



September 30, 2011

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Comments on Proposed Coverage Decision Memorandum for Intensive Behavioral Therapy for Obesity (CAG-00423N)

Dear Ms. McClain:

As a nonprofit, nonpartisan public health advocacy organization dedicated to making disease prevention a national priority, Trust for America's Health is pleased to see that CMS has moved forward with a proposed decision memorandum for Medicare coverage of intensive behavioral therapy for obesity (IBTO).

As we noted in our April 2011 comments to you on the initial Medicare National Coverage Analysis (NCA) for IBTO, the obesity epidemic continues to have serious implications for American's health and related health care spending. In July 2011 we released our eighth annual *F as in Fat* report in conjunction with the Robert Wood Johnson Foundation. The report found that obesity rates increased in 16 states and did not decrease in any over the past year and noted that the epidemic has grown at a staggering pace over the past several decades.¹

Over two-thirds of adults in the United States are overweight or obese.² In 1980, 15 percent of American adults were obese; by 2008, that figure had reached 34 percent.³ From 2009 to 2010, adult obesity rates rose in 28 states, and fell in only one.⁴ There are striking racial and ethnic disparities in obesity rates: in 40 states, adult obesity rates are higher among Blacks and Latinos than among Whites.⁵ Furthermore, obesity is associated with more than 20 major chronic diseases⁶ and obesity-related costs account for almost a tenth of all annual medical expenditures.⁷

¹ Trust for America's Health and the Robert Wood Johnson Foundation, *F as in Fat 2011: How Obesity Threatens America's Future*, July 2011, <http://tfah.org/report/88/>.

² Flegal KM, Carroll MD, Ogden CL, et al. "Prevalence and Trends in Obesity among U.S. Adults, 1999-2008." *Journal of the American Medical Association*, 303(3): 235-41, 2010.

³ National Center for Health Statistics. "Prevalence of Overweight, Obesity and Extreme Obesity among Adults"; Flegal, et al., supra note 1.

⁴ Trust for America's Health.

⁵ *Id.*

⁶ U.S. Centers for Disease Control and Prevention. *National Diabetes Fact Sheet: General Information and National Estimates on Diabetes in the United States, 2007*. Atlanta, GA: U.S. Department of Health and

Now is the time to deploy and develop evidence-based approaches to addressing the obesity epidemic. IBTO, based on a review and recommendation from the U.S. Preventive Services Task Force, in conjunction with other studies and findings, is one critical opportunity for the Medicare program to address obesity and related comorbidities among its beneficiary population.

As the U.S. Preventive Services Task Force found in its 2003 review of available data, intensive counseling led to modest sustained weight loss in obese adults⁸ and further analysis has confirmed that such programs are effective in older adults, a finding important to the Medicare program. We likewise support the initial findings of the proposed coverage decision memorandum that the IBTO coverage is “reasonable and necessary for prevention and early detection of illness or disability.”

We urge CMS however, to reconsider the scope of eligible IBTO practitioners. As the proposed coverage determination memorandum is currently drafted, only a qualified primary care physician or other primary care practitioner operating in a primary care setting would be eligible to receive reimbursement for providing IBTO services.

As we mentioned in our previous comments to the NCA, IBTO services are not solely provided in the physician setting. In fact, research has confirmed that such high-intensity interventions can be effective when offered by trained lay providers. In 2002, the NIH- and CDC-funded Diabetes Prevention Program (DPP) study found that intensive lifestyle interventions, including promotion of physical activity and weight loss, could lead to modest weight loss and reduce the development of diabetes in adults with prediabetes.⁹ A 2008 study reported that the DPP program could be conducted by trained

Human Services, Centers for Disease Control and Prevention, 2008.

http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2007.pdf (accessed February 24, 2010); Lloyd-Jones D, Adams, R. Carnethon M, et al. “Heart Disease and Stroke Statistics 2009 Update. A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee.” *Circulation*, 119(3):e1-e161, 2009; Beydoun MA, Beydoun HA, and Wang Y. “Obesity and Central Obesity as Risk Factors for Incident Dementia and Its Subtypes: A Systematic Review and Meta-Analysis.” *Obesity Review*, 9(3):204-218, 2008; Petry NM, Barry D, Pietrzak RH, et al. “Overweight and Obesity Are Associated with Psychiatric Disorders: Results from the National Epidemiologic Survey on Alcohol and Related Conditions.” *Psychosomatic Medicine*, 70(3): 288-297. 2008; Wang Y, Chen X, Song Y, et al. “Association between Obesity and Kidney Disease: A Systematic Review and Meta-Analysis.” *Kidney International*, 73(1):19-33, 2008; Freedman DS, Mei Z, Srinivasan SR, et al. “Cardiovascular Risk Factors and Excess Adiposity among Overweight Children and Adolescents: The Bogalusa HeartStudy.” *The Journal of Pediatrics*, 150(1): 12-17, 2007.

⁷ Finkelstein EA, Trogon JG, Cohen JW, et al. “Annual Medical Spending Attributable to Obesity: Payer- and Service-Specific Estimates.” *Health Affairs*, 28(5): w822-w831, 2009.

⁸ U.S. Preventive Services Task Force, “Screening for Obesity in Adults: Summary of Recommendations” (Dec. 2003) (online at <http://www.uspreventiveservicestaskforce.org/uspstf/uspsoebes.htm>).

⁹ Diabetes Prevention Program Research Group, “Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin,” *N Engl J Med* 2002; 346:393-403 (February 7, 2002).

lay providers in a community setting at YMCAs and still result in modest weight loss sustained over 12 months.¹⁰

In some instances, IBTO may be even more effective when provided outside the physician setting. A recent study found that patients that were referred to the Weight Watchers program, a commercial service that provides IBTO services to beneficiaries, lost twice as much weight on average as those that were referred to traditional clinical IBTO programs.¹¹

We would also note limiting coverage to physicians and the primary care setting is inconsistent with the original U.S. Preventive Services Task Force (USPSTF) recommendation on this topic. Among the 11 randomized clinical trials that the USPSTF reviewed in arriving at their recommendation, only three explicitly stated the location of the interventions – and only one of these three locations was a primary care physician’s office. The USPSTF recommendation is instead based on intervention itself, which was delivered by not only physicians but dietitians, behavioral therapists, exercise instructors, and multidisciplinary teams.¹²

We thus recommend that the coverage decision memorandum should be expanded to ensure that Medicare patients can receive access to IBTO services when they are provided by a physician or other qualified nonclinical counselor, regardless of the setting where services are provided.

Trained lay providers, or non-physicians or primary care practitioners, have shown to be effective at achieving weight loss results for patients in many settings. As we have commented previously, the availability of these programs in community settings will render them available to far more beneficiaries, allowing this coverage change to make a meaningful impact on the health and lives of the Medicare population.

Leveraging the expertise of non-clinicians produces additional benefits to the Medicare program; they can deliver effective services to Medicare beneficiaries without affecting physician and other clinician caseloads and at a lower cost. Community-based lay providers also have opportunities to direct behavioral interventions that are lacking in the clinical setting.¹³ The sustained improved outcomes that have been demonstrated by these types of interventions can lead to lower prevalence of obesity and associated comorbidities within the Medicare program – which ultimately means lower Medicare expenditures for related health care services and savings for the program overall.

¹⁰ Ronald T. Ackermann et al., “Translating the Diabetes Prevention Program into the Community: The DEPLOY Pilot Study” *American Journal of Preventive Medicine* 35(4): 357-363 (October 2008).

¹¹ Jebb SA, Ahern AL, et al. “Primary care referral to a commercial provider for weight loss treatment versus standard care: a randomised controlled trial.” *Lancet*, Early Online Release. September 2011. Available at: <http://www.lancet.com/journals/lancet/article/PIIS0140-6736%2811%2961344-5/fulltext>

¹² U.S. Preventive Services Task Force.

¹³ Ackermann.

Thank you for the opportunity to comment on this important proposed Coverage Decision Memorandum. If you have any questions, please feel free to contact Becky Salay, Director of Government Relations, at 202-223-9870 x 15 or at bsalay@tfah.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey Levi". The signature is fluid and cursive, with the first name "Jeffrey" and last name "Levi" clearly distinguishable.

Jeffrey Levi, PhD
Executive Director