

Comments to 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 (PPACA)

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Introduction and Background

The passage of the *Patient Protection and Affordable Care Act* (PPACA, Pub. L. 111-148) earlier this year marked a significant positive milestone for the nation. The undersigned members of the Diabetes Action Alliance (DAA), a coalition of diverse organizations who have come together to change how the nation perceives and approaches the problem of diabetes, are pleased with the law's unprecedented focus on prevention and public health. We believe the PPACA holds great promise for reorienting our health care system towards wellness, a belief echoed by Secretary of Health and Human Services Kathleen Sebelius and Assistant Secretary for Health Howard Koh in a recent editorial in the *New England Journal of Medicine*: "...we believe that the Act will reinvigorate public health...and will usher in a revitalized era for prevention at every level of society."¹

Specifically, the PPACA amends part A of title XXVI of the Public Health Service (PHS) Act, relating to coverage for preventive services. Section 2713 of the PHS Act, as added by the PPACA, requires that new health plans beginning on or after September 23, 2010, must cover evidence-based preventive services and eliminate any type of cost-sharing, be it a co-payment, coinsurance or deductible, for these services when they are delivered by a network provider. Thus, these new rules have the potential to improve Americans' access to and utilization of a range of preventive services.

Historically, insurance coverage decisions for various clinical preventive services have been influenced by ratings from the United States Preventive Services Task Force (USPSTF).² Under these Interim Final Rules, this is also the case: Coverage of preventive services by new health plans—which is estimated will affect "in 2011, roughly 31 million people..., growing to approximately 78 million in 2013"³—is determined by the recommendations and ratings of the USPSTF. Thus, these interim rules create a disturbing paradox: While the rules rely on USPSTF ratings/recommendations for decisions regarding coverage and elimination of co-pays for preventive services, the PPACA *itself* calls for a new approach that includes input from "clinical preventive best practice recommendations from AHRQ, NIH, CDC, the Institute of Medicine, specialty medical associations, patient groups, and

¹ Howard Koh and Kathleen Sebelius, Promoting prevention through the ACA, *NEJM*, published online 8-25-10, <http://healthpolicyandreform.nejm.org/?p=12171&query=home>.

² Ho A. Comments and response on the USPSTF recommendation on breast cancer screening. *Annals of Int Med*. 2010; 152: 542-543.

³ Federal Register, Interim Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act. 75(137), July 19, 2010. p. 41732.

scientific societies”⁴—an approach that is in keeping with the expanded role its recommendations will have on care, coverage, and cost-sharing moving forward.

We agree with the approach of broadening the evidence base for clinical preventive services as set forth by PPACA and thus urge that the regulations and rules that enforce the law look beyond USPSTF, particularly for preventive services where the recommendations of the USPSTF differ from the guidelines promulgated by other pertinent medical and scientific entities. This is certainly the case with diabetes screening.

USPSTF Recommendations on Diabetes Screening

Currently, the USPSTF recommends screening for type 2 diabetes *only* in asymptomatic adults with sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg, and states that the evidence is inconclusive regarding screening others. The foundation of this recommendation is not that further testing will not identify millions of people with diabetes and pre-diabetes, but rather that there is insufficient evidence that it is important to identify and take action with regard to the millions of Americans who are undiagnosed. This recommendation was issued in June 2008, and the next review and rating cycle for diabetes screening is not scheduled to take place until 2012/2013.

Although the Diabetes Action Alliance does not consider screening of the general population appropriate, we are united in our position that the limits imposed by relying solely on USPSTF A & B recommendations for diabetes screening create an enormous roadblock to effective diabetes prevention. **Thus, we strongly urge that the final rules and regulations for group health plans and health insurance issuers relating to coverage of preventive services include the expert opinion recommendations for screening supported by the American Diabetes Association (ADA), the National Institute of Diabetes and Digestive and Kidney Diseases⁵, and the Division of Diabetes Translation at the Centers for Disease Control and Prevention⁶. Under these recommendations, testing for diabetes should be covered with no cost sharing:**

- For all adults beginning at age 45. If results are normal, testing should be repeated at least at three-year intervals, with consideration of more frequent testing depending on initial results and risk status.
- For those younger than age 45, testing should be covered as recommended by the treating physician for those who are overweight or obese and have additional risk factors, including a family history of diabetes; habitual physical inactivity; African-American, Hispanic-American, Native American, Asian-

⁴ H.R. 3590, Patient Protection and Affordable Care Act, Section 4003, Clinical and Community Preventive Services, page 424.

⁵ <http://www.diabetes.niddk.nih.gov/dm/pubs/riskfortype2/index.htm#4>

⁶ <http://www.cdc.gov/diabetes/news/docs/screening.htm>

American, or Pacific Islander race/ethnicity; previously identified impaired fasting glucose or impaired glucose tolerance; history of gestational diabetes or delivery of a baby weighing more than nine pounds; hypertension; elevated cholesterol; polycystic ovary syndrome; or history of cardiovascular disease.

Addressing the Diabetes Epidemic: Screening is Critical

Today, diabetes is one of the most prevalent and threatening chronic diseases America faces, costing more than \$218 billion annually⁷ and contributing to more than 230,000 deaths each year.⁸ Nearly 24 million Americans have diabetes, with the vast majority (90-95 percent) having type 2 diabetes. Of the 24 million people with diabetes, about 6 million (25%) are undiagnosed.⁹ In addition, an estimated 57 million people have pre-diabetes¹⁰ and are at very high risk of developing diabetes within 10 years, but only 7% of them are aware they have pre-diabetes.¹¹

The onset and progression of type 2 diabetes, like hypertension, is often silent, with no readily-apparent symptoms, or a variety of symptoms that are non-specific and can easily be misconstrued as signs of aging (such as blurry vision, fatigue, and more frequent urination).

Undiagnosed type 2 diabetes is not benign. Evidence shows that by the time most people with type 2 diabetes are diagnosed, they have already had diabetes for at least 5-7 years, during which time consistent, elevated blood glucose levels have already produced microvascular and macrovascular damage. For example:

- Data from the 10-year follow-up of the landmark United Kingdom Prospective Diabetes Study (UKPDS) confirmed the “legacy effect” in patients with type 2 diabetes, showing that untreated hyperglycemia, such as what might occur with undiagnosed diabetes, has long-term effects on cardiovascular morbidity and mortality, including coronary artery disease, peripheral arterial disease, and stroke, even after blood glucose levels are controlled.¹²
- Data from the Los Angeles Latino Eye Study (LALES) showed that more than 95 percent of diabetic retinopathy in Latinos is undiagnosed and undetected

⁷ Dall TM, Zhang Y, Chen Y et al. The economic burden of diabetes. *Health Affairs*. 2010; 29: 297-303.

⁸ CDC National Diabetes Fact Sheet, 2007, http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf

⁹ CDC National Diabetes Fact Sheet, 2007, http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf

¹⁰ CDC National Diabetes Fact Sheet, 2007, http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf

¹¹ Geiss L et al. Diabetes risk reduction behaviors among U.S. adults with pre-diabetes. *American Journal of Preventive Medicine*. 2010; 38: 403-409.

¹² Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA. 10-year follow-up of intensive glucose control in type 2 diabetes. *N Engl J Med*. 2008; 359: 1577-1589. Chalmers J, Cooper M. UKPDS and the legacy effect [editorial]. *N Engl J Med*. 2008; 359: 1618-1620.

and showed high rates of diabetic retinopathy at the time of diagnosis of type 2 diabetes.¹³

If we as a nation fail to adopt and implement proactive screening policies and programs for diabetes, type 2 diabetes will continue to exact a significant human and financial toll. Individuals with undiagnosed diabetes will not be identified and treated until their disease has progressed to a point where symptoms are severe enough to prompt a clinical visit, or they present in a primary care setting, clinic or hospital with evidence of a complication of diabetes, ranging from vision loss to a heart attack.

In addition, without proactive screening efforts, those with pre-diabetes will also not be identified and therefore will not receive counseling from a health care provider or an opportunity for referral to community-based, evidence-based programs that could help them prevent the onset of diabetes. Such programs, based upon landmark randomized controlled trials—including the Diabetes Prevention Program (DPP) and the Diabetes Prevention Program Outcomes Study (DPPOS)—are now becoming standardized via the CDC and its National Diabetes Prevention Program, and are being implemented, cost-effectively, by groups such as UnitedHealthcare and the YMCA. We know from the DPP that these programs have reduced new cases of diabetes by 58%, but we also know that the prerequisite to implementing these programs is identifying those at highest risk for diabetes.¹⁴

Compelling Data on the Vital Role of Diabetes Screening

Science has proven that the onset of type 2 diabetes can be prevented or significantly delayed in people with pre-diabetes.¹⁵ Science has also proven that

¹³ Rohit Varma MD, MPH, Mina Torres MS, Fernando Peña MD, Ronald Klein MD, MPH, Stanley P. Azen PhD and Los Angeles Latino Eye Study Group. Prevalence of diabetic retinopathy in adult Latinos. *Ophthalmology*. 2004;111:1298-1306

¹⁴ Knowler WC, Barrett-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. Tnomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among patients with impaired glucose tolerance. *N Engl J Med*. 2001;334:1343-50.

¹⁵ Knowler WC, Barrett-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. Tnomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among patients with impaired glucose tolerance. *N Engl J Med*. 2001;334:1343-50. 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. Diabetes Prevention Program Research Group. 10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcome Study. *Lancet* 2009. DOI: 10.1016/S0140-6736(09)61457-4. Lindstrom J, Ilanne-Parikka P, Peltonen M, et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. *Lancet*. 2006;368:1673-1679.

complications of diabetes can be significantly reduced with available treatments.¹⁶ People who are likely to have undiagnosed diabetes, and those likely to have pre-diabetes, can be readily identified and screened through low-cost laboratory tests in a clinical setting and can be appropriately counseled and, if necessary, treated. Type 2 diabetes has well-established risk factors, including family history of the disease, advancing age, race/ethnicity, and overweight or obesity. Primary health care practitioners can easily identify those people at risk who are the appropriate candidates for screening and diagnosis. Additionally, the most frequently used blood tests for diagnosing diabetes (fasting plasma glucose and A1C) are easily administered and inexpensive.

For all of these reasons, it is imperative that we advance and implement policies that support the identification of people with undiagnosed diabetes and also those with pre-diabetes. Targeted screening of at-risk adults for diabetes in clinical settings should be a public health priority.

In the Spirit of PPACA and its “Vibrant Emphasis on Disease Prevention”¹⁷: Consider a Range of Evidence and Experts

The members of the DAA believe in the value of evidence-based medicine; however, we disagree with the conclusions drawn by the USPSTF regarding diabetes and the resulting recommendation for diabetes screening. We believe that this conclusion was based in part on limitations on the types of evidence USPSTF has relied on in the past. Passage of the Patient Protection and Affordable Care Act (PPACA) calls for a new standard—one that includes input from other entities (such as “clinical preventive best practice recommendations from AHRQ, NIH, CDC, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies”¹⁸), and that new approach should be reflected by the Department of Health and Human Services in drafting the final rules and regulations for coverage of preventive service by new health plans.

Secretary Sebelius noted in the HHS Draft Strategic Plan for 2010-2015 that “the biggest change we can make isn’t how we provide health care—it’s when.”¹⁹ With diabetes in particular, advancing targeted diabetes screening that follows the expertise of the groups that have signed this letter, as well as HHS’s own experts at

¹⁶ UKPDS Study Group. Effect of intensive glucose control with metformin on complications in overweight patients with type 2 diabetes. *Lancet*. 1998; 352:854-865. The Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med*. 1993;329:977-86.

¹⁷ Howard Koh and Kathleen Sebelius, Promoting Prevention through the ACA, *NEJM*, published online 8-25-10, <http://healthpolicyandreform.nejm.org/?p=12171&query=home>.

¹⁸ H.R. 3590, Patient Protection and Affordable Care Act, Section 4003, Clinical and Community Preventive Services, page 424.

¹⁹ HHS Secretary Kathleen Sebelius, HHS Draft Strategic Plan 2010-2015, p. 13.

NIH and CDC—that is, screening adults at risk for diabetes—has the potential to positively impact the diabetes epidemic precisely by delivering preventive screening when it is most needed and most beneficial: in the earliest throes of this devastating disease or at a stage when prevention or delay of onset is still possible.

Sincerely,

American Association of Clinical Endocrinologists

American Clinical Laboratory Association

American Diabetes Association

Novo Nordisk, Inc.

Results for Life – Lab Testing: Better Health, Improved Outcomes

The Endocrine Society