National Business Group on Health

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

January 29, 2014

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services (HHS)
Room 120F
200 Independence Avenue, SW
Washington, DC 20001

Re: *Policy Options for Processes to Determine Coverage Guidelines for the United States Preventive Services Task Force (USPSTF) Recommendations and to Assure that USPSTF Places Paramount Importance on Clinical Evidence When Making A or B Recommendations*

Dear Secretary Sebelius:

The National Business Group on Health writes to submit options for you and your leadership team to consider given the increased weight and impact of USPSTF recommendations since the passage of the Patient Protection and Affordable Care Act (ACA). The proposed process recommendations are designed to assist in translating and implementing those recommendations into specific benefits and weighing additional, pertinent criteria beyond clinical evidence in the case of each USPSTF A and B-recommended service.

We applaud all of the work that you and the Department staff are doing to continue implementing the Patient Protection and Affordable Care Act and appreciate the opportunity to make recommendations to further refine such an important process. If you or your staff members are interested, we would be glad to meet with you or them, to follow up with more information and respond to questions. *We believe that having an additional group under your office to address questions of coverage and plan design will significantly improve your ability to meet the Congressional mandate while also fulfilling the President's agenda to ensure high quality care that is suitable and medically appropriate for individual patients but is also affordable to working families and the nation.*

The National Business Group on Health represents approximately 387, primarily large, employers (including 67 of the Fortune 100) who voluntarily provide health benefits and other health programs to over 55 million American employees, retirees, and their families. We believe that health plans, government, and employers should promote policies that speed adoption of evidence-based medical practices and reduce the use of unproven and/or ineffective treatments.

We laud the USPSTF's ongoing efforts to improve the provision of evidence-based clinical preventive services and the ACA's intent to expand access by eliminating cost sharing and requiring expanded coverage, based on the recommendations of a group of scientists, researchers and clinicians who would be driven by evidence of effectiveness.

However, the recommendations now have wide-ranging ramifications beyond the important role of guiding physicians and other health professionals on appropriate clinical preventive services. As you know, the ACA created a new USPSTF-linked mandate for group and individual plans, including employer plans, to cover without cost-sharing USPSTF A and B recommendations. For these reasons, the National Business Group on Health has a ***growing*** concern[1] about the USPSTF's decision-making surrounding recent recommendations, which it issued despite its own misgivings regarding the evidence-base for some of the recommendations.

One example is the recommendation concerning obesity and screening by a physician. Given the obesity epidemic in this country, there is no doubt about the value of clinically appropriate screening to help patients understand the need for lifestyle changes and for taking very seriously obesity's relationship to Type II diabetes, back and knee injuries, depression and more. But, the evidence concerning what treatments work is much less strong yet the USPSTF called for somewhere between 6 and 26 intensive behavioral counseling visits which would have to be provided with no cost sharing.. Moreover, it is not even clear what those visits entail, which ones would be effective, who would deliver the services and what the role of the patient would be if employers and health plans are providing for "free" up to 26 intensive counseling visits in a year.

Because of the new weight and impact of USPSTF A and B recommendations, the National Business Group on Health recommends the consideration of the following potential options for a process to further clarify USPSTF recommendations as well as for the consideration of whether additional criteria beyond clinical evidence are appropriate:

Secretary's Coverage Policy Committee. Similar to the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), this committee would provide recommendations directly to the Secretary who could incorporate those recommendations into subregulatory or regulatory guidance. The charter could require that the members of the committee have experience both in reviewing medical literature, in order to translate that literature into coverage, making and implementing coverage decisions, and related expertise, such as insurance, actuarial, employee benefits and health care strategy. The Coverage Policy Committee would not revisit the evidence of the effectiveness of the original treatment recommendation but rather focus on the coverage policy and related evidence.

National Coverage Determination (NCD) Process Similar to Medicare's NCD. For Medicare, the NCD augments the USPSTF recommendation by further clarifying the population for whom coverage will apply based on setting, symptoms, risk, etc. The NCD also provides specifications about the covered benefit. This process could be used to clarify private coverage as well.

Expand HHS Subregulatory Guidance. The Departments could be mandated, either through legislation or Executive Order, to solicit areas which require clarification from the regulated community, issue draft subregulatory guidance and solicit comment prior to the finalization of that guidance.

[1] National Business Group on Health. Letter to improve the U.S. Preventive Services Task Force. December 10, 2012, http://www.businessgrouphealth.org/pub/3ba809d4-782b-cb6e-2763-2264db839833

Formalize and Expand USPSTF Public Comment Period and Process. The Secretary could extend or make more inclusive comment processes or for the USPSTF to address comments specifically in a public manner. The Secretary could also ask for input from the AHRQ, CBO, OPM and CMS about the costs of what is being considered at the same time as the evidence reviews and recommendations.

Expand USPSTF Partner Organizations. USPSTF could add a representative for self-funded plans to the group of non-federal partners. While fully-funded plans are represented, self-funded plans are not represented and would need to be added in order to ensure the recommendations made by the partners are balanced and representative of each stakeholder community. There should also be an official role for coverage and benefit design experts, OPM, and the American Academy of Actuaries.

Each of these options has advantages and disadvantages and is described more fully in the addendum to this letter. The National Business Group on Health believes that adoption of one or more of these options will help assure that we as a society spend our preventive health care dollars wisely, and ultimately, to enhance the reputation of the USPSTF and the impact of its recommendations.

The USPSTF did not seek out the ability to make coverage decisions and has taken a number of forceful, evidence-based stances on procedures, such as on Prostate-Specific Antigen (PSA) testing[2], etc. in the past. Congress authorized the USPSTF as a voluntary body of practicing clinicians with expertise in prevention and evidence-based medicine to make recommendations about clinical preventive services. The USPSTF does not consider costs in its recommendations. However, the Patient Protection and Affordable Care Act (ACA) changed the impact of the USPSTF's recommendations and requires that all plans, including employer-sponsored health plans, begin covering all A or B recommendations no later than the first plan year that occurs one year after the USPSTF finalizes them. After that point, these recommendations become mandated benefits covered at 100% with no cost-sharing by plan participants.

The impact of many of these recommendations, combined with the services being "free" to the users and profitable for those providing services, are recipes for more hyperinflation of medical claims costs. In fact, with over 30% of U.S. health-care expenditures adding little value for patients stemming from overuse, discretionary use beyond benchmarks, and the unnecessary choice of higher-cost services and providers means that we are currently paying for a lot of things that we should not be and that we have an obligation to increase our current scrutiny of coverage decisions. Some of the USPSTF's recent recommendations have created an almost open-ended entitlement that will add unjustified costs when the country is already struggling under the weight of expensive health care. The recommendations add costs for individuals, private plans and the federal government. As costs keep going up, it will be harder and harder for employers and employees to afford coverage that costs more than the wages for a huge percentage of the working population and, as a result, more and more of these costs will fall back onto the federal government.

[2] U.S. Preventive Services Task Force. *Screening for Prostate Cancer*, Topic Page. May 2012, http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm

In making these recommendations, our goal is not to reduce coverage for needed preventive care, but to emphasize that coverage decisions should consider multiple factors, including how screenings and treatments would actually be administered. *The goal of the Secretary's Coverage Policy Committee, or any other option, would not be to limit coverage but to strengthen the goal of assuring coverage for effective preventive care based on science and evidence. The goal should also be to protect the reputation of the USPSTF's recommendations.*

The National Business Group on Health believes that the Secretary of Health and Human Services should have the same ability to accept, reject, delay the implementation, or place coverage conditions on a USPSTF recommendation for private sector employers based on a thorough review of evidence and weighing of all other pertinent factors, similar to the Secretary's current authority vis-à-vis USPSTF recommendations and the Medicare program. In 2008, the Medicare Improvements for Patients and Providers Act, or MIPPA, gave the Secretary of Health and Human Services (the "Secretary") discretion to extend Medicare coverage to preventive services that have a USPSTF recommendation of A or B and meet other specified criteria.[3] ACA eliminated Medicare copayments, establishing zero out-of-pocket costs for all Medicare-covered A-and B-recommended services,[4] but the decision whether or not to include such services remains in the hands of the Secretary.

Thank you for considering these comments and recommendations to enhance the process by which USPSTF recommendations are translated into coverage. We believe that it is necessary for the financial future of our country and working families as well as the quality and safety of care by targeting recommendations to the most evidence-based preventive services and moving away from recommendations that will drive unnecessary screening, testing and overtreatment. If you would like more information or wish to discuss this issue further, please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy at (202) 558-3012.

Sincerely,

Helen Darling
President and CEO

cc: Richard Kronick, Ph.D., Director, Agency for Healthcare Research and Quality

[3] 42 U.S.C. §1395x(ddd): "(1) The term 'additional preventive services' means services not described in subparagraph (A) or (C) of paragraph (3) that identify medical conditions or risk factors and that the Secretary determines are - (A) reasonable and necessary for the prevention or early detection of an illness or disability;
(B) *recommended with a grade of A or B by the United States Preventive Services Task Force*; and
(C) appropriate for individuals entitled to benefits under part A or enrolled under part B." (emphasis added)
[4] P.L. 111-148, "Patient Protection and Affordable Care Act," §4104.