

September 17, 2010

Department of Health and Human
Attention: OCIO-9992-IFC
P.O. Box 8016
Baltimore, MD 21244-185-

Dear Secretary Sebelius:

On behalf of the nearly 24 million Americans living with diabetes— including the estimated 6 million who do not know they have the disease – and the 57 million more with pre-diabetes, I am writing to provide comments on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act, issued on July 14, 2010.

The American Diabetes Association (Association) applauds the Administration and Congress for making prevention and public health a priority in the recently-passed Patient Protection and Affordable Care Act (PPACA). Without increased attention to the prevention of chronic disease, we will not achieve the goal of a healthier nation, nor will we succeed in reining in our ballooning health care costs. However, we strongly disagree with the decision to rely solely on the grades of the United States Preventive Services Task Force (USPSTF) in determining which preventive services are to be made available without cost-sharing with regard to diabetes.

We have a diabetes epidemic and the approach taken by these regulations ensures that our country will fall short in its effort to stop diabetes, failing to identify many of the nearly 6 million individuals who have undiagnosed diabetes, as well as the 53 million more who do not know they are at high risk for the disease because they currently have undiagnosed pre-diabetes.

Under the proposed regulation, the only asymptomatic people covered for screening will be those with sustained high blood pressure as USPSTF has issued an insufficient evidence (I) recommendation for everyone else. This recommendation is not based on the idea that the blood tests used to identify diabetes are inaccurate or costly or lead to further unnecessary or invasive diagnostic procedures. Nor is USPSTF's conclusion based on a belief that further testing won't end up identifying more people with undiagnosed diabetes and pre-diabetes. Rather, the simple blood tests for diabetes are undeniably inexpensive, accurate, and applying them to all high risk individuals would result in identifying millions of Americans who have diabetes or pre-diabetes. Rather, the basis of USPSTF's conclusion is that there is not enough evidence to establish that it is worth finding people with asymptomatic diabetes and treating them or finding people with pre-diabetes and using interventions to prevent onset of the disease. We disagree. Indeed, the Administration and the Department of Health and Human Services (HHS) have acknowledged numerous times that screening for prevention and early treatment of diabetes is essential. For example, in a November 2009 report entitled "Preventing and Treating Diabetes: Health Insurance Reform and Diabetes in America," HHS states that "measures that can go a long way to ensure diabetes is caught early, like preventive screenings, are not used often enough."

Targeted screening for at-risk individuals results in earlier diagnosis and treatment, which is vital to delaying or preventing dangerous complications. Type 2 diabetes usually has a lengthy pre-symptomatic phase before diagnosis is made, despite the availability of simple tests to determine the

presence of the disease. Today's reality is that frequently, type 2 diabetes is not diagnosed until dangerous and costly complications have already arisen, such as heart disease, stroke, vision loss and/or the need for lower-limb amputation. Evidence tells us that type 2 diabetes is present an average of ten to twelve years prior to diagnosis¹ and the longer a patient remains undiagnosed, the more susceptible he or she is to complications. Indeed, the United Kingdom Prospective Diabetes Study (UKPDS) found that one in five individuals with undiagnosed diabetes is already experiencing complications by the time of diagnosis². Therefore, it is essential to screen at-risk individuals before they start exhibiting symptoms.

Numerous expert organizations support risk-factor based testing like the recommendations of the American Diabetes Association's Clinical Practice Guidelines. The Association recommends individuals with the following risk factors be screened for type 2 diabetes:

1. All adults who are overweight and have additional risk factors:
 - Physical inactivity
 - First degree relative with diabetes
 - Members of a high risk population (such as African American, Latino, Native American, Asian American, or Pacific Islander)
 - Women diagnosed with gestational diabetes or who delivered a baby weighing >9 lb.
 - Hypertension
 - Women with polycystic ovary syndrome
 - Elevated cholesterol
 - Previous diagnosis of Impaired Fasting Glucose (IFG) or Impaired Glucose Tolerance (IGT)
 - History of cardiovascular disease
 - Other clinical conditions associated with insulin resistance.
2. In the absence of the above criteria testing should begin at age 45.
3. If results are normal, testing should be repeated at least at 3 year intervals, with consideration of more frequent testing depending on initial results and risk status.

As the leading federal experts on the treatment and prevention of diabetes, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention's (CDC) Division of Diabetes Translation (DDT) both support similar risk-based diabetes screening for asymptomatic patients.

Reliance on the USPSTF A and B recommendations will mean that many patients, who virtually every expert in diabetes would agree are at high risk for type 2 diabetes, are overlooked for screening. Consider the following example: the USPSTF does not provide an A or B

¹ Harris R, Donahue K, Rathore SS, Frame, P, Woolf SH, Lohr KN. Screening adults for type 2 diabetes: a review of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med* 2003.

² UKPDS Group: *Diabetes Res.* 13: 1-11, 1990.

recommendation for blood glucose screening for a woman who is 55 years old, morbidly obese, has experienced gestational diabetes, and has multiple immediate family members with type 2 diabetes – as long as her blood pressure is below a certain limit. Experts in diabetes would agree this person is at very high risk for the disease and should be screened. They also agree diabetes may well be causing irreparable damage to her and they agree that there are cost-effective means for both primary prevention and treatment if she has either pre-diabetes or diabetes.

Diabetes and pre-diabetes cost the nation a staggering \$218 billion annually and with the increased emphasis on prevention in PPACA, we have the unprecedented opportunity to lower these costs and improve the lives of millions of Americans. The interim final regulation references the dual possibilities of savings from lower health care costs (due to early detection) and new costs to the healthcare system due to increased access to and use of preventive services. Early detection and prompt treatment of diabetes is an essential element of lowering health care costs. Models have shown that screening per the guidelines recommended by the American Diabetes Association is cost effective, at less than \$11,000 per quality adjusted life-year (QALY),³ and leads to improved health outcomes including fewer complications. Another model projects that a 50 percent improvement in diabetes management will reduce diabetes deaths by 49,000 annually; reduce incidence of diabetes-related complications by 239,000 annually; and reduce annual medical costs for diabetes by \$196 billion⁴. The study also found that those results can only be achieved with enhanced screening.

Multiple studies⁵ have shown the benefit of early detection vs. delayed diagnosis including UKPDS, the results of which demonstrate that the risks of serious complications, such as retinopathy, nephropathy and neuropathy can be lowered with good blood glucose control. The proposed regulation acknowledges this, stating on page 29: “Improved blood sugar control could reduce the risk for eye disease, kidney disease and nerve disease by 40 percent in people with type 1 or type 2 diabetes.” And although it is encouraging that the Department recognizes the importance of proper diabetes management, this assessment is at odds with the USPSTF’s conclusions, which are based on the idea that, other than adjusting treatment for high blood pressure, there is no reason to identify people with diabetes. Undeniably, if only those with high blood pressure are screened millions of Americans will not know they have diabetes. A recent study published in the Mayo Clinic Proceedings demonstrated that utilizing the screening recommended by USPSTF resulted in missing a third of those with diabetes when compared with using the American Diabetes Association guidelines⁶. Obviously, those who do not know they have diabetes will be unable to take steps to improve blood sugar control.

³ Kahn R, Alperin P, Eddy D, Borch-Johnston K, Buse J, Feigelman J, Gregg E, Holman R, Kirkman MS, Stern M, Tuomilehto J, Wareham, N. Age at initiation and frequency of screening to detect type 2 diabetes: a cost-effectiveness analysis. *Lancet*, 2010.

⁴ Fitch K, Kosuke I, Pyenson B. Improved Management Can Help Reduce the Economic Burden of Type 2 Diabetes: A 20-year Actuarial Project. Millman, Inc., NYC, April 2010.

⁵ American Diabetes Association, Standards of Medical Care in Diabetes-2010. *Diabetes, Care*, Volume 33, Supplement 1, January 2010. P. S19-S23.

⁶ Sheehy A, Flood G, Tuan W, Liou J, Coursin D. Analysis of Guidelines for Screening Diabetes Mellitus in an Ambulatory Population. *Mayo Clinic Proceedings*; January 2010; 85, 1: ProQuest Medical Library pg. 27.

Additionally, the recommendations of the USPSTF contradict the proposed objectives of Healthy People 2020, the nation's ten-year recommendations for promoting health, as well as its predecessor, Healthy People 2010, both of which include this objective: "Increase the proportion of adults with diabetes whose condition has been diagnosed." This objective presupposes that it is an important public health goal to identify people with diabetes, a goal that will not be effectively met unless those at risk are screened.

The American Diabetes Association is also concerned about screening for gestational diabetes. The USPSTF provides an I recommendation for this screening as well, stating that there is insufficient evidence to recommend for or against routine screening of gestational diabetes. Gestational diabetes can cause dangerous complications for mother and baby, such as preeclampsia, pre-term labor, increased risk of gestational diabetes in subsequent pregnancies, and increased risk for type 2 diabetes for both mother and child.

Yet, despite these risks, a pregnant woman who is morbidly obese, has experienced gestational diabetes before, and has multiple immediate family members with diabetes will not be covered by the proposed rule unless she also has sustained high blood pressure.

The American Diabetes Association offers a more comprehensive set of guidelines for gestational diabetes and recommends that all women of greater than low-risk should be screened early in pregnancy. Low-risk status is defined as women with **all** of the following characteristics:

- Age < 25 years;
- Weight normal before pregnancy;
- Member of an ethnic group with a low prevalence of diabetes;
- No known diabetes in first degree relative;
- No history of abnormal glucose tolerance;
- No history of poor obstetric outcomes.

NIDDK and the American Congress of Obstetricians and Gynecologists cite similar risk factors as criteria for gestational diabetes screening. In order to prevent the possible dangers of gestational diabetes, screening must be made available for pregnant women at risk.

Targeted screening can be instrumental in preventing or delaying new cases of diabetes. On top of the nearly 24 million Americans with diabetes, another 57 million have pre-diabetes, and a mere 7 percent of those with pre-diabetes have been diagnosed. In addition to early detection of the disease, screening can yield a diagnosis of pre-diabetes. This presents an opportunity to prevent the disease entirely.

Research shows that individuals diagnosed with pre-diabetes can prevent the development of type 2 diabetes through modest lifestyle interventions. The Diabetes Prevention Program (DPP) clinical trial performed by NIDDK found that with lifestyle changes and weight loss of approximately five to ten percent, a person with pre-diabetes can reduce their risk for type 2 diabetes by 58 percent⁷.

⁷ Knowler WC, Barret-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med* 2002; 346: 393-403.

Further research by DDT has shown that community-based lifestyle intervention programs modeled after the DPP can achieve the same results at a lower cost of \$253 per year.⁸⁹ However, without targeted, risk-based screening, it is impossible to identify individuals with pre-diabetes who can prevent diabetes through participation in such proven prevention programs.

This is yet another example where reliance on USPSTF A&B recommendations is at cross purposes with other provisions of the PPACA. The National Diabetes Prevention Program (NDPP), authorized through PPACA, seeks to bring to scale across the nation a network of community-based prevention programs as described above. CDC has recognized the value of these programs and is already working to implement the NDPP. These programs, based on the successful clinical trial and administered in community venues, such as the YMCA, not only prevent progression to diabetes, but have been shown to reduce health care costs. A July 2009 report by the Urban Institute stated that a national system of such programs could save the country an estimated \$190 billion in health care costs¹⁰. Yet, the proposed regulation would deny cost-free testing to millions of Americans.

The American Diabetes Association is also concerned about inconsistencies with the criteria USPSTF uses for grading preventive services. Diabetes screening for patients without hypertension is given an I grade by the USPSTF because of a lack of random clinical trials (RCTs) demonstrating that screening leads to improvements in outcomes, despite the other significant evidence of the benefits of early detection and treatment in those with diabetes and of effective community-based interventions in those with pre-diabetes. Yet, while dismissing the substantial indirect evidence for diabetes screening, USPSTF has recommended other screenings with no direct RCT evidence, such as screenings for obesity, hypercholesterolemia, and osteoporosis relying on the type of indirect evidence that also exists for targeted diabetes screening. Thus, USPSTF saw fit to provide a B recommendation for screening all adults for obesity and offering intensive counseling and behavioral intervention for sustained weight loss for obese adults through the very indirect evidence that was not considered adequate to support screening of diabetes, ironically, noting one of the benefits would be improved blood glucose management. Thus, without the direct evidence deemed essential for a diabetes screening recommendation, USPSTF concluded that “changes in intermediate outcomes such as improved glucose metabolism, lipid levels, and blood pressure from modest weight loss provide indirect evidence of health benefits” supported a B recommendation for obesity screening¹¹. This inconsistency demonstrates further weaknesses in relying solely on USPSTF A&B recommendations in our national efforts to fight chronic disease.

⁸ Ackermann RT, Finch EA, Brizendine E, Zhou H, Marrero DG. Translating the Diabetes Prevention Program into the community: The Deploy Pilot Study. *Am J Prev Med* 2008; 35:357-63.

⁹ Brink, S. Report from the Field, The Diabetes Prevention Program: How the Participants Did It. *Health Affairs*, Volume 28, Number 1, pg. 60.

¹⁰ Berenson R, Holahan J, Blumberg L, Bovbjerg R, Wardmann T, Cook A, and Williams A. *How We Can Pay for Health Reform*. Urban Institute and Robert Wood Johnson Foundation, 2009.

¹¹ Screening for Obesity in Adults, Recommendation and Rationale. U.S. Preventive Services Task Force. *AHRQ Pub. No. 04-0528A*, December 2003.

The Association is pleased that the interim final rule does not preclude health insurers from covering without cost sharing services that go beyond the recommendations of the USPSTF. However, with no requirement or incentives to do so, it is unlikely that many insurers will go above and beyond the regulations at a time when they are being required to make many new improvements to their current plans.

The preamble to the draft rules states: “The statute and interim final regulations limit the preventive services covered to those recommend by the Task Force, Advisory Committee, and [Health Resources and Services Administration] because the benefits of these preventive services will be higher than others that may be popular but unproven.” The benefits of targeted diabetes screening are not unproven and reliance on the USPSTF rating stands in stark contrast to the position of diabetes experts in both the public and private sectors and to statements made in the proposed rule itself. The bottom line is a simple one: Diabetes is an epidemic in our country; it will not go away if we don’t find out who has it, who is about to get it, and then take action. Accordingly, we ask that the Department consider the evidence and the conclusions of its own diabetes experts and include screening for type 2 diabetes and gestational diabetes for patients with risk factors defined by entities such as the American Diabetes Association, DDT and NIDDK, as a covered benefit free of cost-sharing.

Thank you for your consideration of our comments. Should you have further questions or concerns, please contact Tekisha Dwan Everette, Director of Federal Government Affairs, at teverette@diabetes.org or (703) 253-4375.

Sincerely,

A handwritten signature in cursive script that reads "Shereen Arent".

Shereen Arent
Executive Vice President
Government Affairs and Advocacy
American Diabetes Association