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RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
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MEMORANDUM

November 28, 2016

To: Subcommittee on Health Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Examining the United States Preventive Services Task Force"

On **Wednesday, November 30th, at 10:30 a.m., in Room 2322 of the Rayburn House Office Building**, the Subcommittee on Health will hold a hearing titled "Examining the United States Preventive Services Task Force."

I. BACKGROUND

A. Clinical Practice Guidelines

Clinical practice guidelines are statements including recommendations intended to optimize patient care, which are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.[1] Clinical practice guidelines have the potential to enhance translation of research into practice and improve healthcare quality and safety as well as influence the development of performance measures.[2]

The important role that clinical practice guidelines play in the U.S. health care system led Congress to direct the National Academy of Medicine (NAM) to study the matter. The Medicare Improvements for Patients and Providers Act of 2008 required NAM to study and issue a report on best practices for conducting systemic reviews of clinical effectiveness research and for developing clinical protocols. According to that law, the purpose of the study was "to ensure

[1] National Academy of Medicine, *Clinical Guidelines We Can Trust* (Feb. 2011) (online at https://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx).

[2] *Id.*

that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent." In 2011, NAM published a report entitled *Clinical Guidelines We Can Trust*, establishing standards for trustworthy clinical practice guidelines.[3] Those standards emphasized the need to promote transparency in guideline development and manage conflicts of interest. For example, the standards state that having members of a guideline development entity with conflicts of interest should be avoided if possible, and that payers of services should have no role in developing guidelines.[4]

B. United States Preventive Services Task Force (USPSTF)

i. Overview

Established in 1984, the United States Preventive Services Task Force (Task Force or USPSTF) is an independent group of national experts who specialize in prevention, evidence-based medicine and primary care. The chief role of the Task Force is to develop evidence-based recommendations for clinical preventive services and health promotion in order to aide primary care professionals, patients, and families in deciding whether a particular preventive service is the right choice for the individual's needs. For instance, the Task Force may develop recommendations for the effectiveness of certain screening tests, counseling services, or preventive medications. USPSTF recommendations address services offered in primary care settings, or services referred by primary care professionals, and apply only to individuals without signs or symptoms of the disease or health condition under consideration.

In 1998, the Public Health Service Act authorized the Agency for Healthcare Research and Quality (AHRQ) to convene the Task Force and to provide continued administrative, research, technical, and dissemination support.[5] The Director of AHRQ appoints new members to the Task Force to serve four year terms. Organizations and individuals are permitted to nominate candidates for membership on the Task Force, which can include self-nomination by individuals. The Task Force is currently composed of 16 non-federal, volunteer members with expertise in fields such as behavioral health, family medicine, geriatrics, internal medicine, pediatrics, obstetrics and gynecology, and nursing.

ii. Grading System

[3] National Academy of Medicine, *Clinical Guidelines We Can Trust* (Feb. 2011) (online at https://www.nationalacademies.org/hmd/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx).

[4] *Id.*

[5] Agency for Healthcare Research and Quality (AHRQ), *U.S. Preventive Services Task Force (USPSTF): An Introduction* (Sept. 2012) (online at http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/uspstf/index.html).

The Task Force assigns a letter grade of A, B, C, D, or I to each recommendation based on the strength of the evidence and the advantages and disadvantages of the service under consideration:

- **A:** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. Offer or provide this service.
- **B:** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. Offer or provide this service.
- **C:** The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small. Offer or provide this service for selected patients depending on individual circumstances.
- **D:** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. Discourage the use of this service.
- **I:** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined. Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.[6]

iii. USPSTF and The Affordable Care Act (ACA)

Cost is a common barrier to individuals accessing important and potentially lifesaving preventive services. Research shows that evidence-based preventive care saves lives by identifying illnesses early on and managing them before they become more serious and costly.[7] For this reason, a critical provision of the ACA requires private health plans to provide coverage for various preventive services without cost sharing (such as copayments, co-insurance, or deductibles), removing a significant obstacle for individuals in need of preventive services. As part of this requirement, insurers must cover evidence-based screening and counseling services that receive an A or B grade from USPSTF. The preventive services required to be covered by the ACA come from recommendations made by experts in the field, including USPSTF.

Additionally, the ACA eliminated cost sharing for Medicare-covered preventive services receiving a grade of A or B from USPSTF. Current law also gives the Secretary of the Department of Health and Human Services (HHS) the authority to cease Medicare coverage for a preventive service that receives a D grade from USPSTF.

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[6] United States Preventive Services Task Force, *Grade Definitions* (Feb. 2013) (online at https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions).

[7] Michael V. Maciosek, *Greater Use of Preventive Services In U.S. Health Care Could Save Lives At Little Or No Cost*, Health Affairs 29.9 (2010):1656-660.

The ACA also charged USPSTF with submitting an annual report to Congress "identifying gaps in research such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations."

II. USPSTF TRANSPARENCY EFFORTS AND MANAGEMENT OF CONFLICTS OF INTEREST

Over the past four years, the USPSTF has sought to increase transparency in the recommendation process through standardization and public engagement.[8] The USPSTF has also strengthened its conflict of interest policy. That effort has included incorporating strategies and processes based on recommendations from the National Academy of Medicine report, *Clinical Guidelines We Can Trust*.

As discussed above, any organization or individual may nominate one or more qualified persons to the Task Force.[9] Once selected for the Task Force, members are required to disclose all information regarding any possible financial and nonfinancial conflicts of interest for all topics that are being considered by the Task Force. Task Force chairs review all disclosures and determine the final action on the member's eligibility to participate on a specific topic based on the nature and significance of the potential conflict. The topic, level of disclosure, nature of the disclosure, date of disclosure, and action taken by the Task Force chairs are publicly posted on the USPSTF website. Conflicts of interest must be updated by all members prior to each meeting.[10]

The Task Force has in place a standardized process to solicit input from the public for all of its recommendations in order to ensure transparency in the guideline development process.[11] As recommended in NAM's standards, the public is invited to comment on all draft research plans, draft evidence reviews, and draft recommendation statements through USPSTF's website. Each public comment period lasts for four weeks, and all comments received are reviewed by

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[8] United States Preventive Services Task Force, *Fifth Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services* (Nov. 2015) (online at https://www.uspreventiveservicestaskforce.org/Page/Name/fifth-annual-report-to-congress-on-high-priority-evidence-gaps-for-clinical-preventive-services).

[9] United States Preventive Services Task Force, *Public Comments and Nominations* (Aug. 2016) (online at https://www.uspreventiveservicestaskforce.org/Page/Name/public-comments-and-nominations).

[10] United States Preventive Services Task Force, *Conflict of Interest Disclosures* (July 2016) (online at https://www.uspreventiveservicestaskforce.org/Page/Name/conflict-of-interest-disclosures).

[11] United States Preventive Services Task Force, *Standards for Guideline Development* (Jan. 2016) (online at https://www.uspreventiveservicestaskforce.org/Page/Name/standards-for-guideline-development).

USPSTF topic leads with the assistance of researchers at Evidence-based Practice Centers.[12] AHRQ contracts with institutions to review all relevant scientific literature on clinical and health services topics to produce evidence reports through the Evidence-based Practice Centers Program.[13] Any organization or individual may nominate a new topic or request reconsideration of a topic at any time through the USPSTF website. These topics are considered at regularly scheduled meetings in March, July, and November. Though all USPSTF recommendations are reviewed on a five-year cycle, requests for reconsideration may be made if there is new evidence or if there are changes in the public health burden of the condition.[14]

III. THE USPSTF TRANSPARENCY AND ACCOUNTABILYT ACT OF 2015

A. Overview

H.R. 1151, the USPSTF Transparency and Accountability Act of 2015 was introduced by Rep. Marsha Blackburn (R-TN) and Rep. Bobby Rush (D-IL) on February 27, 2015. The purpose of this legislation is to revise the operations of the USPSTF. The hearing will focus on an updated Discussion Draft of H.R. 1151 circulated by Rep. Blackburn.

B. Changes to the Composition and Operation of the USPSTF

This draft legislation would grant AHRQ the discretion to establish but also eliminate the USPSTF. It would require AHRQ to take steps to reconstitute the USPSTF by a certain date, currently specified in bracketed text as not later than 180 days after the date of enactment. Under the draft, the USPSTF could not publish any draft or final recommendations on or after a date, currently specified in brackets as the date of enactment, unless and until AHRQ reconstitutes the USPSTF based on the composition and operational requirements of this legislation discussed below. For existing recommendations published prior to the reconstitution of the USPSTF, the draft would allow an outside organization to request that the USPSTF review such recommendations if the organization has additional peer-reviewed scientific evidence that provides new information relevant to the previous recommendation. The draft legislation would require the USPSTF to establish a process consistent with the requirements of this legislation to review the previous recommendation in question and promulgate an updated recommendation if needed. The draft legislation would require the USPSTF to conduct its activities in compliance with the Federal Advisory Committee Act.

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[12] United States Preventive Services Task Force, *Opportunity for Public Comment* (Nov. 2014) (online at https://www.uspreventiveservicestaskforce.org/Page/Name/us-preventive-services-task-force-opportunities-for-public-comment).

[13] AHRQ, *Evidence-based Practice Centers (EPC) Program Overview* (Nov. 2015) (online at http://www.ahrq.gov/research/findings/evidence-based-reports/overview/index.html).

[14] United States Preventive Services Task Force, *Nominate a Recommendation Statement Topic* (Feb. 2011) (online at https://www.uspreventiveservicestaskforce.org/Page/Name/nominating-recommendation-statement-topics).

The draft legislation would specify the scientific fields of expertise of those individuals who make up the USPSTF, including expertise in health sciences research, health economics, health promotion, disease prevention, and clinical care. It also would specify the membership of the USPSTF to include practicing primary care providers, specialty care providers and patient and health care consumers. AHRQ would be required to provide notice in the Federal Register that it is accepting nominations before appointing members to the USPSTF.

The discussion draft would require the USPSTF to publish and request comments on proposed research plans in the Federal Register and make available to the public the final research plan, including a discussion of the comments received about the proposed plan and responses to such comments. The draft legislation would require AHRQ to design and regularly update guidelines for proper methodological standards for incorporation into research plans and facilitate coordination and interaction with federal agencies and departments in the creation of such standards as well as research plans. The draft legislation would require AHRQ to make the draft evidence reports available and request comments through the Federal Register as well as ensure the draft evidence reports are reviewed by provider and patient representatives before publication. AHRQ would also be required to publish draft recommendations and establish a comment period of at least 45 days in the Federal Register. Under the draft, the USPSTF would be required to consult with provider groups, practicing specialists, and patient and disease advocacy organizations prior to voting on a draft recommendation.

The draft legislation would require AHRQ to make comments received by the USPSTF publicly available and that all final recommendation statements also include a description of all public comments received on the draft recommendation and recommendations made by federal entities on the topic. The draft legislation also would require the USPSTF to consider the impact of its recommendations on the health care community in publishing recommendation statements, including how its specific assignment of a grade to a product or service may affect coverage and access to such product or service under federal programs and private health insurance.

A new USPSTF grading system would be established in statute and require AHRQ to make any changes to the grading system through regulations. This section would also require the USPSTF to review and regrade services previously classified within any grade category that is changed through regulation before the change can go into effect.

In addition, the USPSTF would be required to convene a Preventive Services Advisory Board (Advisory Board) composed of representatives from public and private entities to advise the USPSTF on developing, updating, publishing, and disseminating evidence-based recommendations on the use of clinical preventive services. The Advisory Board would include patient groups, providers of clinical services including community-based providers and specialty physicians, federal departments and agencies, and private health care payers. The Advisory Board would be charged with recommending clinical preventive services for review by the USPSTF; suggesting scientific evidence for consideration by the Task Force related to reviews undertaken by the USPSTF; providing feedback regarding the research plan, the evidence report, and draft recommendations; and assisting with efforts to disseminate the USPSTF recommendations.

USPSTF members and Advisory Board members would be required to disclose to AHRQ any potential, relevant financial interests in the same manner and to the same extent as an employee of the executive branch would be required to disclose if the employee were participating in such meeting. The draft legislation also would make clear that members of the USPSTF and Advisory Board are volunteers.

C. GAO Report

The draft legislation would require that the Comptroller General of the United States to (i) issue a report listing the USPSTF recommendations and any updates; (ii) compare the USPSTF recommendations with recommendations from federal health agencies, national medical professional societies, and patient and disease advocacy organizations; and (iii) analyze the impact of the USPSTF recommendations on public and private insurance coverage, access, and outcomes.

D. Changes to the Use of USPSTF Recommendations

The draft legislation also has implications for Medicare. It would eliminate the Secretary's ability to deny payment for services based solely on a USPSTF Task Force grade. It would also restrict the Secretary's ability to modify or eliminate coverage of a preventive service without action by the USPSTF, using the new reforms included in the bill, and consultation with patient and provider groups. Additionally it would restrict the Secretary's discretion in implementing quality measures "related to" recommendations by the USPSTF by requiring USPSTF action and consultation with other agencies and stakeholder groups.

IV. WITNESSES

Panel I:

Kristin Bibbins-Domingo, Ph.D. M.D. MAS
Chairwoman
United States Preventive Services Task Force (USPSTF)

Panel II:

John H. Lynch, M.D.
Member
American Urological Association
Chairman and Professor
Department of Urology, Georgetown University

John Meigs, Jr, M.D., FAAFP
President
American Academy of Family Physicians