" and "Is Obesity a Disease." The Council's recommendations on pharmacy compounding provided important updates to AMA policy on this topic as a basis for responding to emerging legislative initiatives in this area. By developing an updated report on "Genetic Discrimination and the Genetic Information Nondiscrimination Act," the Council contributed to the AMA framework for advancing personalized medicine developed by the Council on Legislation and approved by the Board of Trustees. Council staff co-authored a publication in *JAMA Internal Medicine* on "The Promise and Challenges of Next Generation Genome Sequencing for Clinical Care." The Council also co-sponsored an educational forum at the 2013 Annual Meeting entitled, "The Aging Physician: Opportunities and Challenges," that was well attended and which received excellent reviews.

### *Council on Long Range Planning and Development*

Biennially, the Council on Long Range Planning and Development develops Health Care Trends (HCT) as a valuable resource to educate physicians and medical students on critical factors that will likely influence medicine and the delivery of care in the 21st century. Knowledge of emerging trends and predictions of their impact may

assist physicians as they evaluate the best ways to promote the health of their patients and improve the health care system.

Chapters of the 2013-14 edition of HCT are published through the AMA Online Learning Center. From October 2013 through February 2014, the number of physicians accessing HCT increased 81 percent compared to the same timeframe a year ago. By reading HCT, physicians can earn AMA PRA Category 1 Credit™; one credit for each chapter at no charge. The following link provides access to HCT, [ama-assn.org/go/healthcaretrends](http://ama-assn.org/go/healthcaretrends).

#### MEMBERSHIP

AMA membership had a third consecutive year of growth in 2013 with an overall increase of 1.5% for a total of 227,874 members. All dues paying categories ended the year up.

#### EVP COMPENSATION

During 2013, pursuant to his employment agreement, total cash compensation paid to James L. Madara, MD as AMA Executive Vice President was \$880,474 in base salary and \$523,438 in bonus. Additional taxable amounts per the contract were paid as follows: \$7,524 for life insurance, \$3,960 for executive life insurance, \$3,200 for health club fees and \$1,140 for parking. A \$81,000 contribution to a deferred compensation account was made by the AMA, which will not be taxable until vested pursuant to provisions in the deferred compensation agreement.

### **31. 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) Annual Meeting in compliance with the five-year review process established by the House of Delegates in Policy G-600.020 and AMA Bylaw 8.50.

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 8.20.

The following organizations were reviewed for the 2014 Annual Meeting:

- American Academy of Cosmetic Surgery
- American Academy of Hospice and Palliative Medicine
- American Association for Thoracic Surgery
- American Association of Gynecologic Laparoscopists
- American Association of Plastic Surgeons
- American Association of Public Health Physicians
- American College of Allergy, Asthma and Immunology
- American College of Physician Executives
- American Society for Aesthetic Plastic Surgery, Inc.
- American Society of Hematology
- American Society of Interventional Pain Physicians
- Association of University Radiologists
- Infectious Diseases Society of America
- Society of Laparoendoscopic Surgeons

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

The materials submitted indicate that the: American Academy of Cosmetic Surgery, American Academy of Hospice and Palliative Medicine, American Association for Thoracic Surgery, American Association of Gynecologic Laparoscopists, American Association of Plastic Surgeons, American Association of Public Health Physicians, American College of Allergy, Asthma and Immunology, American Society for Aesthetic Plastic Surgery, Inc., American Society of Interventional Pain Physicians, Association of University Radiologists, Infectious Diseases Society of America and the Society of Laparoendoscopic Surgeons meet all guidelines and are in compliance with the five-year review requirements of specialty organizations represented in the HOD.

The materials submitted also indicate that the American Society of Hematology did 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 Physician Executives did not submit materials for the five year review but submitted a letter withdrawing from participation in the HOD.

## RECOMMENDATIONS

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

1. That American Academy of Cosmetic Surgery, American Academy of Hospice and Palliative Medicine, American Association for Thoracic Surgery, American Association of Gynecologic Laparoscopists, American Association of Plastic Surgeons, American Association of Public Health Physicians, American College of Allergy, Asthma and Immunology, American Society for Aesthetic Plastic Surgery, Inc., American Society of Interventional Pain Physicians, Association of University Radiologists, Infectious Diseases Society of America and the Society of Laparoendoscopic Surgeons retain representation in the American Medical Association House of Delegates.
2. That the American Society of Hematology be given a grace period of one year to meet the membership requirements to retain their position in the American Medical Association House of Delegates.
3. That the American College of Physician Executives representation in the American Medical Association House of Delegates is terminated per the organization's request.

## APPENDIX

### Exhibit A - Summary Membership Information

Organization	AMA Membership of Organization's Total Eligible Membership	
American Academy of Cosmetic Surgery	352 of 1,176	(30%)
American Academy of Hospice and Palliative Medicine	741 of 3,525	(21%)
American Association for Thoracic Surgery	272 of 975	(28%)
American Association of Gynecologic Laparoscopists	1,533 of 4,084	(37%)
American Association of Plastic Surgeons	352 of 1,176	(30%)
American Association of Public Health Physicians	47 of 114	(41%)
American College of Allergy, Asthma and Immunology	370 of 1,572	(24%)
American College of Physician Executives	did not submit data	
American Society for Aesthetic Plastic Surgery, Inc.	389 of 1,899	(20%)
American Society of Hematology	881 of 6,313	(14%)
American Society of Interventional Pain Physicians	491 of 2,300	(21%)
Association of University Radiologists	183 of 869	(21%)

Infectious Diseases Society of America	1,009 of 7,931	(14%)
Society of Laparoendoscopic Surgeons	964 of 2,641	(37%)

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 8.20)

1. To cooperate with the AMA in increasing its AMA membership.
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.
3. To require its delegate to report to the organization on the actions taken by the House of Delegates at each meeting.
4. To disseminate to its membership information as to the actions taken by the House of Delegates at each meeting.
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

8.50 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.

8.51 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.



8.52 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.

8.53 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.

8.531 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.

8.532 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:

8.5321 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.

8.5322 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.

DRAFT

**SPEAKERS' REPORT**

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

**RECOMMENDATIONS FOR POLICY RECONCILIATION**

*No reference committee hearing.*

**HOUSE ACTION: FILED**

*Affected policies rescinded in whole or in part.*

American Medical Association Policy G-600.111 calls for the speaker to “present one or more reconciliation reports for action by the House of Delegates relating to newly passed policies from recent meetings that caused one or more existing policies to be redundant and/or obsolete.” This report presents your speakers’ second such report to the House of Delegates.

**RECOMMENDED RECONCILIATIONS**

Policies adopted in 2012 and 2013 were compared to existing statements to ensure that an older policy was not in conflict with the newer policy, had not been rendered obsolete or was not duplicative. For the most part, new policies do not conflict with older policy statements, but several were in some measure redundant. In these cases the newer policy provides a clearer or more specific statement, meaning the older policy, or at least a portion thereof, should be rescinded. The changes outlined below will be made. For the policies discussed below, the newer policy is listed first, labeled ‘a’; the policy to be altered or rescinded is ‘b.’

*Policies to be Rescinded in Part*

1. At the 2012 Annual Meeting, Policy H-165.920, “Individual Health Insurance,” was reaffirmed by Council on Medical Service Report 6. That policy deals with a number of health insurance-related matters, including employer mandates. An earlier, unrelated policy, H-440.960, deals with a report from the Institute of Medicine on physicians’ roles in the public health arena and includes a reference to an employer mandate for health insurance, which was superseded by Policy H-165.920. The reference to the employer mandate will be removed from Policy H-440.960, which otherwise remains relevant and is in concert with other policies.

- a. H-165.920 Individual Health Insurance

Our AMA: ... (5) supports individually selected and individually-owned health insurance as the preferred method for people to obtain health insurance coverage; and supports and advocates a system where individually-purchased and owned health insurance coverage is the preferred option, but employer-provided coverage is still available to the extent the market demands it;... (BOT Rep. 41, I-93; CMS Rep. 11, I-94; Reaffirmed by Sub. Res. 125 and Sub. Res. 109, A-95; Amended by CMS Rep. 2, I-96; Amended and Reaffirmed by CMS Rep. 7, A-97; Reaffirmation A-97; Reaffirmed: CMS Rep. 5, I-97; Res. 212, I-97; Appended and Amended by CMS Rep. 9, A-98; Reaffirmation I-98; Reaffirmation I-98; Res. 105 & 108, A-99; Reaffirmation A-99; Reaffirmed: CMS Rep. 5 and 7, I-99; Modified: CMS Rep. 4, CMS Rep. 5, and Appended by Res. 220, A-00; Reaffirmation I-00; Reaffirmed: CMS Rep. 2, I-01; Reaffirmed CMS Rep. 5, A-02; Reaffirmation A-03; Reaffirmed: CMS Rep. 1 and 3, A-02; Reaffirmed: CMS Rep. 3, I-02; Reaffirmed: CMS Rep. 3, A-03; Reaffirmation I-03; Reaffirmation A-04; Consolidated: CMS Rep. 7, I-05; Modified: CMS Rep. 3, A-06; Reaffirmed in lieu of Res. 105, A-06; Reaffirmation A-07; Appended and Modified: CMS Rep. 5, A-08; Modified: CMS Rep. 8, A-08; Reaffirmation A-10; Reaffirmed: CMS Rep. 9, A-11; Reaffirmation A-11; Reaffirmed: Res. 239, A-12; Appended: Res. 239, A-12; Reaffirmed: CMS Rep. 6, A-12)

- b. H-440.960 The IOM Report (The Future of Public Health) and Public Health

Our AMA (1) encourages medical societies to establish liaison committees through which physicians in private practice and officials in public health can explore issues and mutual concerns involving public health activities and private practice; (2) seeks increased dialogue, interchange, and cooperation among national organizations representing public health professionals and those representing physicians in private practice or

academic medicine; (3) actively supports promoting and contributing to increased attention to public health issues in its programs in medical science and education; (4) continues to support the providing of medical care to poor and indigent persons through the private sector and the financing of this care through an improved Medicaid program ~~and mandated employer health insurance~~; (5) encourages public health agencies, as the IOM report suggests, to focus on assessment of problems, assurance of healthy living conditions, policy development, and activities such as those mentioned in the "Model Standards"; (6) encourages physicians and others interested in public health programs to apply the messages and injunctions of the IOM report as these fit their own situations and communities; and (7) encourages physicians in private practice and those in public health to work cooperatively, striving to ensure better health for each person and an improved community as enjoined in the Principles of Medical Ethics. (CSA Rep. E, I-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10)

2. At the 2012 Interim Meeting, Council on Medical Service Report 5 established Policy H-330.889, "Strengthening Medicare for Current and Future Generations," which established several principles reflective of the policy title. It also rescinded an earlier policy, H-330.898, which underlay paragraph 8 of Policy H-165.985. Thus, to ensure consistency between the two policies, paragraph 8 of Policy H-165.985 will be stricken. It is otherwise unchanged.

- a. H-330.889, Strengthening Medicare for Current and Future Generations

1. It is the policy of our AMA that a Medicare defined contribution program should include the following: a. Enable beneficiaries to purchase coverage of their choice from among competing health insurance plans, which would be subject to appropriate regulation and oversight to ensure strong patient and physician protections. b. Preserve traditional Medicare as an option. c. Offer a wide range of plans (e.g., HMOs, PPOs, high-deductible plans paired with health savings accounts), as well as traditional Medicare. d. Require that competing private health insurance plans meet guaranteed issue and guaranteed renewability requirements, be prohibited from rescinding coverage except in cases of intentional fraud, follow uniform marketing standards, meet plan solvency requirements, and cover at least the actuarial equivalent of the benefit package provided by traditional Medicare e. Apply risk-adjustment methodologies to ensure that affordable private health insurance coverage options are available for sicker beneficiaries and those with higher projected health care costs. f. Set the amount of the baseline defined contribution at the value of the government's contribution under traditional Medicare. g. Ensure that health insurance coverage is affordable for all beneficiaries by allowing for adjustments to the baseline defined contribution amount. In particular, individual defined contribution amounts should vary based on beneficiary age, income and health status. Lower income and sicker beneficiaries would receive larger defined contributions. h. Adjust baseline defined contribution amounts annually to ensure that health insurance coverage remains affordable for all beneficiaries. Annual adjustments should reflect changes in health care costs and the cost of obtaining health insurance. i. Include implementation time frames that ensure a phased-in approach. 2. Our AMA will advocate that any efforts to strengthen the Medicare program ensure that mechanisms are in place for financing graduate medical education at a level that will provide workforce stability and an adequate supply of physicians to care for all Americans. 3. Our AMA will continue to explore the effects of transitioning Medicare to a defined contribution program on cost and access to care. (CMS Rep. 5, I-12)

- b. H-165.985, Opposition to Nationalized Health Care

Our AMA reaffirms the following statement of principles as a positive articulation of the Association's opposition to socialized or nationalized health care: (1) Free market competition among all modes of health care delivery and financing, with the growth of any one system determined by the number of people who prefer that mode of delivery, and not determined by preferential federal subsidy, regulations or promotion. (2) Freedom of patients to select and to change their physician or medical care plan, including those patients whose care is financed through Medicaid or other tax-supported programs, recognizing that in the choice of some plans the patient is accepting limitations in the free choice of medical services. (Reaffirmed: BOT Rep. I-93-25; Reaffirmed: CMS Rep. I-93-5) (3) Full and clear information to consumers on the provisions and benefits offered by alternative medical care and health benefit plans, so that the choice of a source of medical care delivery is an informed one. (4) Freedom of physicians to choose whom they will serve, to establish their fees at a level which they believe fairly reflect the value of their services, to participate or not participate in a particular insurance plan or method of payment, and to accept or decline a third party allowance as payment in full for a service. (5) Inclusion in all methods of medical care payment of mechanisms to foster increased cost awareness by both providers and recipients of service, which could include patient cost sharing in an

amount which does not preclude access to needed care, deferral by physicians of a specified portion of fee income, and voluntary professionally directed peer review. (6) The use of tax incentives to encourage provision of specified adequate benefits, including catastrophic expense protection, in health benefit plans. (7) The expansion of adequate health insurance coverage to the presently uninsured, through formation of insurance risk pools in each state, sliding-scale vouchers to help those with marginal incomes purchase pool coverage, development of state funds for reimbursing providers of uncompensated care, and reform of the Medicaid program to provide uniform adequate benefits to all persons with incomes below the poverty level. (8) ~~Replacing the present Medicare program with a system developed by the AMA of pre-funded vouchers to older persons to purchase health insurance with comprehensive benefits, including catastrophic coverage.~~ (9) Development of improved methods of financing long-term care expense through a combination of private and public resources, including encouragement of privately prefunded long-term care financing to the extent that personal income permits, assurance of access to needed services when personal resources are inadequate to finance needed care, and promotion of family caregiving. (BOT Rep. U, I-88; Reaffirmed: BOT Rep. 40, I-93; Reaffirmed: Sub. Res. 110, A-94; Reaffirmed: CMS Rep. 7, I-97; Reaffirmed by CMS Rep. 9, A-98; Reaffirmed: CMS Rep. 4, A-99; Reaffirmation I-07; Modified: CMS Rep. 8, A-08; Reaffirmed in lieu of Res. 813, I-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 112, A-09; Reaffirmation A-11; Reaffirmed: Res. 239, A-12)

3. At the 2013 Interim Meeting, Council on Medical Service Report 3 established Policy D-390.954 calling for repeal or significant modification to the Value-Based Payment Modifier program. The new policy restates paragraph 2 of Policy D-450.964, which calls for our AMA to “continue to advocate, educate and seek to delay implementation of the VBM program.” As the latter is now redundant, it will be rescinded.
  - a. D-390.954, Hospital-Based Physicians and the Value-Based Payment Modifier
 

Our AMA will continue to advocate that the Value-Based Payment Modifier program be repealed or significantly modified. (CMS Rep. 3, I-13)
  - b. D-450.964, Medicare Quality and Resource Use Reports
 

Our AMA will: (1) continue to work with the Centers for Medicare & Medicaid Services to improve the design, content, and performance indicators included in the Quality and Resource Use Reports (QRURs) for physicians, so that the reports reflect the quality and cost data associated with these physicians in calculating Value-Based Payment Modifiers (VBM); ~~and (2) continue to advocate, educate and seek to delay implementation of the VBM program.~~ (Res. 810, I-12; Reaffirmed in lieu of Res. 113, A-13)
4. Our AMA has extensive policy dealing with the perils of tobacco use, including policy supporting FDA regulation of tobacco. Policy H-495.973, adopted at the 2013 Annual Meeting, restates AMA support for FDA authority and calls for immediate implementation of that authority. The new policy is stronger than prior policy H-495.988, which includes a call for the FDA to assert its authority at the “earliest practical time” (H-495.988, paragraph 7). That section of the earlier policy will be rescinded and the remaining parts renumbered.
  - a. H-495.973, FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products
 

Our AMA will urge the US Food and Drug Administration (FDA) to immediately implement the deeming authority written into the FDA tobacco law to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the FDA tobacco law. (Res. 206, I-13)
  - b. H-495.988, FDA Regulation of Tobacco Products
 

Our AMA: (1) reaffirms its position that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (2) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (3) reaffirms its position that the Food and Drug Administration (FDA) does have, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (4) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (5) urges Congress to pass legislation to phase in the production of less hazardous and less toxic tobacco, and to authorize the FDA have broad-based powers to regulate tobacco products; (6) encourages the FDA and

other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; (7) ~~encourages the FDA to assert its authority over the manufacture of tobacco products to reduce their addictive potential at the earliest practical time, with a goal for implementation within 5-10 years~~; and (8) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco products. (CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12; Reaffirmation A-13; Modified: Res. 402, A-13)

*Policies to be Rescinded in Full*

5. Board of Trustees Report 22-A-13 modified Policy H-480.974 to call for our AMA to collaborate with the American Telemedicine Association to develop physician- and patient-specific information on the use of telemedicine services, including issues related to data encryption. That new policy echoes Policy D-480.976, which will be rescinded.

- a. H-480.974, Evolving Impact of Telemedicine

Our AMA: (1) will evaluate relevant federal legislation related to telemedicine; (2) urges CMS, AHRQ, and other concerned entities involved in telemedicine to fund demonstration projects to evaluate the effect of care delivered by physicians using telemedicine-related technology on costs, quality, and the physician-patient relationship; (3) urges professional organizations that serve medical specialties involved in telemedicine to develop appropriate practice parameters to address the various applications of telemedicine and to guide quality assessment and liability issues related to telemedicine; (4) encourages professional organizations that serve medical specialties involved in telemedicine to develop appropriate educational resources for physicians for telemedicine practice; (5) encourages development of a code change application for CPT codes or modifiers for telemedical services, to be submitted pursuant to CPT processes; (6) will work with CMS and other payers to develop and test, through these demonstration projects, appropriate reimbursement mechanisms; (7) will develop a means of providing appropriate continuing medical education credit, acceptable toward the Physician's Recognition Award, for educational consultations using telemedicine; (8) will work with the Federation of State Medical Boards and the state and territorial licensing boards to develop licensure guidelines for telemedicine practiced across state boundaries; and (9) will leverage existing expert guidance on telemedicine by collaborating with the American Telemedicine Association ([www.americantelemed.org](http://www.americantelemed.org)) to develop physician and patient specific content on the use of telemedicine services—encrypted and unencrypted. (CMS/CME Rep., A-94; Reaffirmation A-01; Reaffirmation A-11; Reaffirmed: CMS Rep. 7, A-11; Reaffirmed in lieu of Res. 805, I-12; Appended: BOT Rep. 26, A-13; Modified: BOT Rep. 22, A-13)

- b. D-480.976, Security of Telemedicine Communication

Our AMA will: (1) develop appropriate warnings and guidance for physicians for the use of various common telemedicine modalities; and (2) provide physicians useable information and warnings that can be given to patients about the security of common telemedicine modalities if they choose to use such technologies. (Res. 804, I-12)

6. The Council on Medical Service presented “Delivery of Care and Financing Reform for Medicare and Medicaid Dually Eligible Beneficiaries” (CMS 5-A-13) at the 2013 Annual Meeting, establishing principles on financing reform for care of Medicare and Medicaid dually eligible patients (Policy H-290.967). Section G of that policy states “Medicare and Medicaid benefit plans and the delivery of benefits should be coordinated.” Being part of a carefully crafted set of principles, that policy replaces the prior H-290.268, which simply supports efforts to better coordinate care of the dually eligible. The latter policy will be rescinded.

- a. H-290.967, Delivery of Care and Financing Reform for Medicare and Medicaid Dually Eligible Beneficiaries

AMA's principles on the delivery of care and financing reform for Medicare and Medicaid dually eligible beneficiaries: a. Various approaches to integrated delivery of care should be promoted under demonstration such as physician-led patient-centered medical homes with adequate payment to physicians, provision of care management and mental health resources. b. Customized benefits and services from health plans are necessary according to each beneficiary's specific medical needs. c. Care coordination demonstrations should

not interfere with the established patient-physician relationships in this vulnerable population. d. Delivery and payment reform for dually eligible beneficiaries should involve actively practicing physicians and take into consideration the diverse patient population and local area resource. e. States with approved financial alignment demonstration models should provide education and counseling to beneficiaries on options for receiving Medicare and Medicaid benefits. f. Conflicting payment rules between the Medicare and Medicaid programs should be eliminated. g. Medicare and Medicaid benefit plans and the delivery of benefits should be coordinated. h. Care plans for beneficiaries should be streamlined among all clinical providers and social service agencies. (CMS Rep. 5, A-13)

b. H-290.968, Medicare-Medicaid Dual Eligible Demonstration Program

Our AMA strongly support efforts to better coordinate the care of those individuals who are dually eligible for Medicare and Medicaid, and who often face barriers to getting the right care in the right setting. (Res. 123, A-12)

7. Resolution 206-A-13 amended Policy D-440.997 to call on our AMA to “work with Congress and the Administration to prevent further cuts in the funds dedicated under the Patient Protection and Affordable Care Act to preserve state and local public health functions and activities to prevent disease.” This is effectively a restatement of Policy H-165.831, with the latter to be rescinded.

a. D-440.997, Support for Public Health

1. Our AMA House of Delegates request the Board of Trustees to include in their long range plans, goals, and strategic objectives to support the future of public health in order “to fulfill society’s interest in assuring the conditions in which people can be healthy.” This shall be accomplished by AMA representation of the needs of its members’ patients in public health-related areas, the promotion of the necessary funding and promulgation of appropriate legislation which will bring this to pass. 2. Our AMA: (A) will work with Congress and the Administration to prevent further cuts in the funds dedicated under the Patient Protection and Affordable Care Act to preserve state and local public health functions and activities to prevent disease; (B) recognizes a crisis of inadequate public health funding, most intense at the local and state health jurisdiction levels, and encourage all medical societies to work toward restoration of adequate local and state public health functions and resources; and (C) in concert with state and local medical societies, will continue to support the work of the Centers for Disease Control and Prevention, and the efforts of state and local health departments working to improve community health status, lower the risk of disease and protect the nation against epidemics and other catastrophes. (Res. 409, A-99; Modified CLRPD Rep. 1, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Appended: Res. 206, A-13)

b. H-165.831, Use of Prevention and Public Health Fund Dollars for Activities Unrelated to Prevention and Health Promotion

Our AMA supports budget allocations from the Prevention and Public Health Fund at no less than the levels adopted in the Affordable Care Act of 2010 and will actively oppose policies that aim to cut, divert, or use as an offset, dollars from the Prevention and Public Health Fund for purposes other than those stipulated in the Affordable Care Act of 2010. (Res. 211, I-12)

8. Policy H-145.975, dealing with firearm safety and adopted at the 2013 Annual Meeting, states in part that “the rights of physicians to have free and open communication with their patients regarding firearm safety and the use of gun locks in their homes” are supported. This echoes Policy H-145.976, which dates from 2011, although it was reaffirmed in 2013. In addition, two other policy statements deal more generally with communication between patients and physicians. Both of these policies, H-5.989 and H-373.995, were reaffirmed at the most recent Interim Meeting. Taken together, these other policies make narrower policy H-145.976 superfluous, so it will be rescinded.

a. H-145.975, Firearm Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care

1. Our AMA supports: 1) federal and state research on firearm-related injuries and deaths; 2) increased funding for and the use of state and national firearms injury databases, including the expansion of the National Violent Death Reporting System to all 50 states and US territories, to inform state and federal health policy; 3) encouraging physicians to access evidence-based data regarding firearm safety to educate and counsel patients about firearm safety; 4) the rights of physicians to have free and open communication with

their patients regarding firearm safety and the use of gun locks in their homes; 5) encouraging local projects to facilitate the low-cost distribution of gun locks in homes; and 6) encouraging physicians to become involved in local firearm safety classes as a means of promoting injury prevention and the public health. 2. Our AMA supports initiatives to enhance access to mental and cognitive health care, with greater focus on the diagnosis and management of mental illness and concurrent substance abuse disorders, and work with state and specialty medical societies and other interested stakeholders to identify and develop standardized approaches to mental health assessment for potential violent behavior. (Sub. Res. 221, A-13)

#### H-5.989, Freedom of Communication between Physicians and Patients

It is the policy of the AMA: (1) to strongly condemn any interference by the government or other third parties that causes a physician to compromise his or her medical judgment as to what information or treatment is in the best interest of the patient; (2) working with other organizations as appropriate, to vigorously pursue legislative relief from regulations or statutes that prevent physicians from freely discussing with or providing information to patients about medical care and procedures or which interfere with the physician-patient relationship; (3) to communicate to HHS its continued opposition to any regulation that proposes restrictions on physician-patient communications; and (4) to inform the American public as to the dangers inherent in regulations or statutes restricting communication between physicians and their patients. (Sub. Res. 213, A-91; Reaffirmed: Sub. Res. 232, I-91; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmed by Sub. Res. 133 and BOT Rep. 26, A-97; Reaffirmed by Sub. Res. 203 and 707, A-98; Reaffirmed: Res. 703, A-00; Reaffirmed in lieu of Res. 823, I-07; Reaffirmation I-09; Reaffirmation: I-12; Reaffirmed in lieu of Res. 5, I-13)

#### H-373.995, Government Interference in Patient Counseling

1. Our AMA vigorously and actively defends the physician-patient-family relationship and actively opposes state and/or federal efforts to interfere in the content of communication in clinical care delivery between clinicians and patients. 2. Our AMA strongly condemns any interference by government or other third parties that compromise a physician's ability to use his or her medical judgment as to the information or treatment that is in the best interest of their patients. 3. Our AMA supports litigation that may be necessary to block the implementation of newly enacted state and/or federal laws that restrict the privacy of physician-patient-family relationships and/or that violate the First Amendment rights of physicians in their practice of the art and science of medicine. 4. Our AMA opposes any government regulation or legislative action on the content of the individual clinical encounter between a patient and physician without a compelling and evidence-based benefit to the patient, a substantial public health justification, or both... (Res. 201, A-11; Reaffirmation: I-12; Appended: Res. 717, A-13; Reaffirmed in lieu of Res. 5, I-13)

#### b. H-145.976, Censorship of Physician Discussion of Firearm Risk

Our AMA: (1) will oppose any restrictions on physicians being able to inquire and talk about firearm safety issues and risks with their patients; and (2) will oppose any law restricting physicians' discussions with patients and their families about guns as an intrusion into medical privacy. (Res. 219, I-11; Reaffirmation A-13)

#### *Policy Correction*

9. Finally, the House adopted Policy D-100.970, "Drug Enforcement Agency Licensure Fees," at the Interim Meeting. It reads:

Our AMA: (1) will work through appropriate channels with the Drug Enforcement Agency (DEA) and other stakeholders to limit licensure fee increases to no more than that of inflation and decrease the disproportionate amount that physicians have to pay for renewal; and (2) will work through appropriate channels to freeze DEA licensure fees for physicians.

The adopted language incorrectly refers to the DEA as the Drug Enforcement Agency. The policy will be corrected to refer to the Drug Enforcement Administration.

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