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# United States Senate

COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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May 16, 2016

The Honorable Sylvia Mathews Burwell  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell,

We write to seek clarification and express concerns related to the United States Preventive Services Task Force (USPSTF) and the processes used by the USPSTF to assign grades and make recommendations related to preventive services.

The *Patient Protection and Affordable Care Act* (PPACA) requires insurance companies to cover preventive services graded A or B by the USPSTF without any patient cost-sharing. This law shifted USPSTF's role from a scientific advisory body that informs clinical practice to a body with the authority to establish new and expensive federal benefit mandates and coverage requirements. In addition to leading to increased health care costs and insurance premiums, this shift creates unintended consequences for the practice of medicine, innovation and development of preventive tests, and access to preventive services. Further, by explicitly giving an entity not subject to the Federal Advisory Committee Act or the Administrative Procedures Act the authority to make binding recommendations on federal health care benefit mandates, PPACA created an opaque process without the transparency, accountability, and assurance of public notice and comment.

USPSTF recommendations or draft recommendations on cancer screenings, including breast and prostate cancers, could have the effect of eliminating coverage for certain cancer screening activities. Under PPACA, the Secretary can eliminate coverage for preventive services that do not receive an A, B, or I grade from USPSTF.<sup>1</sup> Although the Secretary has not chosen to exercise this authority, USPSTF graded prostate-specific antigen screening with a D in 2012,<sup>2</sup> placing coverage for this service at risk. This recommendation is in the process of being updated.<sup>3</sup> Similarly, the January 2016 breast cancer screening

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<sup>1</sup> 42 U.S.C. 1395(n)

<sup>2</sup> <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/prostate-cancer-screening>

<sup>3</sup> <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryDraft/prostate-cancer-screening>

recommendation maintained a C grade for mammograms for most women between the ages of 40-49.<sup>4</sup> Although the USPSTF recognized the benefit of individualized screening timelines and decisions based on individual patient risk, the explicit link between the C grade and coverage means that as many as 17 million women who choose an individual screening plan might find this benefit eliminated from their insurance coverage.<sup>5</sup>

Given the significant impact of USPSTF's decisions on patients' access and ability to afford preventive services, it is essential that the decision-making process is fully transparent and accountable. Although the USPSTF began accepting comments from the public on its draft recommendation statements, draft research plans, and draft evidence reviews, the comments are not publicly available, and there is no way to know how those comments are incorporated into final plans and recommendations. The transparency process followed by USPSTF in selecting topics, evaluating evidence, and making recommendations is critical for the integrity of resulting recommendations. Therefore, we request that you provide the following information:

#### Membership and Use of Experts

1. How are members of the USPSTF evaluated for independence to address potential conflicts of interest if the USPSTF is not subject to the Administrative Procedures Act or the Federal Advisory Committee Act?
2. Are members of the USPSTF required to have subject matter or clinical expertise on the preventive service being evaluated for a recommendation?
3. What percentage of USPSTF members maintain a full-time clinical practice?
4. Are outside experts consulted to understand how a recommendation would change clinical practices, particularly the impact the recommendation would have on coverage decisions and access to preventive services both individually and across the population?
5. If experts are consulted, explain how are they selected, and provide a full list of the experts' names and qualifications.

#### Processes and Procedures

6. How does USPSTF select recommendations to consider or update? Is there a standard set of criteria, and if so, what criteria are used?
7. USPSTF states that its recommendations "are intended for use in the primary care setting."<sup>6</sup> What does USPSTF consider to be a primary care setting?
8. How does USPSTF reach a determination on the quality of overall evidence and the certainty of the net benefit evaluation?
9. How are studies assessed and weighted in the determination of the grade for overall evidence?

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<sup>4</sup> <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breast-cancer-screening1>

<sup>5</sup> <http://avalere.com/expertise/managed-care/insights/updated-breast-cancer-screening-recommendation-could-eliminate-guaranteed-c>

<sup>6</sup> <http://www.uspreventiveservicestaskforce.org/Page/Name/process-for-recommendation-statements>

10. If there are differences of opinion on what grade to assign a body of overall evidence within the USPSTF and within comments, how are those differences addressed or resolved? Is dissent made public?
11. If there are differences of opinion on how to weigh different benefits and harms of a particular prevention service within the USPSTF and within comments, how are those differences addressed? Is dissent made public?
12. Are subject matter or clinical experts consulted on the adequacy of the studies or appropriate weighting of benefits and harms?
13. Please describe the process by which comments on draft research plans, draft evidence reviews, and draft recommendations are incorporated into final versions.
14. Is it possible for interested stakeholders and members of the public to review all the public comments submitted to the USPSTF? If so, please provide instructions on how to access such public comments.
15. Please provide clear, recent examples of situations where comments on a draft research plan, a draft evidence review, and a draft recommendation resulted in a change to the final version.
16. PPACA explicitly requires USPSTF to “consider clinical preventive best practice recommendations from ... specialty medical associations, patient groups, and scientific societies.”<sup>7</sup> How are recommendations from other medical or scientific organizations, particularly those that guide clinical practice and treatment, given consideration and incorporated into the USPSTF process?
17. We have heard concerns that the breast cancer recommendations conflict with the recommendations of other clinical and scientific experts, including the American College of Obstetrics and Gynecology, the American Cancer Society, and the American College of Radiology. Please explain the factors that go into USPSTF recommendations that differ from those of other clinical and scientific experts and how USPSTF reconciles such differences.

#### Developing a Department-wide Process for Consistent Research and Policy

18. How do USPSTF recommendations interact with the prevention research and policies produced by the National Institutes of Health, the Agency for Healthcare Quality and Research, the Centers for Disease Control and Prevention, and the Food and Drug Administration?
19. How do USPSTF recommendations interact with the reimbursement and payment rules promulgated by the Centers for Medicare and Medicaid Services (CMS)? For example, in 2014, CMS issued a final rule that reimbursed 3D mammography at a higher rate than 2D, while in 2015, USPSTF graded 3D mammography as investigational, which provides no cost-sharing protections. Did USPSTF have access to and rely on the same evidence to make its recommendation as CMS used to determine the reimbursement policy?
20. Is there a Department-level policy or procedure to reconcile differences within the various agencies in terms of preventive services policy? Please provide copies of any policies or guidance documents that speak to this issue.

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<sup>7</sup> 42 USC 299B-4(a)(1)

Thank you in advance for your attention to this request. Should you have additional questions or comments, please have your staff contact Laura Pence at 202-224-6770 or [Laura\\_Pence@help.senate.gov](mailto:Laura_Pence@help.senate.gov). We request a response by June 3, 2016.

Sincerely,



Lamar Alexander  
Chairman



Richard Burr  
U.S. Senator



Johnny Isakson  
U.S. Senator



Orrin Hatch  
U.S. Senator



Pat Roberts  
U.S. Senator