OBESITY CARE ADVOCACY NETWORK

July 6, 2021

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Acting Director, Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

RE: Methods and Leading Practices for Advancing Equity and Support for Underserved Communities through Government [OMB-2021-0005-0001]

Dear Ms. Young:

The Obesity Care Advocacy Network (OCAN) appreciates the opportunity to offer comments in response to the RFI on Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government.

Founded in 2015, OCAN is a diverse group of organizations focused on changing how we perceive and approach obesity in the U.S. OCAN works to increase access to evidence-based obesity treatments by uniting key stakeholders and the broader obesity community around significant education, policy and legislative efforts. We aim to fundamentally change how the U.S. healthcare system treats obesity, and to shift the cultural mindset on obesity so that policymakers and the public address obesity as a serious chronic disease.

Obesity and Health Equity

Obesity also disproportionately impacts communities of color that already face systemic inequities in care. Addressing the disease must be part of our response on health equity issues. Racial and ethnic minorities experience disproportionately poorer health outcomes for infectious and chronic diseases. Race and ethnicity affect both obesity prevalence and obesity treatment outcomes.

American Indians, Black Americans, Hispanic Americans, and Asian Americans are all more likely than white Americans to have diabetes.[1] Additionally, African American women have the highest rates of obesity among any demographic group—approximately 4 out of 5 have overweight or obesity. In pediatric and adult female populations, Black and Hispanic Americans experience higher rates of obesity than white Americans.[2] Both Latino adults and children have higher obesity rates than other groups. When sex is considered, Black women experience the highest obesity rates, followed by Latina women.[3] Disparities exist not only in obesity prevalence, but also in obesity treatment outcomes. Weight loss therapies have been shown to be less effective for racial and ethnic minorities.[4] These disparities are not limited to infectious diseases; racial minorities experience higher rates of chronic diseases, death, and disability compared with white Americans.[5]

The COVID-19 public health emergency has further exposed the significant health disparities that exist in this country. These disparities, including higher rates of serious disease and death due to COVID-19 in communities of color, are made significantly worse by the obesity crisis. This is a daily matter of life and death. A recent Centers for Disease Control and Prevention (CDC) report puts it into stark terms: 78% of people who have been hospitalized with COVID-19 had either overweight or obesity. Research has shown a linear link between obesity and risk for hospitalization, ICU admission, and death from COVID-19.

Addressing obesity is a necessary component to addressing health equity in the United States. Below, we document ways in which the federal government classifies obesity as a disease but fails to actually treat it as one in the way that it treats diabetes, heart disease, and other serious chronic conditions. We then present a variety of ways in which the Federal government could improve access to obesity treatment, particularly within the Medicare program.

The Federal Government Formally Considers Obesity a Disease

Throughout the last four decades, the federal government has made several policy decisions that conclude that obesity is a disease. For example:

- In 1998, the National Institutes of Health published Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults that stated, "Obesity is a complex multifactorial chronic disease."
- In early 2002, the Internal Revenue Service issued a ruling that expenses for obesity treatment would qualify as deductible medical expenses. Later in 2002, the Social Security Administration (SSA) published an evaluation of obesity stating that "Obesity is a complex, chronic disease characterized by excessive accumulation of body fat." This determination explicitly stated that obesity is a valid medical source of impairment for the purpose of evaluating Social Security disability claims.
- In 2004, CMS removed language stating that "obesity is not an illness" from its Coverage Issues Manual. Although this action did not include a specific determination that obesity is a disease, it removed a significant obstacle to further progress and coverage for obesity-related medical services
- In 2006, CMS issued a National Coverage Determination providing coverage for bariatric surgery under Medicare, a decision that followed as a natural consequence of the agency's 2004 reassessment of obesity
- In March of 2014, the federal Office of Personnel Management (OPM) issued specific guidance to Federal Employee Health Benefit Program carriers regarding obesity treatment services – stating that the agency will no longer tolerate plans excluding obesity treatment coverage on the basis that obesity is a "lifestyle" condition or that treatment is "cosmetic."
- In 2015, the Departments of HHS, Treasury and Labor (the Tri-Agencies) issued an FAQ advising against coverage exclusions for weight management services as part of the implementation of the Patient Protection and Affordable Care Act (ACA). As part of that FAQ, the Tri-Agencies highlighted how the 2012 USPSTF recommendation "specifies that intensive, multicomponent behavioral interventions include, for example, the following: group and individual sessions of high intensity (12 to 26 sessions in a year); behavioral management activities, such as weight-loss goals; improving diet or nutrition and increasing physical activity; addressing barriers to change; self-monitoring and strategizing how to maintain lifestyle changes."

Yet Federal Programs and Policies Fail to "Treat Obesity" as a Disease

While obesity is a chronic disease with published evidence-based treatment guidelines, federal policy does not support or promote evidence proven treatment, including USPSTF recommendations[6,7]. For example, evidence overwhelmingly documents that the most effective and efficient approach to intensive behavioral therapy for healthy lifestyle is through community-based programs.

With Healthy People 2030, HHS took a step forward in listing obesity as a health condition.[8] However, the objectives classified under the overweight and obesity heading show that the government still sees obesity primarily the product of lifestyle choices and less so as a medical condition to be addressed by the health care sector. For example, as compared to diabetes in Healthy People 2030,

obesity and overweight have fewer than half as many objectives listed—some of which are actually diabetes measures that were double-counted under obesity. Additionally, a comparatively larger number of the objectives are focused on behavior change process measures and only one objective addresses the health care system at all. Only two of the seven objectives are outcomes measures and reducing the prevalence of adults with overweight or obesity is starkly absent from the objectives.

While the Medicare program has taken some positive steps to provide evidence-based therapy for those with obesity through both obesity coverage policy and through coverage of services to prevent diabetes, a weight related condition, Medicare coverage policies contain significant barriers to evidence-based treatment. And, the Medicare's Diabetes Prevention Program (MDPP) contains serious limits to the accessibility and usability of the benefit through duplicative bureaucratic requirements and reimbursement that is unlikely to cover costs. More on these counterproductive policies follows.

Benefit Restrictions on Intensive Behavioral Therapy for Obesity

Medicare has covered intensive behavioral therapy (IBT) for obesity since 2011,[9] but the benefit suffers from serious problems that harm access. Chiefly, the service is restricted to only being billed by primary care providers and only when delivered in a primary care setting. This restricts patients' access to other highly trained providers—including obesity medicine specialists, registered dietitian nutritionists, psychologists, and others—and to evidence-based community-based weight loss programs.

In 2011, CMS was obliged to use the USPSTF's outdated 2003 recommendations for "Screening Obesity in Adults" as the basis of its assessment, as they were the most current, prevailing USPSTF obesity recommendations available at the time.[10] Not only were these 2003 recommendations based primarily on literature from the 1990s, they were also drafted before the Task Force overhauled its processes, terminology, and manner of communicating the recommendations themselves as part of the USPSTF's "commit[ment] to continually updating its methods and recommendations to maintain relevance to primary care practice"[11] and in anticipation of the USPSTF's transformed role under the ACA.

CMS has considered rule making for obesity treatments for more than a decade and the Biden administration has shown a commitment to action on critical health concerns. But there is no more urgent time to act than now. For the millions of people living with obesity who have struggled to manage their disease and face additional health risks like severe COVID-19, diabetes, heart disease, stroke, or cancer, modernizing Medicare could save their lives.

The IBT for obesity benefit is also governed by restrictions that differ from how other chronic disease benefits are structured. Under the current benefit design, patients who do not lose an arbitrary amount of weight in the first 6 months lose access to care. For any other chronic disease, a lack of effect from treatment would warrant more intensive intervention, not less. Under the current policy, Medicare essentially gives up on patients with obesity if they struggle to lose weight, even if they have achieved documented improvements in clinical markers other than weight or have reported positive behavior change.

This is especially problematic for beneficiaries from low-income rural or urban communities who may have reduced access to healthy foods and safe spaces to be active. The hard cut-points for weight loss and time are also problematic for individuals from low-income communities who may struggle with attendance. And, in fact, the NCD implies that beneficiaries who have not lost enough weight by 6 months are simply not "ready to change." Boiling weight loss down to how much an individual wants to lose weight is ignoring the litany of social and economic factors that can impede weight loss. These cut-points also eliminate health care providers' ability to use their clinical judgement to assess whether continued intensive behavioral therapy would be clinical beneficial to their patients.

Counterproductive Payment Policies for the Diabetes Prevention Program

The Medicare Diabetes Prevention Program (MDPP) has similar problems with its benefit design that bake structural racism into the program. Evidence supports weight loss of at least 3% is associated with reduction in diabetes risk.[12] Specifically, for those with risk for T2DM, the professional practice guidelines state:

> "In overweight and obese adults at risk for type 2 diabetes, average weight losses of 2.5 kg to 5.5 kg at ≥ 2 years, achieved with lifestyle intervention (with or without orlistat) reduces the risk of developing type 2 diabetes by 30% to 60%."[13]

A lower weight loss standard associated with reduction in risk for T2DM would encourage enrollment of MDPPs serving lower socio-economic communities, where participation in healthy lifestyle programs reduces risk, but where structural access to healthy foods or other community resources can impede attainment of the 5% weight loss goal of the DPP. If the goal is to provide DPP's flexibility for objective, evidence-based measures of T2DM risk reduction, it could and should consider a lower percentage weight loss criterion, by itself, as even weight loss of 3% reduces risk of T2DM.

Lack of Coverage of Anti-Obesity Medications by Medicare Part D

Another glaring hole in Medicare coverage of obesity treatment is the complete lack of coverage of any FDA-approved anti-obesity medications in Medicare Part D. No other disease is singled out within the Part D program as ineligible for treatment, and we cannot stress enough the critical need for providing this coverage.

Congress as a whole, voiced these sentiments in the report language of the Consolidated Appropriations Act for FY 2021, which "encourages CMS to work to ensure beneficiary access to the full continuum of care for obesity, including access to FDA-approved anti-obesity medications under Medicare Part D... and that CMS reexamine its Medicare Part B national coverage determination for intensive behavioral therapy for obesity considering current United States Preventive Services Task Force recommendations." Additionally, nearly 190 bipartisan Members of Congress have been on record supporting the Treat and Reduce Obesity Act, which would close the gaps in Medicare coverage of obesity treatment. The broad, bipartisan support for this legislation, coupled with the budget language, is a strong signal that Congress supports Medicare coverage of comprehensive obesity treatment.

Omission from the Medicare Merit-based Incentive Payment System

While we support the population health measure of BMI screening, this measure falls short of the USPSTF recommendations and fails to link to treatment for the chronic disease of obesity. Specifically, the documentation of "follow up" for those with a BMI of 30 or more should be specific to the standards of care that exist and therefore should measure referral to or provision of the appropriate therapy whether that be intensive behavioral therapy (USPSTF preventive service recommendation) or another empirically validated intervention like medication. As it stands now, this measure simply incents providers to weigh patients, mention that the patient might consider losing weight, and note in the record that weight loss was recommended. An extensive evidence base indicates that active referral to an intervention (behavioral counseling, medication, or surgery) is effective to motivating patients to take action to manage their weight.

Removal of Obesity from Medicaid Quality Measures

In 2019, CMS removed the Adult Body Mass Index Assessment (ABA-AD) measure from the Adult Core Set of health care quality measures for Medicaid,[14] leaving no assessment of weight status in the 2020 or 2021 Adult Core Set.[15] The decision to remove the ABA-AD measure with no replacement not only contradicts the prevailing USPSTF recommendation to screen and offer or refer patients with

obesity to counseling, but it risks lowering the priority of obesity treatment among the health care community. Remaining in the Adult core Set however, are a number of measures focused on controlling chronic conditions that are associated with obesity, including high blood pressure, diabetes, and heart failure, further indicating a lack of commitment by the Federal government to address obesity as a disease in its own right.

One of the reasons stated for removing the ABA-AD measure was that obesity may require a broader societal response than other health conditions, which makes it more challenging for the health care system to address. It is certainly true that obesity is a complex disease and that prevention efforts should focus on societal issues, such as access to nutritious food and opportunities to be physically active. Instead of using this as a rationale to dedicate resources to both clinical treatment of obesity (community-based programs such as the Diabetes Prevention Program, intensive behavioral therapy, pharmacotherapy and surgery) and obesity prevention, CMS chose to *reduce* the focus on the disease.

<u>Poor Enforcement of Essential Health Benefits Policies</u>

The obesity community continues to be extremely frustrated regarding HHS's failure to prohibit discriminatory benefit design regarding obesity treatment in essential health benefit (EHB) plans. While we have taken every opportunity (numerous face-to-face meetings with CMS and HHS and submission of formal comments on the EHB proposed regulations, and comments regarding federal oversight of State EHB benchmark plan selection) to secure federal guidance specific to this issue, HHS continues to ignore our concerns regarding clear discriminatory practices that are being employed by qualified health plans.

Most states' essential benefit benchmarks exclude "weight management programs," the cost-effective programs that align with USPSTF recommendations for intensive behavioral therapy for healthy lifestyle. These programs are critical to preventing disease progression for diabetes, heart disease, high blood pressure, obesity, and a host of other weight related conditions. Health plans' preventive benefits coverage of USPSTF recommendations for intensive behavioral counseling for healthy lifestyle to be provided to those with obesity, overweight and a CVD Risk factor, and to those with prediabetes is rare. Typically, payers limit coverage to screening for the risk factors and do not provide coverage for intensive behavioral counseling for healthy lifestyle that meets the USPSTF standards. As a result, the very service that reduces risk and prevents chronic conditions is not offered or covered. This is true even for diabetes prevention programs (DPP) which are rarely covered by payers despite widespread evidence that they delay the onset of type 2 diabetes and reduce health care costs.

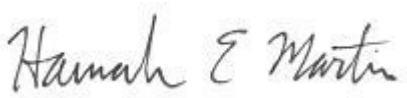
Additionally, plans currently being offered in state marketplaces continue to include clear discriminatory benefit design language. For example, some plans that include bariatric surgery coverage in their EHB benchmark plan are limiting bariatric surgical procedures to one per lifetime and/or imposing excessive cost sharing compared to other covered surgical services such as 50 percent or higher. Enforcement against these discriminatory practices must be undertaken to ensure equitable access to care for people with obesity.

Conclusion

Obesity is a pivotal health equity issue. OCAN has worked with previous administrations on these issues, with little success. We hope that this administration's laser focus on equity will be the push that is needed to bring these necessary policy changes to the forefront. Addressing the inadequate coverage of obesity treatment services is both highly achievable, and a necessary first step as Medicare payment policies are often used as a benchmark for private and state Medicaid plans.

We would like to thank the Administration for its strong focus on equity and we look forward to working together to achieve this goal. Please be in touch if you would like addition information on any of our recommendations.

Sincerely,



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