



January 8, 2024

Department of the Treasury (31 CFR Part 33)
Centers for Medicare and Medicaid Services (42 CFR Parts 435 and 600, 45 CFR Parts 153, 155, and 156 [CMS-9895-P]; RIN 0938-AV22)
Department of Health and Human Services; Attention: CMS-9895-P, Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program

To Whom It May Concern:

The undersigned members of the Diabetes Advocacy Alliance (DAA) are writing to express our support for various provisions of the Notice of Benefit and Payment Parameters (NBPP) for 2025, specifically moving from USP Medicare Model Guidelines (MMG) to the USP Drug Classification (USP DC) system for use in the essential health benefit (EHB) package described in section 1302(a) of the Affordable Care Act (ACA). As you may know, there are about 38 million people living with diabetes in the United States, and it is estimated that about 98 million U.S. adults have prediabetes.¹ We appreciate that CMS is considering moving to the USP DC, as such a move would have great benefits for the millions of people living with prediabetes and diabetes.

The undersigned members of the DAA broadly support uninterrupted access to health care coverage for all people with diabetes and prediabetes, who are at high-risk of developing the disease, which includes a robust health benefits package, consisting of a broad spectrum of diabetes management tools like affordable insulin and other medications, technological devices and supplies, and adequate preventive care. It is also critical that people with diabetes have health care coverage for associated chronic diseases, including heart disease, kidney, obesity, and other conditions. For example, as included in the American Diabetes Association's (ADA) Standards of Care, "in people with type 2 diabetes and overweight or obesity, modest weight loss improves glycemia and reduces the need for glucose-lowering medications, and larger weight loss substantially reduces A1C and fasting glucose and has been shown to promote sustained diabetes remission through at least 2 years."² Thereby treating and reducing comorbid diseases, like obesity, improves not only the health and quality of life of people with diabetes, but more important, it can have disease modifying impacts.

The DAA is diverse in scope, with our members representing patient, professional and trade associations, other non-profit organizations, and corporations, all united to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic. More recently, DAA members have

worked to raise awareness of and advocate for policies and legislation that would improve prevention, treatment, and care for people who have obesity or overweight, which can affect their risk for developing type 2 diabetes, or if diagnosed with diabetes, their outcomes and quality of life.

The Benefits to People with Prediabetes and Diabetes if USP DC Is Used in the EHB Package

We strongly support CMS's conclusion after reviewing public comments submitted earlier this year in response to an EHB RFI (87 FR 74097 through 74102): "We agree that using the USP DC to categorize the drugs provided as EHB would assist in strengthening the drug benefit due to its inclusion of additional drug categories and classes relevant to enrollees within the private insurance market."³ We appreciate that CMS notes that "USP MMG includes notable gaps in coverage related to the treatment of chronic conditions such as obesity, infertility agents, and sexual disorder agents. We also note that inclusion of additional categories and classes of drugs used to manage chronic conditions would assist in mitigating future risks and complications associated with a lack of access to these therapies, particularly for vulnerable populations."⁴

If CMS moves to using the USP DC system in the EHB package, physicians and other medication prescribers and their patients will have access to more preventive and lifesaving therapies than are available in the MMG's list of Part D eligible drugs. Moreover, given that the USP DC system is reviewed annually, versus every three years for the MMG, new and cutting-edge FDA approved therapies are more likely to become options for prescribers and patients.

As one example, for people with prediabetes, use of the USP DC would open the door to medications for the chronic disease of obesity. These medications can prevent the onset of type 2 diabetes when used as directed in conjunction with an evidence-based diet and physical activity intervention (such as programs recognized by the Centers for Disease Control and Prevention's Diabetes Prevention Recognition Program.)

For people with diagnosed diabetes, use of USP DC would expand the options available to prescribers and patients for addressing not only high blood glucose levels, but also obesity, and the eye, kidney, liver, nerve, and metabolic/cardiovascular complications triggered by diabetes or comorbid with diabetes. For example, obesity and overweight are associated with diabetes, and addressing obesity is a critical part of the care program for many people with diabetes. [Science](#) recently announced new obesity treatments as the "2023 Breakthrough of the Year," reporting about GLP-1 drugs that this "new class of therapies is breaking the mold, and there's a groundswell of hope that they may dent rates of obesity and interlinked chronic diseases."⁵

Also, the undersigned DAA members urge CMS to revise preventive services regulations to eliminate current access barriers to evidence based intensive behavioral therapy (IBT) for obesity as soon as possible. These barriers include 1.) lack of coverage for IBT for those with obesity, CVD risk, and/or prediabetes, and 2.) weight bias and stigma, which impede treatment and coverage for weight health in an evidence-based manner with interventions science clearly supports. Intensive multi-component healthy lifestyle counseling is a USPSTF B rated preventive service that should be provided in conjunction with anti-obesity medications (AOMs), and FDA labeling recognizes that AOMs are indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management. Therefore, we recommend CMS require that health plans cover evidence-based and/or appropriately recognized intensive lifestyle intervention/coaching/counseling programs for weight loss and management as part of EHBs, to make these programs available for beneficiaries.

The undersigned members of the DAA appreciate this opportunity to comment on the proposed rule and we reiterate our strong support for the proposal to use the USP DC system instead of the MMG. We believe that it is incumbent upon CMS to ensure those living with prediabetes and diabetes, who get their health insurance through the ACA marketplace, have access to the therapies they need to treat their prediabetes and diabetes and the associated comorbidities of diabetes, including access to the full continuum of care for obesity.

Sincerely,

The undersigned members of the Diabetes Advocacy Alliance

Academy of Nutrition and Dietetics
American Diabetes Association
American Podiatric Medical Association
Association of Diabetes Care & Education Specialists
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Endocrine Society
National Council on Aging
National Kidney Foundation
Noom, Inc.
Omada Health
WW International, Inc. (Weight Watchers)
YMCA of the USA

¹ Centers for Disease Control and Prevention. A Report Card: Diabetes in The United States. Accessed on January 8, 2024. <https://www.cdc.gov/diabetes/library/socialmedia/infographics/diabetes.html>

² American Diabetes Association, Diabetes Care, Volume 46, Supplement 1, January 2023, Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes: Standards of Care in Diabetes-2023, S128

³ Federal Register. Vol. 88, No. 225. Friday, November 24, 2023. Proposed Rules, p. 82599

⁴ Federal Register. Vol. 88, No. 225. Friday, November 24, 2023. Proposed Rules, p. 82600

⁵ Science. 2023 Breakthrough of the Year. Obesity meets its match. Accessed on December 19, 2023.

https://www.science.org/content/article/breakthrough-of-the-year-2023#section_breakthrough