



July 26, 2016

The Honorable Sylvia M. Burwell  
Secretary, Department of Health and Human Services  
200 Independence Ave SW  
Washington, D.C. 20201

The Honorable Tom Perez  
Secretary, Department of Labor  
200 Constitution Avenue, NW  
Washington, DC 20210

The Honorable Jacob Lew  
Secretary, Department of Treasury  
1500 Pennsylvania Ave, NW  
Washington, DC 20220

Dear Secretaries Burwell, Lew and Perez:

The Diabetes Advocacy Alliance (DAA) is writing to urge the Departments of Health and Human Services (HHS), Labor and Treasury to issue a FAQ regarding coverage of preventive services under the Affordable Care Act (ACA) specifically as it relates to the U.S. Preventive Services Task Forces' (USPSTF) final recommendation on Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening published on October 26, 2015. This final recommendation, if implemented by health care payers and providers, will delay diabetes and reduce its impact on our population. Clarity from the Tri-Departments is urgently needed to aid health plans, health systems, employers and advocates who are confused about the full scope and coverage implications of the guideline which is effective January 2017.

The DAA is a coalition of 21 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes. Over the last several years, the DAA strongly urged USPSTF to update its diabetes screening guideline and, with its issuance, are now committed to ensuring health care stakeholders implement its evidence-based recommendations to reduce the impact of diabetes.

### **Background – USPSTF Guideline**

In October 2015, the USPSTF issued a long-awaited final recommendation statement entitled [\*Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening\*](#). The final USPSTF boxed recommendation states: "*The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity.*"<sup>1</sup> In addition, under

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<sup>1</sup> Sui AL, on behalf of the U.S. Preventive Services Task Force. Screening for abnormal blood glucose and type 2 diabetes mellitus: U.S. preventive services task force recommendation statement. *Ann Intern Med* 2015; 163(11):861-868.

“Clinical Considerations”, USPSTF recommends that clinicians screen those under age 40 who have 1 or more of the following characteristics: family history of diabetes, history of gestational diabetes (GDM) or polycystic ovarian syndrome (PCOS), or are members of certain racial/ethnic groups (that is, African Americans, American Indians or Alaskan Natives, Asian Americans, Hispanics or Latinos, or Native Hawaiians or Pacific Islanders).

When the final guideline was initially released last year, the DAA and others in the diabetes community were extremely concerned that its wording would be confusing for health care payers as it was written for primary care providers. On several occasions since that time, including on April 19th, 2016 at a meeting in Washington, DC that the DAA co-hosted with the HHS Office of Disease Prevention and Health Promotion, Dr. Quyen Ngo-Metzger, USPSTF Scientific Director, confirmed that the coverage and practice is to be guided by the full final recommendation statement including the “Clinical Considerations” section. And, Dr. Ngo-Metzger specifically clarified that both diabetes screening and participation in intensive behavioral counseling are considered preventive health services and should be covered with no co-pay under the Affordable Care Act.

### **Coverage Implications**

There is broad agreement among health plan issuers that the USPSTF guideline requires private health plans beginning in January 2017 to cover prediabetes/diabetes screening with no co-pay for individuals age 40 to 70 who are overweight or obese. However, in conversations about the USPSTF guideline with health plans and other stakeholders in the diabetes community, two questions/concerns consistently come up:

- First, whether or not health plans are required to cover participation in an intensive behavioral counseling program with no co-pay for individuals with abnormal blood glucose.
- Second, whether clinicians should screen based on the full set of risk factors – boxed recommendation and those under “Clinical Considerations” – which would trigger no co-pay for patients who would qualify for screening.

Misinterpretation of the USPSTF guideline, specifically as it relates to the second concern mentioned above, is evidenced in the study published July 12, 2016 by O’Brien et al which looked at whether the USPSTF guideline appropriately identifies high-risk population subgroups. The authors narrowly interpreted the final guideline to only recommend screening for prediabetes and diabetes based on age and weight and not the full set of risk factors included under “Clinical Considerations”.<sup>2</sup>

Dr. Ngo-Metzger’s repeated verbal assurances have confirmed to the DAA that the intent of the USPSTF was to cover screening for the full set of risk factors and intensive behavioral counseling with no-copay. However, the only means that exists to communicate the USPSTF intent is a FAQ from the Tri-Departments that can dispel confusion. Without a clear FAQ, the DAA is concerned health plans will not understand the full scope of the final USPSTF screening recommendation and will therefore not comply.

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<sup>2</sup> O’Brien MJ, Lee JY, Carnethon MR, et al. Detecting dysglycemia using the 2015 united states preventive services task force screening criteria: a cohort analysis of community health center patients. PLoS Med. DOI:10.1371/journal.pmed.1002074. Published July 12, 2016.

Our concerns about potential health plan non-compliance stem largely from events that transpired when the USPSTF issued a final recommendation statement in June 2012 on screening and management for obesity in adults. In interview research commissioned in 2014 by Weight Watchers International Inc., a DAA member, all senior staff at four large health plans indicated that they were unaware of any ACA regulations related to weight management or of any requirements on coverage of screening for obesity by physicians. Weight Watchers led the effort in advocating that the Tri-Departments issue a FAQ on this, and as a result, one was published in October 2015 clarifying the intent of the USPSTF guideline. Only since issuance of the obesity FAQ have carriers begun to cover obesity screening and management as ACA intended. Similar to the obesity guideline, health insurance issuers are, at best, confused about coverage of the USPSTF B rated recommendation on abnormal blood glucose and type 2 diabetes screening and prevention and seek clarification and guidance.

### **Public Health Impact**

As you may know, nearly 30 million Americans have diabetes and an additional 86 million adults have prediabetes/abnormal blood glucose and are at risk of developing the disease.<sup>3</sup> By 2050, it is estimated that one out of every three Americans will have diabetes.<sup>4</sup> In addition, the annual cost of this public health emergency has skyrocketed to \$322 billion<sup>5</sup> and will continue to rise unless something is done. Both the human and economic toll of this disease is devastating.

Screening for prediabetes and diabetes, and participation in intensive behavioral counseling (e.g. the Centers for Disease Control and Prevention's National Diabetes Prevention Program) has the potential to change the trajectory of the disease. As recognized by the USPSTF, the National DPP provides an evidence-based solution to the diabetes epidemic and most individuals who participate in the program significantly reduce their risk of developing type 2 diabetes.

The USPSTF is not the only entity recognizing the value of diabetes prevention. In March 2016, many DAA members heard you, Secretary Burwell, make a momentous announcement with YMCA of the USA (the Y) in Washington, DC, that Medicare would release rules on how it would cover the National DPP for Medicare beneficiaries with prediabetes. The announcement was based on a successful demonstration project the Y completed through the Centers for Medicare and Medicaid Innovation (CMMI) that found participation in the YMCA's Diabetes Prevention Program saved \$2,650 over 15 months. Medicare's recognition of the value of identifying people with prediabetes and providing coverage for National DPP is in perfect alignment with the USPSTF diabetes screening guideline and must be communicated clearly through a FAQ to carriers and other health care stakeholders.

However, we should note that based on the Medicare Diabetes Prevention Program (MDPP) guidance issued as part of the 2017 Physician Fee Schedule proposed rule, confusion about the USPSTF recommendation exists even within the federal government. The Centers for Medicare and Medicaid Services (CMS) stated in the MDPP guidance, that the National DPP has not

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<sup>3</sup> Centers for Disease Control and Prevention. National diabetes statistics report: estimates of diabetes and its burden in the United States, 2014.

<sup>4</sup> Centers for Disease Control and Prevention. Number of americans with diabetes projected to double or triple by 2050. October 2010.

<sup>5</sup> Dall TM et al. The economic burden of elevated blood glucose levels in 2012: diagnosed and undiagnosed diabetes, gestational diabetes mellitus, and prediabetes. *Diabetes Care* 2014; 37(12): 3172-3179.

received a recommendation with a grade of A or B by the USPSTF. As we have already stated, the intent of the USPSTF was to cover diabetes screening and referral to intensive behavioral counseling, which would include National DPP, for individuals with abnormal blood glucose. Confusion within CMS about the USPSTF diabetes screening guideline underscores the need for a FAQ.

### **OPM Interpretation**

In addition to hearing directly from Dr. Ngo-Metzger about the correct interpretation of the USPSTF guideline, the U.S. Office of Personnel Management (OPM) included in its FEHB Program Carrier Letter for 2017 and a subsequent memo providing guidance on population health and wellness instructions on coverage for diabetes prevention. The memo explicitly states that carriers should review and ensure that programs directed at diabetes prevention, specifically CDC-recognized National DPPs, be covered.<sup>6</sup> OPM encourages carriers to not only cover these services, but to emphasize the importance of screening and wellness with enrollees.

Finally, the DAA would like to point out that OPM in a 2015 memo made clear that carriers must cover all USPSTF A and B rated recommendations, and noted that intensive behavioral counseling must be provided for obesity and CVD risk reduction. In stating this, OPM interpreted the USPSTF obesity guideline to include the full recommendation statement, not just the boxed recommendation. This further underscores that USPSTF's intent in issuing guidelines is for the entire recommendation to be taken into account when considering the implications on coverage and cost-sharing.<sup>7</sup>

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The DAA recognizes your Departments have many important roles and responsibilities and that you often must weigh the urgency of various requests. The diabetes epidemic is a serious and costly concern to health insurers, employers, health care professionals and patients which is why we strongly urge you to prioritize development and publication of a FAQ on the USPSTF diabetes screening guideline to provide guidance to health plans and others as they are currently considering their 2017 plan offerings. If you have any questions or need additional information, please free to contact one of the DAA Co-chairs: Meghan Riley at [mriley@diabetes.org](mailto:mriley@diabetes.org); Karin Gillespie at [kgil@novonordisk.com](mailto:kgil@novonordisk.com); or Dr. Henry Rodriguez at [hrodrig1@health.usf.edu](mailto:hrodrig1@health.usf.edu).

Sincerely,

Academy of Nutrition and Dietetics  
American Association of Clinical Endocrinologists  
American Association of Diabetes Educators  
American Clinical Laboratory Association  
American Diabetes Association  
American Medical Association  
American Podiatric Medical Association

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<sup>6</sup> U.S. Office of Personnel Management. Updated FEHB Guidance on Population Health and Wellness. March 2016. Available online: <https://www.opm.gov/healthcare-insurance/healthcare/carriers/2016/2016-04.pdf>

<sup>7</sup> U.S. Office of Personnel Management. Updated FEHB Guidance on Preventive Care. July 2015. Available online: <https://www.opm.gov/healthcare-insurance/healthcare/carriers/2015/2015-14.pdf>

Diabetes Hands Foundation  
Endocrine Society  
Healthcare Leadership Council  
National Association of Chain Drug Stores  
National Community Pharmacists Association  
National Kidney Foundation  
Novo Nordisk, Inc.  
Omada Health  
VSP Vision Care  
Weight Watchers International  
YMCA of the USA