

## **JOINT REPORT OF THE COUNCIL ON MEDICAL SERVICE AND THE COUNCIL ON SCIENCE AND PUBLIC HEALTH**

The following report was presented by Peter S. Lund, MD, Chair, Council on Medical Service; and S. Bobby Mukkamala, MD, Chair, Council on Science and Public Health.

### **1. VALUE OF PREVENTIVE SERVICES**

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

#### **HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS**

##### **REMAINDER OF REPORT FILED**

*See Policy H-110.986, H-185.939, H-410.953 and H-460.894*

The Affordable Care Act (ACA) focused on prevention by requiring all individual and small group non-grandfathered health insurance plans to cover the preventive services, with no cost-sharing, recommended by the US Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), the Health Resources and Services Administration (HRSA) Bright Futures Project, and the Institute of Medicine (IOM) Committee on Preventive Services for Women (now known as the Women's Preventive Services Institute or WPSI).

Policymakers have raised concern that the number of preventive services covered with no cost-sharing is excessive and includes services that do not merit such "first dollar" coverage. At the same time, concerns have been raised that some high value services, such as secondary preventive services that reduce hospitalizations and morbidity, can be unaffordable for some patients, particularly with increased patient cost-sharing in the form of deductibles and coinsurance.

The Councils believe both concerns merit consideration and that the American Medical Association (AMA) is in a position to promulgate policies that remove barriers to preventive services that are evidence-based and cost effective. This report describes how preventive services are identified as such, notes the importance of secondary prevention, highlights concerns about health care costs, and includes a discussion regarding prioritization of preventive services. The Councils provide recommendations with the goal of right-sizing coverage of preventive services.

#### **BACKGROUND**

The combined recommendations for coverage from the four committees named by the ACA include more than 100 tests and treatments that are now free of any cost-sharing for appropriate populations (e.g., folic acid supplements for women of child-bearing age, diabetes screening in people who are over 40 and obese, age-specific vaccinations for infectious diseases, etc.). Each of these committees develops its own criteria for evaluating and recommending what constitutes preventive services.

Cost-sharing, particularly the growth of deductible amounts, has attracted the attention of policymakers and the media. Deductible growth was occurring prior to enactment of the ACA. In 2013, the year before the key coverage provisions of the ACA were implemented, the Urban Institute reported that 44.4 percent of adults with incomes above 138 percent of the federal poverty level with nongroup (individual) coverage had annual per-person deductibles of at least \$2,000, compared with 23.3 percent of adults with employer-sponsored insurance (ESI).<sup>1</sup>

Under the ACA, the trend has continued for ESI as well as for ACA exchange policies.<sup>2,3</sup> In the benchmark silver plans of the ACA marketplaces, combined medical and pharmaceutical deductibles grew 20 percent to \$3,703 in 2017 (combined deductibles in gold and platinum plans declined in 2017, the first such decline since 2014).<sup>4</sup> Individuals with incomes less than 250 percent of the federal poverty level receive cost-sharing subsidies that can substantially reduce their cost-sharing obligations.

Because of the preventive service benefits of the ACA, CMS estimates that exchange policies cover seven common health care services (most often generic drugs and primary care visits) in addition to preventive services, with no or low cost-sharing before patients meet their deductibles. Accordingly, deductibles may not apply to the most frequent

health care needs of some patients.<sup>5</sup> Non-grandfathered ESI plans also cover the ACA-mandated preventive services with no cost-sharing.

Recommendations for diagnostic tests and secondary prevention services that can reduce hospitalizations and morbidity typically are not developed by the four expert committees named in the ACA. Perhaps accordingly, cost-sharing for such services varies by plan, with no consensus that an evidence base exists to support value-based benefit design decisions.

During the drafting of this report, the ACA “repeal and replace” legislation, the American Health Care Act of 2017, would have removed the requirement that plans offer an essential health benefit package. Proponents of this approach believe that doing so would provide health insurers more flexibility in their plan designs, including offers of less comprehensive coverage at lower cost. The Congressional Budget Office (CBO) announced in December 2016 that in order for it to analyze the cost of any proposal, coverage will have to meet two criteria: 1) coverage must at a minimum cover high-cost medical events and various services, including those provided by physicians and hospitals; and 2) coverage must adhere to ACA regulations to the extent that the regulations are still in effect. Accordingly, CBO would not be able to score “mini-med” plans that offer limited benefits. Particularly given the uncertainty over what legislation will be introduced, the Councils agreed to proactively consider policy modifications that may be helpful in guiding AMA advocacy.

## PREVENTIVE SERVICES GUIDELINES GROUPS

Under the ACA, recommendations of the USPSTF, ACIP, Bright Futures, and WPSI are required to be covered with no cost-sharing by private insurers. Even prior to the ACA, the Councils note that the recommendations of these committees resulted in significant benefits for public health, such as substantial reductions in pediatric morbidity and mortality after widespread implementation of childhood vaccine recommendations. Additional information about the four groups follows.<sup>6,7,8,9</sup>

**USPSTF.** Administered and funded by the Agency for Healthcare Research and Quality, the USPSTF develops recommendations for preventive services performed mainly by primary care physicians, usually in asymptomatic pediatric and adult patient populations. The ACA mandates coverage of all “A” and “B” recommendations (those that recommend a service be performed). Currently, there are 50 “A” and “B” recommendations. Recommendations are updated on a rolling schedule, with a goal of every 5 years.

**ACIP.** Administered and funded by the Centers for Disease Control and Prevention, the ACIP develops recommendations for immunizations in pediatric and adult populations. Currently, 14 adult and 15 child/adolescent immunizations are recommended. Recommendations are updated when new data become available.

**Bright Futures.** Administered by the American Academy of Pediatrics (AAP) through funding by HRSA/Maternal and Child Health Bureau, Bright Futures is a compilation of guidelines on preventive screening and services for pediatric and adolescent populations, covering 10 health promotion themes. Bright Futures guidelines are updated approximately every 6-8 years, with the most recent edition having been released in February 2017.

**WPSI.** Administered by the American College of Obstetricians and Gynecologists (ACOG), WPSI develops women’s health-related preventive service recommendations in topic areas not already covered by the USPSTF, ACIP, or Bright Futures. In 2011, the IOM Committee on Preventive Services for Women released the first version of these recommendations. In 2016, HRSA awarded a five-year cooperative agreement to ACOG to form the WPSI and update the recommendations. The most recent update was released in December 2016. WPSI recommendations currently address nine topics.

### *Methods of the Guidelines Groups*

Each of the four expert committees recognized by the ACA develops recommendations using separate approaches, some elements of which overlap.<sup>6,7,8,9</sup> Each of the groups strives to adhere to principles that promote high-quality recommendations, such as transparency, conflict of interest mitigation, and use of best evidence possible. The USPSTF and WPSI have explicitly stated that they follow, to the best extent possible, recommendations for developing rigorous and trustworthy clinical practice guidelines set forth by the IOM in its 2011 report “Clinical

Practice Guidelines We Can Trust.”<sup>10</sup> Below, the methods of each group as they relate to principles for developing high quality recommendations are summarized.

**Transparency.** The methodologies and processes used by each of the four groups are publicly available on their respective websites. In addition, ACIP meetings are open to the public and meeting minutes are posted to the ACIP website. Once finalized, all recommendations and evidence summaries developed by each of the four groups are publicly available.

**Conflict of Interest Management.** Candidates for membership to each of the four groups must provide written disclosure of all potential conflicts of interest. For the ACIP, candidates with vaccine-related interests are not considered for appointment, and for the USPSTF, whenever possible, candidates do not have conflicts. Members of the USPSTF, ACIP, and WPSI with conflicts must disclose and discuss the conflicts prior to each meeting. Members of the USPSTF and ACIP with conflicts may not be permitted to participate in workgroup activities and topic discussions, and may be removed from the voting process. Members of the ACIP also are required to file confidential financial reports every year with the Office of Government Ethics.

**Member Composition.** USPSTF is comprised of 16 members who are experts in primary care, clinical preventive services, and evidence-based medicine, including methodological experts and clinicians. They are volunteers and are not federal employees. Currently, 13 of the 16 members are physicians. ACIP is comprised of 15 voting members who collectively have expertise in vaccinology, immunology, pediatrics, internal medicine, infectious disease, preventive medicine, or public health. Members must be U.S. citizens and must not be employed by the federal government. Currently, 13 of the 15 members are physicians. Bright Futures is comprised of expert panels covering infancy, childhood, middle childhood, and adolescence. Panel members are experts in pediatrics and primary care, and include physicians (23 of the 40 current expert panel members), dentists, nurses, physician assistants, and psychologists. WPSI members have expertise in the fields of women’s health, primary care, chronic disease management, mental health, and gerontology. They include physicians (12 of 20 current members), nurses, public health professionals, and patient representatives.

**Establishing Evidence Foundations.** The USPSTF and WPSI commission independent systematic reviews on topics from Evidence-based Practice Centers. The ACIP reviews data on morbidity and mortality associated with the disease in the general U.S. population and in specific risk groups along with available scientific literature (both published and unpublished) on the safety, efficacy, effectiveness, cost-effectiveness, and acceptability of the immunizing agent, with consideration of the relevant quality and quantity of data. Bright Futures establishes an Evidence Panel, comprised of consultants who are experts in finding and evaluating evidence from clinical studies, to examine studies and systematic evidence. The Evidence Panel also uses systematic evidence reviews performed for the USPSTF and the Cochrane Collaboration.

The USPSTF and ACIP have established categories to denote the type and quality of the overall evidence for a service. Both consider randomized controlled trials to be in the highest category, with observational studies and randomized controlled trials with limitations being placed in middle categories, and expert opinion placed in the lowest category. Bright Futures evidence searches are limited to clinical trials, meta-analyses, and randomized controlled trials; recommended preventive services for which evidence is not as strong but the service is still likely to be beneficial include explanatory rationale. WPSI uses a “best evidence approach” that prioritizes randomized controlled trials and large prospective cohort studies; other study designs, such as case-control and modeling studies, are included when evidence is lacking or when they demonstrate new findings.

**External Review/Stakeholder Engagement Opportunities.** All four groups provide opportunity for external review by stakeholders at various points in their recommendation development process. The USPSTF posts draft research plans, draft evidence reviews, and draft recommendation statements for 30-day public comment periods. In addition, it solicits review and feedback from individuals who are scientific and clinical experts in the topic under study. ACIP draft recommendations are subjected to extensive review by scientific staff of the CDC, other relevant federal agencies, ACIP members, liaison representatives and external expert consultants. Public comments are solicited during each ACIP meeting and are considered in the decision-making process. Each edition of the Bright Futures Guidelines undergoes review by national organizations concerned with infant, child, and adolescent health and welfare; guidelines are refined based on feedback. WPSI releases a draft of each recommendation for a one-month online public comment period. WPSI also solicits input from a number of organizations and individuals that

represent a broad array of perspectives and expertise on women's preventive health care. It is currently exploring a process for in-person public comment.

**AMA and Federation Representation.** Three of the four guidelines groups, USPSTF, ACIP, and Bright Futures, have partner organizations on which they rely to provide feedback on draft recommendations, assist in the dissemination and implementation of recommendations, and provide input on topic priority. The USPSTF Dissemination and Implementation Partner group is comprised of organizations involved in primary care delivery, and includes the AMA and the following members of the Federation: AAP, American Academy of Family Physicians (AAFP), American College of Physicians (ACP), ACOG, American College of Preventive Medicine (ACPM), American Osteopathic Association (AOA), and American Psychiatric Association (APA). Representatives of the Dissemination and Implementation Partners are invited to attend each USPSTF meeting. ACIP Liaisons are comprised of health professional organizations and foundations that have broad responsibility for administration of vaccines to various segments of the population. ACIP Liaisons include the AMA and the following members of the Federation: AAP, AAFP, ACOG, ACP, AOA, Infectious Diseases Society of America (IDSA), and National Medical Association (NMA). Representatives of the Liaison organizations are invited to attend ACIP meetings. The Bright Futures Project Implementation Advisory Committee is comprised of organizations involved in the promotion of children's health. Members include the AMA and the following members of the AMA Federation: AAP and NMA. While the WPSI does not have a similar separate stakeholder group, its multi-disciplinary steering committee (the committee that develops and votes on recommendations), is made up of a number of professional societies involved in the delivery of women's health. AMA is not represented on the steering committee, but the following members of the Federation are: AAFP, ACOG, ACP, American College of Radiology, AAP, AOA, APA, and ACPM.

## SECONDARY PREVENTION

Prevention can be divided into three stages: primary, secondary, and tertiary.<sup>11</sup> However, inconsistencies exist in the way that each term is used and the types of preventive services that characterize the categories.<sup>12</sup> For the purposes of this report, we consider "secondary prevention" as interventions intended to slow or prevent the progression of early-stage disease, thereby reducing the risk of further, more serious health outcomes. By contrast, "tertiary prevention" refers to interventions that treat existing pathological disease with the goal of minimizing loss of function. Secondary prevention measures are intended to restore health by treating previously unrecognized disease before irreversible pathological changes take place. Examples of secondary prevention include statin therapy in those with established atherosclerotic cardiovascular disease to prevent myocardial infarction, stroke, or other cardiovascular events; or behavioral intervention programs to support weight loss and prevent type 2 diabetes and cardiovascular disease in patients with obesity. While the expert committees recognized by the ACA focus mainly on primary prevention recommendations, the USPSTF, Bright Futures, and WPSI also have made some secondary prevention recommendations, such as the USPSTF recommendation that patients at increased risk for breast cancer take a selective estrogen receptor modulator, and the WPSI recommendation that women at risk for domestic violence be provided with counseling, education, harm reduction strategies, and appropriate supportive services.

Health outcomes improvement and cost-effectiveness evidence is strong for many secondary prevention measures. For example, for those identified as having impaired glucose intolerance, treatment with lifestyle intervention programs delays or prevents progression to type 2 diabetes and results in cost savings.<sup>13,14</sup> Similarly, treating adolescents with major depressive disorder with a collaborative care model both improves depressive symptoms and is cost effective.<sup>15,16,17</sup> However, while evidence-based and cost-saving secondary prevention measures such as these are usually covered by a patient's insurance, many are not covered without cost-sharing unless they fall within the recommendations of the expert committees named by the ACA. Patients without insurance or who are unable to afford co-pays and deductibles are therefore not always able to access secondary prevention measures. Given the health-improving and cost-saving potential of many secondary preventive measures, a need exists for a process by which such measures could be routinely and rigorously evaluated for coverage without cost-sharing, similar to the processes by which preventive services topics are evaluated by the committees named in the ACA.

## PRIORITIZING PREVENTIVE SERVICES

A 2003 study estimated that a primary care provider would need to spend 7.4 hours per working day to deliver the preventive services recommended by the USPSTF,<sup>18</sup> an estimate that has likely grown given the number of additional services recommended since that time. The reality of clinical time constraints and competing demands

means that not every preventive service is delivered as recommended. On average, patients receive only approximately 55 percent of recommended services,<sup>19</sup> implying that physicians employ prioritization tactics to best determine which services to deliver. Given the near impossibility of delivering every preventive service to those for whom they are recommended, calls have been made for more systematic prioritization that takes into account factors such as health impact and cost-effectiveness.<sup>20,21,22,23</sup>

Physicians' clinical judgment is often adequate in determining which preventive services are most beneficial for each of their patients, especially for interventions that are strongly linked to the prevention of adverse health outcomes, like counseling about tobacco cessation, and for interventions that are appropriate for almost every person, such as immunizations.<sup>20</sup> But estimating the benefit of some services is complex and challenging. For example, the benefit of screening for certain cancers can vary up to tenfold based on patient-specific demographic, clinical, behavioral, and genetic factors.<sup>20</sup> Risk prediction calculators, such as those intended to determine cardiovascular disease risk, have been proposed as a tool to assist in revealing the relative benefit of different prevention measures, including blood pressure control, lipid control, and weight control.<sup>20</sup> EHR- and web-based clinical decision support systems can run algorithms that take into account patient characteristics to predict individual risk level, thereby suggesting what type of intervention may be optimal.<sup>20,24,25</sup> Patient preferences also are important to consider, since patients may be more willing to engage in some preventive services than others. For example, recommending that a patient undergo screening colonoscopy is more valuable for a patient who is willing to undergo the colonoscopy than for a patient who is not.<sup>20</sup> EHR systems can track patient preferences and readiness for change over time so that physicians can address the specific concerns of the patient in their future conversations about prevention.

Prioritization using personalized decision-making at the point of care has been tested using mathematical modeling that measures increases in life expectancy when a number of recommended preventive services are delivered to patients with different clinical characteristics.<sup>22</sup> For a hypothetical male patient who is 62 years of age and obese, smokes, and has high blood pressure, high cholesterol, and a family history of colorectal cancer, life expectancy is most increased by preventive services that encourage the patient to quit smoking, lose weight, and lower his blood pressure.<sup>22</sup> For a patient with the same characteristics, but also with type 2 diabetes, controlling his blood sugar provides the largest increase in life expectancy. This kind of approach would likely be most effective with the use of an EHR system that can apply modeling to each patient's personal characteristics and provide decision support about which preventive services will have the largest impact on life expectancy.

Others have included cost-effectiveness as a prioritization tactic. Maciosek et al. recently evaluated a large number of preventive services recommended by the USPSTF and the ACIP for their clinically preventable burden and cost-effectiveness, in an effort to determine high-priority preventive services.<sup>21</sup> While several services were determined to be either cost-saving or to have the highest clinically preventable burden, only three were deemed to fit into both categories: the childhood immunization series, brief counseling about tobacco use in youth, and screening for and providing brief interventions to reduce tobacco use in adults. The study also found that, on average, preventive services that address health behaviors, such as alcohol misuse, diet, physical activity, and tobacco use provide the greatest opportunities to improve population health even when accounting for realistic levels of nonadherence.<sup>21</sup>

While these studies should not be construed as definitive methods for determining which preventive services have the highest value, they present examples of mechanisms that might better ensure that patients receive the recommended preventive services most likely to benefit them. It is important to note that a number of complex factors figured into these prioritization mechanisms, so application to local or regional populations would need to take into account local and regional utilization rates to more precisely determine value.

### *The Cost Imperative*

Health care costs continue to rise precipitously despite widespread efforts to insert value into models of care delivery and benefit design. In 2015, the U.S. spent \$3.2 trillion, or \$9,990 per person on health care. Health care spending accounts for nearly 18 percent of the U.S. economy.<sup>26</sup> Federal reform efforts have sought to address costs through delivery reform, payment reform, benefit design, and other initiatives.

With respect to preventive services, there is concern that an excessive number of preventive services are covered with no cost-sharing, potentially contributing to high premiums and health care spending.<sup>27</sup> At the same time,

concerns have been raised that some high value services, such as secondary preventive services that reduce hospitalizations and morbidity, can be unaffordable for some patients, particularly those with high deductibles.

Each year, chronic disease accounts for 70 percent of deaths, and about half of all adults have one or more chronic conditions.<sup>28</sup> An emphasis on value-based insurance design could improve adherence to health benefits that best treat chronic conditions.

#### AMA POLICY

AMA Policy H-165.846 broadly defines the adequacy of health insurance coverage in the context of federal guidelines regarding types of health insurance coverage (e.g., Title 26 of the U.S. Tax Code and Federal Employees Health Benefits Program [FEHBP] regulations). It further specifies that the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program be used as the model for any essential health benefits package for children.

Policy H-185.939, "Value-Based Insurance Design," supports flexibility in the design and implementation of value-based insurance design (VBID) programs, which explicitly consider the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements. It calls for the active involvement of practicing physicians; the use of high-quality, evidence-based data; and transparency of both the methodology and criteria used to determine high- or low-value services or treatments and the coverage and cost-sharing policies. The policy states that VBID should not restrict access to patient care and must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties. The policy also calls for plan sponsors to engage in ongoing evaluation of the plan designs to ensure VBID coverage rules are updated in accordance with evolving evidence.

Various AMA policies call for first-dollar (free) coverage, including H-440.860 regarding adult vaccines, H-185.969 regarding immunizations, D-330.935 regarding Medicare preventive service benefits, H-290.972 regarding first-dollar preventive coverage for health savings account holders, and H-440.840 regarding tuberculosis testing. All of these policies are accomplished with the ACA preventive service requirement.

At the same time, AMA policy calls for benefit mandates to be minimized to allow markets to determine benefit packages and permit a wide choice of coverage options (Policy H-165.856). Increasing the number of mandates included in the EHB package could result in an increase in the cost and reduce the affordability of health insurance coverage, in terms of both deductibles and other cost-sharing, and premiums.

Policy H-460.909 outlines AMA principles for comparative effectiveness research (CER), stating that CER entities (e.g., the Patient-Centered Outcomes Research Institute) must not have a role in making or recommending coverage or payment decisions for payers. However, Policy H-110.986 supports the inclusion of the cost of alternatives and cost-effectiveness analysis in CER. Accordingly, the AMA supports the use of cost as a factor in CER, but does not support CER entities making coverage or payment decisions. CER data that includes a consideration of cost would allow the expert committees that establish guidelines to have a better informed deliberation about value.

The CER policy calls for transparency, conflict disclosure, and physician and patient oversight. Policy H-410.953 similarly calls for processes that result in clinical practice guidelines that are trustworthy, rigorous, transparent, independent, and accountable. These processes include scientifically rigorous methods and standards for weighting evidence, access to appropriate expertise among members or consultants, procedures to minimize financial or other conflicts of interest, funding that is independent of entities that have an interest in the recommendations being developed, rigorous and independent peer review, and clear information about methodology.

#### DISCUSSION

A persistent criticism of the ACA, among most opponents and some supporters, has been that the broad scope of the preventive services covered with no cost-sharing contributed to premium and deductible increases and provided health plans with few options for varying their benefit designs. Alongside complaints that too many preventive services were being offered without cost-sharing, there are also concerns that some high-value secondary preventive services, such as treatment for diabetes and hypertension, may be avoided because of increasingly high health plan

deductibles. The Councils acknowledge these concerns and present recommendations to better align preventive service coverage with evidence.

The preventive services covered without cost-sharing under the ACA rely on the recommendations of four expert committees, all of which are developed using rigorous but differing processes and methodologies. Since all four groups include participation by the AMA and/or members of federation of medicine, some of our recommendations aim to help the representatives to these committees lead an effort to promote transparency and uniformity in how the committees develop their recommendations. It is the hope of the Councils that the expert committees will work to align their methodologies. The expert committees regularly seek input from national medical specialty societies and the public during review and comment periods, and we encourage medical societies to participate in such opportunities.

We evaluated the possibility of making recommendations for health plans and payers to routinely consider evidence and cost-effectiveness in making coverage determinations, and believe AMA policy on benefit adequacy and value-based insurance design remain appropriate to address these concerns. In addition, policy supports federal responsibility to conduct comparative effectiveness research and promote uniformity in market rules, and state government responsibility to regulate markets and seek to minimize benefit mandates. However, public and private payers should be encouraged to prioritize coverage of preventive services. In addition, consensus on the value of secondary prevention will require a research focus on the long-term effects of early intervention for chronic diseases.

Consistent with Policy H-410.953, it is suggested that significant physician involvement should be required in all steps identified for determining relative levels of coverage of preventive services, and that the process be transparent and free of conflicts of interest.

## RECOMMENDATIONS

The Council on Medical Service and the Council on Science and Public Health recommend that the following be adopted, and that the remainder of the report be filed.

1. That our American Medical Association (AMA) reaffirm Policy H-185.939, which supports the use of value-based insurance design in determining patient cost-sharing requirements based on the clinical value of a treatment.
2. That our AMA reaffirm Policy H-110.986, which supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.
3. That our AMA reaffirm Policy H-410.953, which calls for development processes that result in clinical practice guidelines that are trustworthy, rigorous, transparent, independent, and accountable.
4. That our AMA encourage committees that make preventive services recommendations to:
  - a. Follow processes that promote transparency and clarity among their methods;
  - b. Develop evidence reviews and recommendations with enough specificity to inform cost-effectiveness analyses;
  - c. Rely on the very best evidence available, with consideration of expert consensus only when other evidence is not available;
  - d. Work together to identify preventive services that are not supported by evidence or are not cost-effective, with the goal of prioritizing preventive services; and
  - e. Consider the development of recommendations on both primary and secondary prevention.
5. That our AMA encourage relevant national medical specialty societies to provide input during the preventive services recommendation development process.
6. That our AMA encourage comparative-effectiveness research on secondary prevention to provide data that could support evidence-based decision making.

7. That our AMA encourage public and private payers to cover preventive services for which consensus has emerged in the recommendations of multiple guidelines-making groups.

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#### APPENDIX - Policies Recommended for Reaffirmation

##### H-185.939, Value-Based Insurance Design

Our AMA supports flexibility in the design and implementation of value-based insurance design (VBID) programs, consistent with the following principles: a. Value reflects the clinical benefit gained relative to the money spent. VBID explicitly considers the clinical benefit of a given service or treatment when determining cost-sharing structures or other benefit design elements. b. Practicing physicians must be actively involved in the development of VBID programs. VBID program design related to specific medical/surgical conditions must involve appropriate specialists. c. High-quality, evidence-based data must be used to support the development of any targeted benefit design. Treatments or services for which there is insufficient or inconclusive evidence about their clinical value should not be included in any targeted benefit design elements of a health plan. d. The methodology and criteria used to determine high- or low-value services or treatments must be transparent and easily accessible to physicians and patients. e. Coverage and cost-sharing policies must be transparent and easily accessible to physicians and patients. Educational materials should be made available to help patients and physicians understand the incentives and disincentives built into the plan design. f. VBID should not restrict access to patient care. Designs can use incentives and disincentives to target specific services or treatments, but should not otherwise limit patient care choices. g. Physicians retain the ultimate responsibility for directing the care of their patients. Plan designs that include higher cost-sharing or other disincentives to obtaining services designated as low-value must include an appeals process to enable patients to secure care recommended by their physicians, without incurring cost-sharing penalties. h. Plan sponsors should ensure adequate resource capabilities to ensure effective implementation and ongoing evaluation of the plan designs they choose. Procedures must be in place to ensure VBID coverage rules are updated in accordance with evolving evidence. i. VBID programs must be consistent with AMA Pay for Performance Principles and Guidelines

##### H-110-986, Incorporating Value into Pharmaceutical Pricing

1. Our AMA supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion. 2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research. 3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size.

##### H-410.953, Ethical Considerations in the Development of Clinical Practice Guidelines

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines help inform physician judgment and decision making by physicians and patients. Clinical practice guidelines also have significant potential to meaningfully inform efforts to provide care of consistently high quality for all patients and to help shape development of sound public policy in health care. To achieve those ends, clinical practice guidelines must be trustworthy. Patients, the public, physicians, other health care professionals and health administrators, and policymakers must have confidence that published guidelines are the ethically and scientifically credible product of development processes that are rigorous, independent, transparent, and accountable. To that end, the development or updating of clinical practice guidelines should meet the following expectations:

1. Guidelines/updates are developed independent of direct financial support from entities that have an interest in the recommendations to be developed.
2. Formal, scientifically rigorous methods and explicit standards are adopted for the review and weighting of evidence, the integration of expert judgment, and the strength of clinical recommendations.
3. Guideline panels have access to appropriate expertise among members or consultants, including not only relevantly qualified clinical experts but also appropriately qualified methodologists, representatives of key stakeholders, and, ideally, one or more individuals skilled in facilitating groups.
4. Ideally, all individuals associated with guideline development will be free of conflicts of interest during the development process and will remain so for a defined period following the publication of the guideline.
5. Formal procedures are adopted to minimize the potential for financial or other interests to influence the process at all key steps (selection of topic, review of evidence, panel deliberations, development and approval of specific recommendations, and dissemination of final product). These should include: a) required disclosure of all potential conflicts of interest by panel members, consultants, staff, and other participants; b) clearly defined criteria for identifying and assessing the seriousness of conflicts of interest; and

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